THE AYURVEDIC PHARMACOPOEIA OF INDIA

THE AYURVEDIC PHARMACOPOEIA OF INDIA

PART - II (FORMULATIONS)
VOLUME - II

First Edition

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY,
NEW DELHI
2008

PDH, 68 Part II, Vol. II
5000-2008 (DSK II)

Effective from 1st January, 2009

Price	:	Inland Foreign	Rs. 500/- US $ 100/-
ISBN	:	978 – 81 905952 – 0 – 9	
Published by	:	THE CONTROLLER OF PUBLICATIONS CIVIL LINES, DELHI - 110054	
On Behalf of	:	GOVERNMENT OF INDIA DEPARTMENT OF AYURVEDA, YOGA-NATUROPATHY UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) INDIAN RED CROSS SOCIETY BUILDING, SANSAD MARG, NEW DELHI	
WEBSITE	:	www.indianmedicine.nic.in	
Printed at	:	Cirrus Graphics Pvt. Ltd, New Delhi	

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स्वास्थ्य एवं परिवार कल्याण मंत्रालय
आयुर्वेद, योग व प्राकृतिक चिकित्सा,
यूनानी, सिद्ध एवं होम्योपैथी (आयुष) विभाग
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Foreword

With the growing popularity and demand of Ayurvedic Medicines in the country and abroad, availability of quality standards of Ayurvedic formulations has become a top priority for maintaining uniform, safe and quality medicines for the consumption of patients. Evolving Pharmacopoeial standards for Ayurveda, Siddha and Unani Medicine is essential for implementing the relevant provisions under the Drugs and Cosmetic Act, and Rules thereunder. The Ayurvedic Pharmacopoeia Committee has been assigned the task of evolving Pharmacopoeial standards of the commonly used formulations in the country.

Bringing out the Pharmacopoeial standards of Ayurvedic formulations requires expertise of various disciplines like Ayurvedic Pharmacognosy, Pharmacy, Phytochemistry and Pharmaceutical Chemistry. The present volume also contains standard manufacturing procedures including in-process standardization procedures, final product standardization with physico-chemical and chromatographic techniques. It is needless to say that the present volume is the result of untiring efforts of scientists from various laboratories and members of the Pharmacopoeia Committee.

I have no doubt that this publication on Compound Formulations will provide required technical assistance for manufacturers, regulators, scientists, teachers, researchers and students. I place on record my appreciation for the members for Ayurvedic Pharmacopoeia Committee, Scientists working in various laboratories, Dr. S.K. Sharma, Adviser (Ayurveda), Department of AYUSH, Dr. D.R. Lohar, Director, Pharmacopoeia Laboratory for Indian Medicine (PLIM) and his team and Dr. G.S. Lavekar, Director, Central Council for Research in Ayurveda & Siddha (CCRAS) and his team for bringing out this volume. My congratulations to Shri Shiv Basant, Joint Secretary, Department of AYUSH whose overall coordination has made this enormous work possible.

Anita Das

(Anita Das)

New Delhi,
1st August 2008.

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Avaleha:

C¦r´a:

Gh¨ta:

Guggulu:

LEGAL NOTICES

In India there are laws dealing with drugs that are the subject of monographs which follow. These monographs should be read subject to the restrictions imposed by these laws wherever they are applicable.

It is expedient that enquiry be made in each case in order to ensure that the provisions of the law are being complied with.

In general, the Drugs & Cosmetics Act, 1940 (subsequently amended in 1964 and 1982), the Dangerous Drugs Act, 1930 and the Poisons Act, 1919 and the rules framed thereunder should be consulted.

Under the Drugs & Cosmetics Act, the Ayurvedic Pharmacopoeia of India (A.P.I.), Part-II, Vol. II, is the book of standards for compound formulations included therein and the standards prescribed in the Ayurvedic Pharmacopoeia of India, Part-II, (Formulation) Vol. II, would be official. If considered necessary these standards can be amended and the Chairman of the Ayurvedic Pharmacopoeia Committee's authorized to issue such amendments. Whenever such amendments are issued, the Ayurvedic Pharmacopoeia of India, Part-II (Formulation), Vol. II, would be deemed to have been amended accordingly.

GENERAL NOTICES

Title : The title of the book is "Ayurvedic Pharmacopoeia of India, Part-II (Formulations) Volume-II. Wherever the abbreviation "API, Pt.-II, Vol.-II" is used, it may be presumed to stand for the same and the supplements or amendments thereto.

Name of the Formulation: The name given on top of each monograph is in Samskrt, as mentioned in the Ayurvedic Formulary of India (AFI) and will be considered official. These names have been arranged in English alphabetical order under each category of dosage form.

Ingredients and Processes: Formulations are prepared from individual ingredients that comply with the requirements for those individual ingredients for which monographs are provided in the volumes of API, Part-I. Where water is used as an ingredient it should meet the requirements for Potable Water covered by its monograph in the Ayurvedic Pharmacopoeia of India-Part-I.

Monograph for each formulation includes the full composition together with directions for its preparation. Such composition and directions are intended for preparation of small quantities for short-term supply and use. When so prepared, no deviation from the stated composition and directions is permitted. However, if such a preparation is manufactured on a large scale with the intention of sale or distribution, deviations from the directions given are permitted, but maintaining the same ratio as stated in the monographs with the ingredients complying with the compendial requirements, and also that the final product meets the following criteria:

(a) complies with all of the requirements stated in the monograph on compound formulations,

(b) in the composition of certain formulations it has been allowed that a specified part of the plant may be substituted by another part of the same plant. In such cases the manufacturer should mention on the label the actual part of the plant used in the formulation.

(c) wherever an 'official substitute' is provided for, deviation from the original formulation is permitted, using the 'official substitute'.

(d) wherever a formulation composition specifies a drug that is banned from commerce, this may be omitted, and the fact mentioned on the label.

If a preparation is intended to be stored over a period of time, deterioration due to microbial contamination may be inhibited by the addition to the formula of a permitted preservative. In such circumstances the label should state the concentration of the preservative and the appropriate storage conditions. It is implied that such a preparation will be effectively preserved according to the appropriate criteria applied.

The direction that an ingredient in a formulation must be freshly prepared indicates that it must be prepared and used within 24 hours.

Monograph: Each monograph begins with a definition and introductory paragraph indicating the formulation composition, scientific names of the drugs used with their botanical parts along with a brief account of the method of preparation.

The requirements given in the monographs are not framed to provide against all impurities, contaminants or adulterants; they provide appropriate limits only for possible impurities that may be permitted to a certain extent. Material found to contain an impurity, contaminant or adulterant which is not detectable by means of the prescribed tests are also to be considered as impurity should rational consideration require its absence.

Standards: For statutory purposes, the following shall be considered official standards: Definition, Formulation composition, Identification, Physico-chemical parameters, Assay and Other requirements.

Added Substances: A formulation contains no added substances except when specifically permitted in the individual monograph. Unless otherwise specified in the individual monograph, or elsewhere in the General Notices, suitable substances may be added from the approved list of Drugs and Cosmetics Rules, under Rule 169 to a formulation to enhance its stability, usefulness, elegance, or to facilitate its preparation. Such auxiliary substances shall be harmless in the amounts used, shall not exceed the minimum quantity required to provide their intended effect, shall not impair the therapeutic efficacy or the bioavailability and safety of the preparation and shall not interfere with the tests and assays prescribed for determining compliance with the official standards. Particular care should be taken to ensure that such substances are free from harmful organisms. Though the manufacturer of a formulation is given the freedom to use an added substance, the manufacturer must guarantee the innocuousness of the added substance. The manufacturer shall also be responsible to explain to the appropriate authority, if needed, regarding the purpose of the added substance(s).

Description: Statement given under this title is not to be interpreted in a strict sense although they may help in the evaluation of an article. However substantial departure form the requirement will not be acceptable.

Capital Letters in the Text: The names of the Pharmacopoeial substances, preparations and other materials in the text are printed in capital initial letters, and these infer that materials of Pharmacopoeial quality have been used.

Italics: Italic types are used for Scientific names of the plant drugs and microorganisms, and for some sub-headings and certain notations of the chemical names. Italic types have also been used for words which refer to solvent system in TLC procedure, reagents and substances, processes covered under Appendices. Chemicals and Reagents and Substances of Processes in Appendices have also been printed in Italics.

Odour and Taste: Wherever a specific odour has been observed it has been mentioned as characteristic for that formulation, but the description as 'odourless' or 'no odour' has generally been avoided in the Description where a substance has no odour. Where a characteristic odour is said to be present it is examined by smelling the drug directly after opening the container. If such an odour is discernible, the contents are rapidly transferred to an open vessel and re-examined after 15 minutes. If odour persists to be discernible, the sample complies with the description for odour, characteristic for that formulation.

The taste of a drug is examined by taking a small quantity of drug by the tip of moist glass rod and allowing it on tongue previously moistened with water. *This does not apply in the case of poisonous drugs.*

Powder fineness: Wherever the powder of a drug is required, it shall comply with the mesh number indicated in the Monograph.

Where particle size is prescribed in a Monographs, the specified sieve number are used to fractionate a weighed representative sample from the container, each fraction weighed separately, and expressed as a percentage of the weight taken initially, to obtain compliance with the monograph.

Weights and Measures: The metric system of weights and measures is employed. Weights are given in multiples or fractions of a gram (g) or of a milligram (mg). Fluid measures are given in multiples of fraction of milliliter (ml). The amount stated is approximate but the quantity actually used must be accurately weighed and must not deviate by more than 10 per cent from the one stated.

When the term "drop" is used measurement is to be made by means of a tube which delivers 20 drops per gram of distilled water at 15^0.

Identity, Purity and Strength: Under the heading "Identification", tests are provided as an aid to identification and are described in the respective monographs. Microscopical characters are prescribed for the individual ingredients where these do not exceed ten in number, added '*in situ*'. Appendix 2.1 gives detailed procedure

Vegetable drugs used in formulations, should be duly identified and authenticated and be free from insects, pests, fungi, micro organisms, pesticides, and other animal matter including animal excreta, be within the permitted and specified limits for lead, arsenic and heavy metals, and show no abnormal odour, colour, sliminess, mould or any sign of deterioration.

The quantitative tests like total ash, acid-insoluble ash, water-soluble ash, alcohol-soluble extractive, water-soluble extractive, moisture content, volatile oil content and assays are the parameters upon which the standards of Pharmacopoeia depend. Except for Assays, which are covered under each monograph, the methods of determination for others are given in Appendices, with a suitable reference to the specific appendix.

The analyst is not precluded from employing an alternate method in any instance if he is satisfied that the method, which he uses will give the same result as the Pharmacopoeial method described under assay. However, in the event of doubt or dispute the methods of analysis of the Pharmacopoeia are alone authoritative. Unless otherwise prescribed, the assays and tests are carried out at a temperature between 20^0 and 30^0.

In the performance of assay or test procedures, not less than the specified number of dosage units should be taken for analysis. Proportionately larger or smaller quantities than the specified weights and volumes of assay or test substances and Reference Standards or Standard Preparations may be taken, provided the measurement is made with at least equivalent accuracy and provided that any subsequent steps, such as dilutions, are adjusted accordingly to yield concentrations equivalent to those specified and are made in such manner as to provide at least equivalent accuracy.

Where it is directed in the assay for Tablet formulation to "weigh and powder not less than" a given number, usually 20, of the tablets, it is intended that a counted number of tablets shall be weighed and reduced to a fine powder. Likewise, where it is directed in the assay for Capsules to remove, as completely as possible, the contents of not less than a given number, usually 20, of the capsules, it is intended that a counted number of capsules should be carefully opened and the contents quantitatively removed, combined, mixed, and weighed accurately. The portion of the powdered tablets or the mixed contents of the capsules taken for assay is representative of the whole tablets or capsules, respectively, and is, in turn, weighed accurately. The result of the assay is then related to the amount of active ingredients per tablet in the case of tablets and per capsule in the case of capsules from the weight of contents of each tablet/capsule.

Limits for Heavy metals, Microbial load, Pesticide residues and Aflatoxins : Formulations included in this volume are required to comply with the limits for heavy metals, microbial load, pesticide residues and aflatoxins prescribed in individual monographs and wherever limit is not given they must comply with the limits given in Appendix. The methods for determination of these parameters are given in Appendices.

Thin Layer Chromatography (TLC): Under this title, wherever given, the R_f values given in the monographs are not absolute but only indicative. The analyst may use any other solvent system and detecting reagent to establish the identity of any particular chemical constituent reported to be present in the formulation. However in case of dispute the pharmacopoeial method would prevail. Unless specified in the individual monograph all TLC have been carried out on pre-coated Silica gelG F_{254} aluminium plates.

Reference Standards: Reference substance and standard preparation are authentic substances that have been verified for there suitability for use as standards for comparison in some assays, tests and TLC of the API.

Constant Weight: The term "constant weight" when it refers to drying or ignition means that two consecutive weighing do not differ by more than 1.0 mg per gram of the substance taken for the determination, the second weighing following an additional hour of drying or further ignition.

Percentage of Solutions – In defining standards, the expression per cent (%), is used, according to circumstances, with one of the four meanings given below.
Per cent w/w (percentage weight in weight) expresses the number of grams of active substance in 100 grams of product.

Per cent w/v (percentage weight in volume) expresses the number of grams of active substance in 100 milliliters of product.

Per cent v/v (percentage volume in volume) expresses the number of milliliters of active substance in 100 milliliters of product.

Per cent v/w (percentage volume in weight) expresses the number of milliliters of active substance in 100 grams of product.

Percentage of Alcohol: All statements of percentage of alcohol (C_2H_5OH) refer to percentage by volumes at 15.56^0c.

Temperature: Unless otherwise specified all temperatures refer to centigrade (Celsius), thermometric scale and all measurement are made at 25^0.

Solutions: Unless otherwise specified in the individual monograph, all solutions are prepared with Purified Water.

Reagents and Solutions: Reagents required for the assay and tests of the Pharmacopoeia are defined in the Appendix showing the nature, degree of the purity and strength of solutions to be made from them.

Filtration: Where it is directed to filter, without further qualification, it is intended that the liquid be filtered through suitable filter paper or equivalent device until the filtrate is clear.

Soluble substances: The following table indicates the meaning of degree of solubilities:

Descriptive Terms	**Relative quantities of solvent**
Very soluble	less than 1 part
Freely soluble	from 1 to 10 parts
Soluble	from 10 to 30 parts
Sparingly soluble	from 30 to 100 parts

Slightly soluble	from 100 to 1000 parts
Very slightly soluble	from 1000 to 10,000 parts
Practically insoluble	more than 10,000 parts

The term 'partly soluble' is used to describe a mixture of which only some of the components dissolve.

Therapeutic uses: Therapeutic uses of the formulations mentioned in this Pharmacopoeia are as given in the Ayurvedic Formulary of India.

Doses: The doses mentioned in each monograph are in metric system which are the approximate conversions from classical weights mentioned in Ayurvedic texts. A conversion table is appended giving classical weights with their metric equivalents.(Appendix 8) Doses mentioned in the Ayurvedic Pharmacopoeia of India (API) are intended merely for general guidance and represent, unless otherwise stated, the average range of quantities per dose which is generally regarded suitable by clinicians for adults only when administered orally. They are not to be regarded as binding upon the prescribers.

The medical practitioner will exercise his own judgment and act on his own responsibility in respect of the amount of the formulation he may prescribe or administer or on the frequency of its administration. If it is usual to administer a medicine by a method other than by mouth, the single dose suitable for that method of administration is mentioned.

Storage: Statement under the heading 'Storage' constitutes non-mandatory advice. The substances and preparations of the Pharmacopoeia are to be stored under conditions that prevent contamination and, as far as possible, deterioration. Precautions that should be taken in relation to the effects of the atmosphere, moisture, heat and light are indicated, where appropriate, in the individual monographs.

Specific directions are given in some monographs with respect to the temperatures at which Pharmacopoeial articles should be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms.

Cold- Any temperature not exceeding 8^0 and usually between 2^0 and 8^0. A refrigerator is cold place in which the temperature is maintained thermostatically between 2^0 and 8^0.

Cool- Any temperature between 8^0 and 25^0. An article for which storage in a cool place is directed may, alternately, be stored in a refrigerator, unless otherwise specified in the individual monograph.

Room temperature - The temperature prevailing in a working area

Warm - Any temperature between 30^0 and 40^0

Excessive heat- Any temperature above 40^0

Protection from freezing- Where, in addition to the risk of breaking of the container, freezing results in loss of strength or potency or in destructive alteration of the characteristics of an article the label on the container bears an appropriate instruction to protect from freezing.

Storage under non-specific conditions- Where no specific storage directions or limitations are given in the individual monograph, it is to be understood that the storage conditions include protection from moisture, freezing and excessive heat.

Containers: The container is the device that holds the article. The immediate container is that which is in direct contact with the article at all times. The closure is a part of the container.

The container is designed so that the contents may be taken out for the indented purpose in a convenient manner. It provides the required degree of protection to the contents from the environmental hazards.

The container should not interact physically or chemically with the article placed in it so as to alter the strength, quality or purity of the article beyond the official requirements.

Prior to its being filled, the container should be clean. Special precautions and cleaning procedures may be necessary to ensure that each container is clean and that extraneous matter is not introduced into or onto the article.

Light-resistant Container- A light resistant container protects the contents from the effects of actinic light by virtue of the specific properties of the material of which it is made. Alternatively, a clear and colourless or a translucent container may be made light-resistant by means of an opaque (light-resistant) covering and/or stored in a dark place: in such cases, the label on the container should bear a statement that the opaque covering or storage in dark place is needed until the contents have been used up.

Well-closed Container- A well-closed container protects the contents from extraneous solids and liquids and from loss of the article under normal conditions of handling, shipment, storage and distribution.

Tightly-closed Container- A tightly-closed container protects the contents form contamination by extraneous liquids solids or vapours, from loss or deterioration of the article from effervescence, deliquescence or evaporation under normal conditions of handling, shipment, storage and distribution.

Single Unit Container- A single unit container is one that is designed to hold a quantity of the drug product intended for administration as a single finished device intended for use promptly after the container is opened. The immediate container and/or outer container

or protective packaging is so designed as to show evidence of any tampering with the contents.

Multiple Unit Container- A multiple unit container is container that permits withdrawals of successive portions of the contents without changing the strength, quality or purity of the remaining portion.

Tamper-evident Container- A tamper-evident container is fitted with a device or mechanism that reveals irreversibly whether the container has been opened.

Labelling: In general, the labeling of drugs and pharmaceuticals is governed by the Drugs and Cosmetics Act, 1940 and Rules there under.

ABBREVIATIONS FOR TECHNICAL TERMS

gram(s)	-	-	g
milligram(s)	-	-	mg
kilogram(s)	-	-	kg
milliliter(s)	-	-	ml
litre(s)	-	-	l
hour(s)	-	-	h
Minute(s)	-	-	min
Second(s)	-	-	sec
^{0}C	-	-	^{0}
Micron	-	-	µ
Ortho	-	-	*o*
Meta	-	-	*m*
Para	-	-	*p*
parts per million	-	-	ppm
parts per billion	-	-	ppb
volume	-	-	vol
weight	-	-	wt
weight in weight	-	-	w/w
weight in volume	-	-	w/v
volume in volume	-	-	v/v
quantity sufficient	-	-	Q.S.
Ksara sūtra	-	-	KS

ABBREVIATIONS FOR PARTS OF PLANTS

Aerial root	-	-	A. Rt.
Androecium	-	-	Adr.
Aril	-	-	Ar.
Bulb	-	-	Bl.
Exudate	-	-	Exd.
Flower	-	-	Fl.
Fruit	-	-	Fr.
Fruit rind	-	-	Fr. R.
Heart wood	-	-	Ht. Wd.
Inflorescence	-	-	Ifl.
Kernel	-	-	Kr.
Leaf	-	-	Lf.
Leaf rachis	-	-	Lf. R.
Latex	-	-	Lx.
Pericarp	-	-	P
Plant (whole)	-	-	Pl.
Rhizome	-	-	Rz.
Root	-	-	Rt.
Root bark	-	-	Rt. Bk.
Root tuber	-	-	Rt. Tr.
Seed	-	-	Sd.
Stamens	-	-	Stmn.
Stem	-	-	St.
Stem bark	-	-	St. Bk.
Stem tuber	-	-	St. Tr.
Style & stigma	-	-	Stl./Stg.
Ripe fruit Pulp	-	-	Rp. Fr. Pp.
Subterranean root tuber	-	-	Sub. Rt. Tub.

Subterranean root	-	-	Sub. Rt.
Dry			Dr.
Ext.	-	-	Extract
Bud	-	-	Bd.
Siliceous Concretion	-	-	S.C.
Resinous encrustation	-	-	Res. Enc.
Endosperm (Bija majja)	-	-	Enm.
Oleo-resin			O.R.

INDO-ROMANIC EQUIVALENTS OF DEVANĀGARĪ ALPHABETS

अ	-	a	ड	-	²a
आ	-	ā	ढ	-	²ha
इ	-	i	ण	-	´a
ई	-	ī	त	-	ta
उ	-	u	थ	-	tha
ऊ	-	ū	द	-	da
ऋ	-	¨	ध	-	dha
ए	-	e	न	-	na
ऐ	-	ai	प	-	pa
ओ	-	o	फ	-	pha
औ	-	au	ब	-	ba
ं	-	¼	भ	-	bha
ः	-	ª	म	-	ma
क	-	ka	य	-	ya
ख	-	kha	र	-	ra
ग	-	ga	ल	-	la
घ	-	gha	व	-	va
ङ	-	¬a	श	-	śa
च	-	ca	ष	-	¾a
छ	-	cha	स	-	sa
ज	-	ja	ह	-	ha
झ	-	jha	क्ष	-	k¾a
ञ	-	®a	त्र	-	tra
ट	-	°a	ज्ञ	-	j®a
ठ	-	°ha			

PREFACE

In Ayurvedic Formulary of India Part I and Part II there are 636 formulations, out of these nearly 65 percent are solid dosage forms (Cūr´a, Va℡ī, Gu℡ika etc.) about 20 percent are liquid preparations (Āsva, Ari¾°a, Taila) and about 15 percent are semisolid (Avaleha, Gh¨ta, Lepa). Each of the formulations contains a number of ingredients, a few even going upto 75. It is observed that nearly 70 percent each of the liquid and semisolid preparations contain over ten ingredients. Since the spectrum of the tests which can be applied to liquids and semisolids for pharmacopoeial monographs are more limited than those available for solids, these preparation are particularly difficult to deal with. Considering the total 636 formulations about 50 percent contain over 10 ingredients. This means that in 318 monographs of solids, semisolids and liquids, standards and tests would involve an average of 25 ingredients in each this is really a complex and formidable task to accomplish. In addition to sheer volume, the unique processing methods used for manufacture, turn a simple mixture of single drugs into a very complex material from which separation and identification let alone estimation of components is no longer an easy and routine affair. It calls for complete knowledge of manufacturing complexities for a pharmaceutical - analytical chemist, for proper appreciation and interpretation of test results. At present, very few generalized quality parameters are adopted. Only a few Ayurvedic drug manufacturers may be having in house standard methods of preparations (SOPs) and quality parameters for finished compound formulations. But there exists no uniformity in the SOPs and quality parameters in the country. This results in lot of variability in quality of the same classical Ayurvedic formulation produced by different manufacturers. An effort has been made now to optimize and to develop uniform SOPs in order to ensure that such differences in quality of the same product produced by different manufacturers are not beyond permissible limits.

Under part I of Ayurvedic Pharmacopoeia of India (on single drug) so far six volumes have been published viz. Vol I (80 monographs), Vol II (78 monograph), Vol III (100 Monographs), Vol IV (68 monographs) and Vol V (92 monographs) and Vol VI (101 monographs) for Ayurvedic single drugs of plant origin, which go into one or more compound formulations included in the Ayurvedic Formulary of India, Part-I and Part-II. The first volume of the Ayurvedic Pharmacopoeia of India, Part-II published in 2007 contains official standards for 50 compound formulations selected from Ayurvedic Formulary of India, Part-I and Part-II.

In continuation of the work of the quality standards of classical Ayurvedic compound formulations, the present Vol-II of the Ayurvedic Pharmacopoeia of India, Part-II contain official standards for compound formulations included in the Ayurvedic Formulary of India, Part-I and Part-II.

The title of the monograph for each compound formulation is given in Sanskrit as mentioned in the Ayurvedic Formulary of India. This is followed by the Definition,

Formulation Composition, Method of Preparation, a brief Description of the Formulation, Standards for Identity and Purity in so far as these are reflected by microscopy, chromatography (thin layer chromatography or gas liquid chromatography), Physico-chemical parameters. Others requirements include limits for heavy metals and microbial load. Information on therapeutic uses, dose, mode of administration and storage is included. Each ingredient of the compound formulations complies with the standards prescribed in the Ayurvedic Pharmacopoeia of India. In a few cases, where pharmacopoeial standards for individual ingredient are not available, the collaborating institute develops standards for such an ingredient before using it in the formulation. The monograph for majority of the compound formulations provides Assay method for and range of limits of any one chemical constituent or group of chemical constituents.

The general notice provide guidance for the Ayurvedic drug manufacturers and analysts. Appendices given in the Pharmacopoeia include details of the apparatus/equipment, reagents, solutions used methods of tests employed and preparations of sample for microscopic examination.

The Ayurvedic Pharmacopoeial Committee hopes that the publication of Ayurvedic Pharmacopoeia of India, Part-II (formulations) Vol-II containing quality standards and method of preparation of compound formulation would serve to assist in the implementation of the Drugs and Cosmetic Act and Rules there under. It is also expected that such implementation would generate feedback information which is necessary compound formulations given in this Vol-II of the Ayurvedic Pharmacopoeia of India, Part-II.

The Ayurvedic Pharmacopoeial committee urges the Government of India to recommend the adoption of these monographs published in the Ayurvedic Pharmacopoeia of India, Part-II (formulations) – Vol II for the purpose of methods of preparations and quality standards of Ayurvedic compound formulation for use in their Government, Semi government, Government aided institutions and Voluntary public organizations. Ayurvedic Pharmacopoeia of India, Part-II (formulations) Vol-II may also be notified by the Government of India as a book of standards for implementation of Drugs and Cosmetic Act 1940 and Rules there under (as amended from time to time) all over India, just as the Ayurvedic Pharmacopoeia of India Part-I Vol-I, II, III, IV,V, VI and the Ayurvedic Pharmacopoeia of India, Part-II (formulations), Vol-I have been included in the First Schedule of the Drugs and Cosmetic Act 1940.

Prof. S.S.Handa	*Dr. S.K.Sharma*	*Dr. G.S.Lavekar*
Chairman	**Vice-Chairman**	**Member Secretary**
(APC)	**(APC)**	**(APC)**

ACKNOWLEDGMENT

The Ayurvedic Pharmacopoeial committee duly acknowledges the contributions made by the staff of the participating institutions associate with the APC project work for developing quality standards of Ayurvedic compound formulations.

The committee expresses gratitudes of the Secretary, Department of AYUSH. Ms. Anita Das and Shri Shiv Basant for providing constant support for completion of this work and its further continuation and also sincerely thanks to Dr. MM Padhi, Deputy Director [Tech.]; Shri. Vasantha Kumar, Asst. Director [Chem.]; Dr. Pramila Pant, Research Officer [Chem.]; Dr. Chhote Lal, Dr. AKS Bhadoria and Dr. MN Rangne; Dr. Bishnupriya Dhar, Research Officer [Phar]; Dr. K. Sandhya Rani, S.R.F. [Ayu.]; Dr. Nikhil Jirankalgikar S.R.F. [Ayu.]; Dr. Rajesh Singh S.R.F. [Ayu.] and other associated officers, for their constant efforts in bringing out this volume. Thanks to Mr. Ashish, Ms. Deepti, Ms. Meenakshi and Mr. Sandeep Kumar, D.E.O., who took pains in typing and arranging all the technical data into a final shape.

INTRODUCTION

The Ayurvedic system of medicine has been prevalent in India since the Vedic period, and still remains the mainstay of medical relief to over 60 per cent of the population of the nation. In earlier times the practitioners of Ayurveda (Vaidya) were themselves collecting herbs and other ingredients and preparing medicines. For the purpose of acquiring raw materials Vaidyas now depend on commercial organizations trading in crude herbal drugs. Likewise, with passage of time a number of Ayurvedic Pharmaceutical units have come up for the manufacture of Ayurvedic drugs and formulations on commercial scale.

Under the circumstances and responding to opinions of the scientific community after independence, the Govt. of India began a series of measures to introduce a quality control system, from 1964 onwards similar to that existing already under the Drugs and Cosmetics Act, 1940, for western medicine. The Government of India introduced an amendment in 1964 to the Drug and Cosmetics Act 1940, to control to a limited measure the Ayurvedic, Siddha and Unani drugs.

The Act was accordingly amended in 1964, to ensure only a limited control over the production and sale of Ayurvedic medicines namely:-

i. The manufacture should be carried out under prescribed hygienic conditions, under the supervision of a person having prescribed qualifications;

ii. The raw materials used in the preparation of drugs should be genuine and properly identified; and

iii. The formula or the true list of all the ingredients contained in the drugs should be displayed on the label of every container.

To start with, development of standards for the identity, purity and strength of single drugs and those of formulations at a later stage, assumed importance for the effective enforcement of the provision of the Act. If the raw materials to be used in a medicine and stage-by-stage processes of manufacturers are standardised, the final product namely, the compound formulation could be expected to conform to uniform standards. The requirement that the list of ingredients be displayed on the label will enable analysts to verify label claims. It will also ensure that the manufacture do not make false claim. Arrangements to evolve and lay down physical, chemical and biological standards, wherever even necessary, to identify the drugs and ascertain their quality and to detect adulterations are an urgent necessity of the profession. Setting up of Drug Standardisation Units, Research Centres, Drug Testing Institutes and Central Drug Laboratories for Ayurvedic Medicines both at national and regional level for this purpose are therefore, essential. The several Committees appointed by the Government of India to assess and evaluate the status and practice of Ayurvedic Medicine have stressed the

importance of preparing an Ayurvedic Pharmacopoeia, which is precisely a book of standards.

Having regard to all these considerations, the Central Council of Ayurvedic Research recommended the constitution of Ayurvedic Pharmacopoeia Committee consisting of experts on Ayurveda and other sciences. The Government of India accepted the recommendations of the Central Council of Ayurvedic Research and constituted the First Ayurvedic Pharmacopoeia Committee, vide their letter No. 14-8/62-ISM, dated the 20th September, 1962 for a period of three years with effect from the date of its first meeting under the Chairmanship of Col. Sir R.N. Chopra with the following member :-

1. Col. Sir Ram Nath Chopra, Drugs Research Laboratory, Srinagar *Chairman*

2. Vaidya B.V. Gokhale, 29/14-15, Erandavane, Deccan Gymkhana, Poona-4 *Member*

3. Vaidya D.A. Kulkarni, Principal, Post Graduate, Training Centre in Ayurveda, Jamnagar. *Member*

4. Kaviraj B.N. Sircar, 779-780, Nicholson Road, Kashmere Gate, Delhi-6 *Member*

5. Shri A.N. Namjoshi, Navyug Mansion, 19-A, Sleater Road, Bombay-7 *Member*

6. Dr.B.B.Gaitonde, Profossor of Pharmacology, Grant Medical College, Bombay *Member*

7. Dr. C.G. Pandit, Director, Indian Council of Medical Research, New Delhi *Member*

8. Dr. G.K. Karandikar, Dean, Medical College, Aurangabad *Member*

9. Dr. G.S. Pande, Honorary Director, Indian Drug Research Association, 955-Sadashiv Peth, Lakshmi Road, Poona-2 *Member*

10. Dr. M.V. Venkataraghava, Chellakoti, Nungabakkum, Madras-34 *Member*

11. Ayurvedachara Kaladi K. Parameswaran Pillai, Laksmivilasam Vaidyasala, Vanchiyur, Trivandrum. *Member*

12. Dr. V. Narayanaswamy, 70, Tana Street, Vepeiy, Madras-7 *Member*

13. Vaidya P.V.Dhamankar Shastri, Pardeshi Lane, Panvel, District Kolaba, Bombay *Member*

14. S.K. Borkar, Drug Controller (India), Directorate General of Health Services, Government of India, New Delhi *Member*

15. Shri Bapalal G.Vaidya, Principal, O.H. Nazar Ayurveda Mahavidyalaya, *Member*

Surat.

16. Kumari Savita Satakopan, Drugs Control Laboratory, Near Polytechnic, National Highway 8, Baroda. *Member*

17. Vaidya Vasudev M. Dwivedi, Director of Ayurveda, Government of Gujrat, Ahmedabad *Member*

18. Shri P.V. Bhatt, M.Sc., Chemist, The Ayurvedic Rasashala, Deccan Gymkhana, Poona. *Member*

19. Vaidya Ram Sushil Singh, Assistant Director of Ayurveda, Director of Medical Services (Ayurveda), Govt. of U.P. *Member*

20. Dr.Y. Kondal Rao, Secretary, Indian Medical Practitioner's Cooperative Pharmacy & Stores Limited, Adyar, Madras-20 *Member*

21. Dr. V. Srinivasan, M.Sc., M.B.B.S., Ph.D., Director, Sarabhai Chemicals Research Institute, Shahibag, Ahmedabad-4 *Member*

22. Dr. C. Dwarakanath, Adviser in Indian System of Medicine, Ministry of Health, New Delhi *Member Secretary*

The Committee was assigned the following functions :-

1. To prepare an official Formulary in two parts :-

   (a) Single drugs, of whose identity and therapeutic value there is no doubt; and

   (b) Compound preparations, which are frequently used in Ayurvedic practice throughout the country.

2. To provide standards for drug and medicines of therapeutic usefulness or pharmaceutical necessity commonly used in Ayurvedic practice.

3. To lay down tests for identity, quality and purity.

4. To ensure as far as possible uniformity, physical properties and active constituents; and

5. To provide all other information regarding the distinguishing characteristics, methods of preparation, dosage, method of administration with various anupanas or vehicles and their toxicity.

As a first step in this direction the Ayurvedic Pharmacopoeia Committee started preparing the official Formulary of Ayurveda in two parts as mentioned under the assigned functions of the Committee. Since the work of preparation of Ayurvedic Formulary could not be completed after the expiry of first three years, the Government of India extended the term of the Committee by another three years vide their notification No. F. 20-1/66-RISM, dated 14th January, 1966 and a gain for a further period of three years vide their notification No. F. 1-1/69-APC, dated 9th January, 1969.

During the years that followed, Ayurvedic Formulary, Part I and II and Ayurvedic Pharmacopoeia of India, Part – I, Volume I - V were published, the former containing the compound formulations from classical Ayurvedic texts prescribed in Schedule - I to the Drug and Cosmetics Act, and the later, laying down standards for single drugs of plant origin. Amendment to the provisions introduced in 1982 further strengthen the ASU system by defining misbranded, adulterated and spurious drugs in the ASU system.

Subsequently under the 10th Five Year Plan a project was initiated by the Department to develop Method of Preparation, Standard Operative Procedures, Pharmacopoeial Standards and Shelf Life of Compound formulations of Ayurveda appearing in Ayurvedic Formulary of India, Parts I & II.

The work of the Ayurvedic Pharmacopoeia Committee was transferred along with some technical staff to Central Council for Research in Ayurveda and Siddha, New Delhi as a secretariat for APC vide letter no. X-19011/6/94-APC (AYUSH), dated 29th March, 2006.

Prof. A.N. Namjoshi (*1972, 1981*, *1988* and *1994*) and Vaidya I. Sanjeeva Rao (*1998*) and Dr. P.D. Sethi *(2001)* were Chairmen of reconstituted Ayurvedic Pharmacopoeia Committee during the specified periods.

The present Ayurvedic Pharmacopoeia Committee (APC) was reconstituted under the Deptt. of AYUSH vide letter No.X-19011/6/94-APC (AYUSH) dated 9st March, 2006 consisting of following members.

Ms. Savita Satakopan, M.Sc. (Former Drug Analyst), Government of Gujarat, 7/4, Padmam Flats, Seventh Street, Nanganallur, Chennai – 600 061.	Chairperson (9th May 2005 to 22nd June 2006)
Prof. S.S. Handa, M. Pharma, Ph.D., (Former Director, RRL, Jammu), 522-A, Block 'C', Sushant Lok, Phase-I, Gurgaon, Haryana – 122 001.	Chairman (23rd June, 2006 to onwards)

Dr. S.K. Sharma, M.D. (Ayu.), Ph.D. — Vice-Chairman
Advisor (Ayurveda),
Department of AYUSH,
Red Cross Society Building,
New Delhi – 110 001.

OFFICIAL MEMBERS

1. Dr. G.S. Lavekar, AVP; Ph.D. — Member-Secretary (Ex-officio)
Director,
Central Council for Research in Ayurveda & Siddha,
61-65, Institutional Area,
D-Block, Janakpuri,
New Delhi – 110 058.

2. Dr. D.R. Lohar, M.Sc.; Ph.D. — Member (Ex-officio)
Director,
Pharmacopoeial Laboratory for Indian Medicine,
Central Govt. Offices Complex,
Kamla Nehru Nagar,
Ghaziabad – 201 002.

3. Managing Director, — Member (Ex-officio)
Indian Medicines Pharmaceutical Corporation Ltd.,
Mohan, Via – Ram Nagar,
Distt.- Almora, Uttranchal.

4. Drugs Controller General (India), — Member (Ex-officio)
Ministry of Health & Family Welfare,
Nirman Bhawan, New Delhi – 110 011.

NON-OFFICIAL MEMBERS

Phytochemistry & Chemistry Sub-Committee

1. Prof. V.K. Kapoor, M. Pharm., Ph.D. — Chairman
(Former Dean and Chairman,
University Institute of Pharmaceutical Sciences,
Panjab University, Chandigarh)
1473, Pushpac Complex, 49B,
Chandigarh - 160 047.

2. Dr. P.D. Sethi, M. Pharm., Ph.D., — Member
(Former Director,
Central Indian Pharmacopoeial Laboratory)
B-140, Shivalik Enclave,
New Delhi – 110 017.

3. Shri J.K. Dhing, M.Sc. — Member
Former Chief Manager (Exploration),
Hindustan Copper Ltd., SF-8, Sector-5,
(Gayatri Nagar) Hiran Magri,
Udaipur – 313 002. (Rajasthan).

Pharmacognosy Sub-Committee

1. Ms. S. Satakopan, M.Sc. — Chairman
(Former Drug Analyst),
Government of Gujarat,
7/4, Padmam Flats, Seventh Street,
Nanganallur, Chennai – 600 061.

2. Dr. (Mrs.) Shanta Mehrotra, M.Sc., Ph.D., — Member
Emeritus Scientist,
National Botanical Research Institute,
Rana Pratap Marg, P.B. No.-436,
Lucknow – 226 001 (U.P.).

3. Dr. M.A. Iyengar, M. Pharma, Ph.D, — Member
Prof. of Pharmacognosy (Retd.),
14, HIG, HUDCO, Manipal – 576 119.

4. Dr. J. Mohanasundraram, M.D., — Member
Former Professor of Pharmacology
& Deputy Director of Medical Education,
Chennai.

Formulary Sub-Committee

(Rasa Shastra / Bhaishajya Kalpana – Ayurvedic Pharmacy)

1. Prof. S.K. Dixit, A.B.M.S.; D.Ay.M; Ph.D. — Chairman
(Former Head, Deptt. of Rasa Shastra, BHU),
B-3/402, Shivala, Varanasi 221 005 (UP.).

2. Dr. B.L. Gaur, Ph.D.; — Member
Vice-Chancellor,
Jodhpur Ayurvedic University,
Jodhpur, Rajasthan,

3. Prof. Siddhinandan Mishra, G.B.M.S.; Ph.D. — Member
Pharmacy In-charge, SDM Ayurvedic College,
P.O. Kuthpady, Udupi – 574 118,

(South Karnataka).

4. Prof. Ved Vrat Sharma, H.P.A. — Member
(Former Principal, DAV Ayurvedic College),
House No. 65, Sector-8, Panchkula, Haryana.

5. Dr. P.K. Prajapati, M.D. (Ay.), Ph. D., — Member
Reader & Head, Deptt. of Ras Shastra,
IPGT & RA, Gujarat Ayurved University,
Jamnagar, Gujarat – 361 008.

6. Dr. Narendra Bhatt, M.D. (Ay.), — Member
Chief Executive Officer,
Zandu Pharmaceutical Works Ltd.,
70, Ghokhle Road (South), Dadar,
Mumbai – 400 025.

7. Shri Ranjit Puranik, — Member
General Manager,
Shree Dhootapapeshwar Ltd.,
135, Nanubhai Desai Road, Khetwadi,
Mumbai.

Ayurveda Sub-Committee
(Single Drugs of Plants, Minerals, Metals, Animal origin)

1. Prof. V.K. Joshi, M.D. (Ay.), Ph.D. — Chairman
Deptt. Dravyaguna,
Institute of Medical Sciences,
Banaras Hindu University (BHU),
Varanasi – 221 005 (U.P.).

2. Prof. K.C. Chunekar, Ph.D. — Member
(Former Reader, Deptt. of Dravyaguna, BHU),
18/7, Ratan Phatak,
Varanasi, (U.P.).

3. Vaidya Devender Triguna, Ayurvedacharya, — Member
"PADAM SHREE", 143-Sarai Kale Khan,
Nizamuddin East, New Delhi.

4. Dr. M.R. Uniyal, M.D. (Ay.), Ph.D. — Member
(Former Director, CRIA, CCRAS),
Director (Drugs), Maharishi Ayurved Products,
17/18, NOIDA Export Processing Zone,
NOIDA – 201 305.

5. Prof. V.V. Prasad, Member
Director,
Rashtriya Ayurveda Vidyapeeth,
Dhanvantri Bhawan,
Road No. 66, Punjabi Bagh (West),
New Delhi – 110 026.

CO-OPTED MEMBERS

1. Dr. G.V. Satyavathi,
Former Director General-ICMR,
Prasad-Nilaya, D-55/82, EAST-END (B),
Main Road, 9th Block,
Jaynagar, Bangalore –500069.

2. Dr. G.P. Dubey,
Ex.Dean, Ayurveda,
Project Investigator,
Center of Psychosomatic & Biofeedback
Medicine,
Faculty of Ayurveda,
Institute of Medical Sciences,
Banaras Hindu University,
Varanasi – 221 005.

1. The term of the Committee shall be for a period of three years from the date of its first meeting and the members shall hold office for that period.
2. The Chairman of the APC shall have the powers to form sub-committees whenever required and to co-opt experts from outside for such sub-committees.
3. The Committee shall have the power to frame procedures of functioning.
4. The functions of the Committee shall be as follows:

(i) To prepare Ayurvedic Pharmacopoeia of India of single and compound drugs.
(ii) To prescribe the working standards for compound Ayurvedic formulations including tests for identity, purity, strength and quality so as to ensure uniformity of the finished formulations.
(iii) Keeping in view the time constraint, to identify such methods, procedures and plan of work as would enable to publish the formulary and standards of all commonly used drugs to be brought out in a phased manner.
(iv) To prepare remaining parts of the official formulary of compound preparations from the classical texts including standardized composition of reputed institution.
(v) To develop and standardize methods of preparations, dosage form, toxicity profile etc.
(vi) To develop quality standards, safety, efficacy profile of intermediates likes extracts of Ayurvedic raw drugs.
(vii) To develop the quality standards, safety, efficacy profile of different parts of the plants; as well as to include new plants as Ayurvedic drugs.

(viii) Any other matter relating to the quality standards, shelf life, identification, new formulations etc.

5. The following are the targets focus of the Committee:

(i) To evolve standards of single drugs mentioned in the Ayurvedic Formularies of India.

(ii) To evolve standards for compound formulations mentioned in the Ayurvedic Formularies of India & other Ayurvedic formulations of National Priority.

(iii) To prepare drafts SOP of Ayurvedic Formularies of India from the classical texts and other authentic sources.

CONTRIBUTING LABORATORIES & INSTITUTIONS

The following institutions have carried out the scientific work of Monographs under APC scheme.

University Institute of Pharmaceutical Sciences,
Punjab University,
Chandigrah 160 014.
(P. I. - Dr. Karan Vasisht)

National Institute Pharmaceutical Education and Reaserch(NIPER),
SAS Nagar,
Mohali,
(P.I. - Dr. K.K.Butani)

Captain Srinivasa Murty Drug Research Institute Ayurveda (CSMDRIA),
Aringner Anna Government Hospital Campus,
Arumbakkam,
Chennai 600 016.
(P.I.-Dr. (Ms.) A. Saraswathy)

B. V. Patel, Pharmaceutical Education,
and Research Development (PERD) Centre,
Thaltej, Ahmedabad 380 054.
(P.I. - Dr. (Mrs.) M. Rajani)

National Botanical Research Institute,
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Rana Pratap Marg,
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(P.I. - Dr. A. K. S. Rawat)

Ram Narayan Ruia College,
Matunga,
Mumbai
(P.I. - Dr. Sunita Shaljan)

Complied by Dr. Mrs. Pramila Pant CCRAS, New Delhi

MONOGRAPHS

ĀSAVA AND ARI½¯A

General Description:

Āsavas and *Ari¾ºas* are medicinal preparations made by soaking the drugs, either in coarse powder form or in the form of decoction *(ka¾āya)*, in a solution of sugar or jaggery, as the case may be, for a specified period of time, during which it undergoes a process of fermentation generating alcohol, thus facilitating the extraction of the active principles contained in the drugs. The alcohol, so generated, also serves as a preservative.

Ari¾ºa

The drugs mentioned in the texts are coarsely (*yavakūºa)* powdered and *ka¾āya* is prepared. The *ka¾āya* is strained and kept in the fermentation vessel. Sugar, jaggery or honey*, according to the formula, is dissolved, boiled, filtered and added. Drugs mentioned as *Prak¾epa dravyas* are finely powdered and added. At the end, *dhātakī pu¾pa*, if included in the formula, should be properly cleaned and added. The mouth of the vessel is sealed. The container is kept either in a special room (Alternatively, in an underground cellar or in a heap of paddy, so as to ensure that for the duration of fermentation, as far as possible, a constant temperatures may impede or accelerate the fermentation).

After the specified period, the lid is removed, and the contents examined to ascertain whether the process of fermentation *(sandhāna)* has been completed. The fluid is first decanted and then strained after two or three days. When the fine suspended particles settle down, it is strained again and bottled.

Āsavas

The required quantity of water, to which jaggery or sugar as prescribed in the formula is added, is boiled and cooled. This is poured into the fermentation pot, vessel or barrel. Fine powders of the drugs mentioned in the formula are added.The container is covered with a lid and the edges are sealed with clay-smeared cloth wound in seven consecutive layers. The rest of the process is as in the case of *Ari¾ºa*.

If the fermentation is to be carried in an earthen vessel, it should not be new. Water should be boiled first in the vessel. Absolute cleanliness is required during the process. Each time, the inner surface of the fermentation vessel should be fumigated with *pippalī cūr´a* and smeared with ghee before the liquids poured into it (in large scale manufacture, wooden-vats, porcelain-jars or metal vessels are used in place of earthen vessels.).

The filtered *Āsava* or *Ari¾ºa* should be clear without froth at the top. It should not become sour (*cukra*). The preparation has the characteristics of aromatic alcoholic odour.

Āsavas and *Ari¾ºas* can be kept indefinitely. They should be kept in well-stoppered bottles or jars.

***** Honey, where mentioned, should be added as such without being dissolved or boiled.

ABHAYĀRI½¯A
(AFI, Part-I, 1: 1)

Definition:

Abhayāri¾°a is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Abhayā (Harītakī API)	*Terminalia chebula*	P.	4.8 kg
2	M¨dvīkā (Drāk¾ā API)	*Vitis vinifera*	Dr. Fr.	2.4 kg
3	Vi²a¬ga API	*Embelia ribes*	Fr.	480 g
4	Madhūka Kusuma (Madhūka API)	*Madhuca indica*	Fl.	480 g
5	Jala API for decoction reduced to	Water		49.152 l 12.288 l
6	Gu²a API	Jaggery		4.8 kg
7	Śvada¼¾°rā (Gok¾ura API)	*Tribulus terrestris*	Fr.	96 g
8	T¨iv¨tā (Triv¨t API)	*Operculina turpethum*	Rt.	96 g
9	Dhānya (Dhānyaka API)	*Coriandrum sativum*	Fr.	96 g
10	Dhātakī API	*Woodfordia fruticosa*	Fl.	96 g
11	Indravāru´¡ī API	*Citrullus colocynthis*	Rt.	96 g
12	Cavya API	*Piper retrofractum*	St.	96 g
13	Madhūrikā (Miśreyā API)	*Foeniculum vulgare*	Fr.	96 g
14	Śu´°hī API	*Zingiber officinale*	Rz.	96 g
15	Dantī API	*Baliospermum montanum*	Rt.	96 g
16	Mocarasa (Śālmalī API)	*Salmalia malabarica*	Exd.	96 g

Method of preparation:

Take the raw material of pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 and 3 *(Kvātha dravya)* of the formulation composition and pass through the sieve number 44 to obtain coarse powder.
Wash and clean the ingredient numbered 2 and 4 *(Kvātha dravya)* of the formulation composition.
Clean, dry and powder the ingredients numbered 7 to 16 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add specified amount of water to the *Kvātha dravya,* soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.
Add the ingredient number 6 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the muslin cloth.
Transfer the filtrate to a clean container; add *Dhātakī* and other finely powdered *prak¾epa dravyas.* Seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.

Filter the fermented material through a clean muslin cloth.
Pack in air tight containers and allow for maturation.

Description:

Clear dark brown liquid without frothing and significant sedimentaton; with aromatic odour and bitter taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 1 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 5 µl of test solution prepared as above and 5 µl of marker solution prepared by dissolving 1 mg of *gallic acid in* 1 ml of *methanol,* on TLC plate. Develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (3 : 3 : 0.8 : 0.2) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.41 (blue, corresponding to *gallic acid)* and 0.59 (light blue).

Physico-chemical parameters:

Total phenolic content:	0.2 to 0.3 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 17.5 per cent w/v,	Appendix 3.8
Specific gravity (at 25^o):	1.01 to 1.12,	Appendix 3.2
*p*H*:*	3.6 to 4.2,	Appendix 3.3
Reducing sugars:	Not less than 9.50 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.40 per cent w/v,	Appendix 5.1.3
Alcohol content :	6.5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Assay :

The formulation contains 0.4 to 0.8 per cent w/v of *gallic acid,* when assayed by following method.

Estimation of gallic acid: Dissolve 1 mg of *gallic acid* in 1ml of *methanol.*
Apply 1.0 to 8.0 µl of (5 data point) of *gallic acid* solution prepared under Thin layer chromatography on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (3 : 3 : 0.8 : 0.2) as mobile phase. Derivatise the plate with *Natural product reagent* and dry in a current of cold air and scan in the TLC scanner at a wavelength of 366 nm. Note the peak areas under curve for the peak corresponding to *gallic acid and* prepare the calibration curve by plotting peak area *vs* concentration of *gallic acid.*

Dry about 50 ml, of the formulation accurately measured, in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh accurately. Dissolve about 1 mg, accurately weighed, residue in 1 ml of *methanol* taken from a graduated pipette. Apply 5 µl of the test solution on TLC plate. Develop, dry and scan the plate as described in preceding paragraph for calibration curve of *gallic acid.* Calculate the amount of *gallic acid* in the test solution from the calibration curve of *gallic acid* .

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Arśa (piles), Udara (diseases of abdomen), Mūtravibandha (retention of urine), Agnimāndya (digestive impairment); Varcovibandha (constipation).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

AM§TĀRI½¯A
(AFI, Part-I, 1:2)

Definition:

Am¨tāri¾°a is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Am¨tā (Gu²ūcī API)	*Tinospora cordifolia*	St.	4.8 kg
2	Bilva API	*Aegle marmelos*	St. Bk.	480 g
3	Śyonāka API	*Oroxylum indicum*	St. Bk.	480 g
4	Gambhārī API	*Gmelina arborea*	St. Bk.	480 g
5	Pā°alā API	*Stereospermum suaveolens*	St. Bk.	480 g
6	Agnimantha API	*Premna mucronata*	St. Bk.	480 g
7	Śālapar´ī API	*Desmodium gangeticum*	Pl.	480 g
8	P¨¾nipar´ī API	*Uraria picta*	Pl.	480 g
9	B¨hatī API	*Solanum melongena* var. *indicum*	Pl.	480 g
10	Ka´°akārī API	*Solanum surattense*	Pl.	480 g
11	Gok¾ura API	*Tribulus terrestris*	Pl.	480 g
12	Jala API for decoction reduced to	Water		49.152 l 12.288 l
13	Gu²a API	Jaggery		14.4 kg
Prak¾epa dravyas:				
14	Ajājī (Śveta jīraka API)	*Cuminum cyminum*	Fr.	768 g
15	Raktapu¾paka (Parpa°a API)	*Fumaria parviflora*	Pl.	96 g
16	Saptacchadā (Saptapar´a API)	*Alstonia scholaris*	St. Bk.	48 g
17	Śu´°hī API	*Zingiber officinale*	Rz.	48 g
18	Marica API	*Piper nigrum*	Fr.	48 g
19	Pippalī API	*Piper longum*	Fr.	48 g
20	Nāgakeśara API	*Mesua ferrea*	Stmn.	48 g
21	Abda (Mustā API)	*Cyperus rotundus*	Rz.	48 g
22	Ka°vī (Ka°ukā API)	*Picrorrhriza kurroa*	Rz.	48 g
23	Prativi¾ā (Ativi¾ā API)	*Aconitum heterophyllum*	Rt.	48 g
24	Vatsabīja (Indrayava API)	*Holarrhena antidysenterica*	Sd.	48 g

Method of preparation:

Take the raw material of pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 to 11 *(Kvātha dravya)* of the formulation composition individually and pass through the sieve number 44 to obtain coarse powder.
Clean, dry and powder the ingredients numbered 14 to 24 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add specified amounts of water to the *Kvātha dravya*, soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.
Add the ingredient number 13 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the muslin cloth.
Transfer the filtrate to a clean container; add the finely powdered *prak¾epa dravyas* and seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean muslin cloth.
Pack in air tight containers and allow for maturation.

Description:

Clear, dark brown liquid without frothing and significant sedimentaton; with astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 20 mg of residue in 1 ml of *methanol.*
Apply seperatly 2 µl of solution prepared in preceeding paragraph and 5µl of marker solution of *luteolin* and *apigenin* prepared by dissolving 0.5 mg of *luteolin* and 0.1 mg of *apigenin* in 1 ml of *methanol* separately on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent*, dry and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.27 (brillient blue), 0.41 (orange, corresponding to luteolin), 0.52 (brilliant blue) and 0.66 (light blue, corresponding to apigenin).

Physico-chemical parameters:

Total phenolic content:	0.080 to 0.103 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 25.0 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.05 to 1.20,	Appendix 3.2
*p*H*:*	3.40 to 4.40,	Appendix 3.3

Reducing sugars:	Not less than 16 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.80 per cent w/v,	Appendix 5.1.3
Alcohol content :	5 to 8 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Assay:

The formulation contains 0.01 to 0.07 per cent w/v of *luteolin* when assayed by the following method:

Estimation of luteolin: Apply separately 1.0 to 8.0 µl (5 data point) of standard solution of *luteolin* prepared under thin layer chromatography, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1). Derivatise the plate with *Natural product reagent* and dry in a current of cold air and scan in the TLC scanner at a wavelength of 366 nm. Record the peak area under curve and plot the calibration curve for the peak corresponding to *luteolin* by plotting the peak area *vs* concentration of *luteolin*.

Dry about 50 ml, accurately measured, of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve about 20 mg, accurately weighed, residue in 1 ml of *methanol* taken from a graduated pipette.

Apply 2 µl on TLC plate and carry out thin layer chromatography. Develop, dry and scan the plate as described in preceding paragraph for calibration curve of *luteolin*.

Calculate the amount of *luteolin* in the test solution from the calibration curve of *luteolin*.

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: All types of Jvara (fever).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

ARAVINDĀSAVA

(AFI, Part-I, 1: 4)

Definition:

Aravindāsava is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation Composition:

1	Aravinda (Kamala API)	*Nelumbo nucifera*	Fl.	16 g
2	Uśīra API	*Vetivera zizanioides*	Rt.	16 g
3	Kāśmarī(Gambhārī API)	*Gmelina arborea*	Fr.	16 g
4	Nīlotpala (Utpala API)	*Nymphaea stellata*	Fl.	16 g
5	Ma®ji¾°hā API	*Rubia cordifolia*	Rt.	16 g
6	Balā API	*Sida cordifolia*	Rt.	16 g
7	Mā¼sī (Ja°āmā¼sī API)	*Nardostachys jatamansi*	Rz.	16g
8	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	16 g
9	Ambuda (Mustā API)	*Cyperus rotundus*	Rz.	16 g
10	Sārivā (Śvetasārivā API)	*Hemidesmus indicus*	Rt.	16 g
11	Śivā (Harītakī API)	*Terminalia chebula*	P.	16 g
12	Bibhītaka API	*Terminalia bellirica*	P.	16 g
13	Vacā API	*Acorus calamus*	Rz.	16 g
14	Dhātrī (Āmalakī API)	*Emblica officinalis*	P.	16 g
15.	Śathī (Śa°ī API)	*Hedychium spicatum*	Rz.	16 g
16	Śyāmā (Triv¨t API)	*Ipomoea turpethum*	Rt.	16 g
17.	Nīlinī (Nīlī API)	*Indigofera tinctoria*	Rt.	16 g
18.	Pa°ola API	*Trichosanthes dioica*	Lf. / Pl.	16 g
19.	Parpa°a API	*Fumaria parviflora*	Pl.	16 g
20	Pārtha (Arjuna API)	*Terminalia arjuna*	St. Bk.	16 g
21	Madhūka API	*Madhuca indica*	Fl.	16 g
22.	Madhuka (Ya¾°ī API)	*Glycyrrhiza glabra*	Rt.	16 g
23.	Murā API	*Selinium tenuifolium*	Rt.	16 g
24.	Drāk¾ā API	*Vitis vinifera*	Dry Fr.	320 g
25.	Dhātakī API	*Woodfordia fruticosa*	Fl.	256 g
26.	Jala API	Water		8.19 l
27.	Śarkarā API	Sugar		1.6 kg
28.	Māk¾ika (Madhu API)	Honey		0.8 kg

Method of Preparation:

Take the raw materials of Pharmacopoeial quality.

Wash, dry and powder the ingredients numbered 1 to 23 of the formulation composition individually and pass through the sieve number 44 to obtain coarse powder.

Wash and clean the ingredients numbered 24 and 25 of the formulation composition.

Add specified amount of water to the ingredient number 27 of the formulation composition, allow to dissolve and filter through the *muslin cloth.*

Transfer the filtrate to a clean container; add *Madhu, Drāk¾ā, Dhātakī* and coarsely powdered other drugs. Seal the mouth of the container.

Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean muslin cloth.
Pack in air tight containers and allow for maturation.

Description:

Clear light brown liquid without frothing and significant sedimentaton; with aromatic odour and acrid taste

Identification:
Thin Layer Chromatography:
Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water*, shake and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 20 mg of residue in 1 ml of *methanol* and carry out the thin layer chromatography.
Apply 20 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (3 : 3 : 0.8 : 0.2) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent*, dry and examine under ultraviolet light (366 nm). It shows major spots at 0.48 (dark blue), 0.59 (light blue) and 0.65 (light blue).

Physico-chemical parameters:

Total phenolic content:	Not less than 0.05 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	10 to 20 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.0 to 1.1	Appendix 3.2
*p*H*:*	3.0 to 4.5	Appendix 3.3
Reducing sugars :	3.5 to 5.5 per cent w/v,	Appendix 5.1.3
Non-reducing sugars :	Not more than 1.0 per cent w/v,	Appendix 5.1.3
Alcohol content :	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other Requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protected from light and moisture.

Therapeutic Uses: Agnimāndya (digestive impairment); Kārśya (emaciation); Balak¾aya (loss of strength / immunity); Sarva bāla roga (all children diseases); Grahado¾a (certain psychotic syndrome); Āyu¾ya (life prolonging)

Dose: 3 to 12 ml orally with equal amount of water after meals twice a day over one year of age and 10 to 20 drops upto one year, 2-3 times a day.

AŚOKĀRI½¯A
(AFI, Part-I, 1:5)

Definition:

Aśokāri¾°a is a fermented liquid preparation, made with the ingredients in Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Aśoka API	*Saraca asoca*	St. Bk.	4.800 kg
2	Jala API for decoction reduced to	Water		49.152 l 12.288 l
3	Gu²a API	Jaggery		9.6 kg
Prak¼epa dravya:				
4	Dhātakī API	*Woodfordia fruticosa*	Fl.	768 g
5	Ajājī (Śveta jīraka API)	*Cuminum cyminum*	Fr.	48 g
6	Mustaka (Mustā API)	*Cyperus rotundus*	Rz.	48 g
7	Śu´°hī API	*Zingiber officinale*	Rz.	48 g
8	Dārvī (Dāruharidrā API)	*Berberis aristata*	St.	48 g
9	Utpala API	*Nymphaea stellata*	Fl.	48 g
10	Harītakī API	*Terminalia chebula*	P.	48 g
11	Bibhītaka API	*Terminalia belerica*	P.	48 g
12	Āmalakī API	*Emblica officinalis*	P.	48 g
13	Āmrāsthi (Āmra API)	*Mangifera indica*	Enm.	48 g
14	Jīraka (Śveta jīraka API)	*Cuminum cyminum*	Fr.	48 g
15	Vāsā API	*Adhatoda vasica*	Rt.	48 g
16	Candana (Śveta candana API)	*Santalum album*	Ht. Wd.	48 g

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and powder the ingredient numbered 1 *(Kvātha dravya)* of the formulation composition and pass through the sieve number 44 to obtain coarse powder.
Clean, dry and powder the ingredients numbered 5 to 16 *(Prak¼epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add specified amount of water to the *Kvātha dravya*, soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.
Add the ingredient number 3 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the muslin cloth.
Transfer the filtrate to a clean container; add *Dhātakī* and other finely powdered *Prak¼epa dravyas*. Seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean *muslin cloth*.
Pack in air tight containers and allow for maturation.

Description:

Clear, dark brown liquid without frothing and significant sedimentaton; ; with astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 20 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply 5 µl of test solution prepared as above on TLC plate and 2µl each of marker solutions prepared by dissolving 1 mg each of *gallic acid* and *kaempferol* in 1 ml each of *methanol* separately, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.09 (yellow), 0.32 (blue, corresponding to *gallic acid*), 0.52 (creamish white) and 0.64 (light green, corresponding to *kaempferol*).

Physico-chemical parameters:

Total phenolic content:	0.061 to 0.083 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 11.0 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.02 to 1.12,	Appendix 3.2
*p*H*:*	3.5 to 4.5,	Appendix 3.3
Reducing sugars:	Not less than 5.50 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 1.00 per cent w/v,	Appendix 5.1.3
Alcohol content :	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Assay:

The formulation contains 0.06 to 0.7 per cent w/v *gallic acid*, when assayed by the following method.

Estimation of gallic acid : Apply 1.0 to 8.0 µl of (5 data point) *gallic acid* solutions prepared under thin layer chromatography on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. Derivatise the plate with *Natural product reagent* and dry in a current of cold air and scan in the TLC scanner at a wavelength of 366 nm. Note the area under curve for the peaks corresponding to *gallic acid* and prepare the calibration curve by plotting peak area *vs* concentration of *gallic acid*.

Dry about 50 ml, accurately by measured formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve about 20 mg, accurately weighed, residue in 1 ml of *methanol* taken from a graduated pipette. Apply 5 µl of the test solution on TLC plate. Develop, dry and scan the plate as described above for calibration curve of *gallic acid*. Calculate the amount of *gallic acid in* the test solution from the calibration curve of *gallic acid.*

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: As¨gdara rujā (dysmenorrhoea); Yonirujā (pain in female genital tract); Śvetapradara (leucorrhoea); Jvara (fever); Raktapitta (bleeding disorders); Arśa (piles); Mandāgni (dyspepsia); Arocaka (tastelessness); Meha (polyuria); Śotha (inflammation).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

AŚVAGANDHĀDYARI½¯A

(AFI, Part-1, 1:6**)**

Definition:

Aśvagandhādyari¾°a is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Aśvagandhā API	*Withania somnifera*	Rt.	2.4 kg
2	Muśalī API	*Chlorophytum tuberosum*	Rt.	960 g
3	Ma®ji¾°hā API	*Rubia cordifolia*	Rt.	480 g
4.	Harītakī API	*Terminalia chebula*	P.	480 g
5	Haridrā API	*Curcuma longa*	Rz.	480 g
6	Dāruharidrā API	*Berberis aristata*	St.	480 g
7	Madhuka (Ya¾°ī API)	*Glycyrrhiza glabra*	Rt.	480 g
8	Rāsnā API	*Pluchea lanceolata*	Rt./Lf.*	480 g
9	Vidārī API	*Pueraria tuberosa*	Rt. Tr.	480 g
10	Pārtha (Arjuna API)	*Terminalia arjuna*	St. Bk.	480 g
11	Mustaka (Mustā API)	*Cyperus rotundus*	Rz.	480 g
12	Triv¨t API	*Ipomoea turpethum*	Rt.	480 g
13	Anantā (Śveta sārivā API)	*Hemidesmus indicus*	Rt.	384 g
14	Śyāmā (K¨¾´a sārivā API)	*Cryptolepis buchanani*	Rt.	384 g
15	Śveta candana API	*Santalum album*	Ht. Wd.	384 g
16	Rakta candana API	*Pterocarpus santalinus*	Ht. Wd.	384 g
17	Vacā API	*Acorus calamus*	Rz.	384 g
18	Citraka API	*Plumbago zeylanica*	Rt.	384 g
19	Jala API for decoction	Water		98.304 l
	reduced to			12.288 l
Prak¾epa dravyas				
20	Māk¾ika (Madhu API)	Honey		14.4 kg
21	Dhātakī API	*Woodfordia fruticosa*	Fl.	768 g
22	Śu´°hī API	*Zingiber officinale*	Rz.	96 g
23	Marica API	*Piper nigrum*	Fr.	96 g
24	Pippalī API	*Piper longum*	Fr.	96 g
25	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	192 g
26	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	192 g
27	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	192 g
28	Priya¬gu API	*Callicarpa macrophylla*	Fl.	192 g
29	Nāgakeśara API	*Mesua ferrea*	Stmn.	96 g

* Actual part used in the formulation.

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 to 18 *(Kvātha dravya)* of the formulation composition individually and pass through the sieve number 44 to obtain coarse powder.
Clean, dry and powder the ingredients numbered 22 to 29 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add specified amounts of water to the *Kvātha dravya*, soak overnight, heat, reduce to one eighth and filter through *muslin cloth* to obtain *Kvātha*. Allow to cool.
Transfer the filtrate to a clean container; add ingredient numbered 20, 21 of the formulation composition. Finally add the finely powdered *prak¾epa dravyas* and seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean *muslin cloth*.
Pack in air tight containers and allow for maturation.

Description:

Clear, dark brown liquid without frothing and significant sedimentaton; with astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3) and *chloroform* (50 ml x 3). Filter and concentrate the *chloroform* extract under vacuum and weigh. Dissolve 20 mg of residue in 1 ml of *chloroform* and carry out the thin layer chromatography.
Apply separately 10 µl of solution prepared as above and 5 µl of standard solution of *withanolide D* prepared by dissolving 1 mg in 1 ml of *methanol*, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and spray with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 minutes and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.27 (dark purple), 0.44 (purple, corresponding to *withanolide D*), 0.61 (light grey), and 0.70 (dark brown).

Physico-chemical parameters:

Total phenolic content:	0.104 to 0.260 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 18.5 per cent w/v,	Appendix 3.8
Specific gravity (at 250^0):	1.05 to 1.20,	Appendix 3.2
*p*H*:*	3.50 to 4.50,	Appendix 3.3
Reducing sugars:	Not less than 13 per cent w/v,	Appendix 5.1.3

Non-reducing sugars:	Not more than 0.70 per cent w/v,	Appendix 5.1.3
Alcohol content :	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

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Therapeutic uses: Mūrcchā (syncope), Apasmāra (epilepsy), Śo¾a (cachexia), Unmāda (mania/psychosis), Kārśya (emaciation), Arśa (piles), Agnimāndya (digestive impairment), Vātaroga (neurological disorders).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

BABBŪLĀRI½¯A
(AFI, Part-II, 1:3)

Definition:

Babbūlāri¾°a is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Babbūla API	*Acacia arabica*	St. Bk.	9.600 kg
2.	Jala API for decoction reduced to	Water		49.152 l 12.288 l
3	Gu²a API	Jaggery		4.8 kg
4	Dhātakī API	*Woodfordia fruticosa*	Fl.	768 g
5	K¨¾´ā (Pippalī API)	*Piper longum*	Fr.	96 g
6	Jātīphala API	*Myristica fragrans*	Sd.	48 g
7	Ka¬kola API	*Piper cubeba*	Fr.	48 g
8	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	48 g
9	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	48 g
10	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	48 g
11	Keśara (Nāgakeśara API)	*Mesua ferrea*	Stmn.	48 g
12	Lava¬ga API	*Syzygium aromaticum*	Fl.	48 g
13	Marica API	*Piper nigrum*	Fr.	48 g

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and powder the ingredient numbered 1 *(Kvātha dravya)* of the formulation composition and pass through the sieve number 44 to obtain coarse powder.
Clean, dry and powder the ingredients numbered 5 to 13 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add specified amounts of water to the *Kvātha dravya*, soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.
Add the ingredient number 3 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the muslin cloth.
Transfer the filtrate to a clean container; add *Dhātakī* and other finely powdered *prak¾epa dravyas*. Seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean muslin cloth.
Pack in air tight containers and allow for maturation.

Description:

Clear, dark brown liquid without frothing and significant sedimentaton; with astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 30 ml *methanol* to dissolve the extract. Filter and dry the methanolic extract in vacuum and weigh. Dissolve 10 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 15 µl of solution prepared as above and 5 µl each of *gallic acid and caffeic acid* solutions, prepared by dissolving 1 mg of *gallic acid and* 0.1mg of *caffeic acid* in one ml *methanol* separately, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (3 : 3 : 0.8 : 0.2) as mobile phase. After development, allow the plate to dry in air and spray with *Natural product reagent*, dry and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.35 (light blue), 0.44 (blue, corresponding to *gallic acid)* and 0.57 (purple, corresponding to *caffeic acid*).

Physico-chemical parameters:

Total phenolic content:	0.187 to 0.208 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 16.5 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.05 to 1.10,	Appendix 3.2
*p*H*:*	4.0 to 4.50,	Appendix 3.3
Reducing sugars:	Not less than 4.20 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.80 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Assay:

The formulation contains 0.02 to 0.10 per cent w/v of *gallic acid*, when assayed by the following method:

Estimation of gallic acid : Apply 1.0 to 8.0 µl of (5 data point) standard solution of *gallic acid* prepared under thin layer chromatography on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid: methanol* (3 : 3 : 0.8 : 0.2) as mobile phase. Derivatise the plate with *Natural product reagent* and dry in a current of cold air and scan in the TLC scanner at a wavelength of 366 nm. Record the peak area under curve for a peak corresponding to *gallic acid* and plot the calibration curve by plotting the peak area *vs* concentration of *gallic acid.*
Dry about 50 ml, accurately measured, of the formulation in vacuum to remove the self generated alcohol. Add 30 ml *methanol* to dissolve the extract. Filter and dry the methanolic extract in vacuum and weigh. Dissolve about 10 mg, accurately weighed, of the residue in 1 ml of *methanol* taken from graduated pipette. Apply 15 µl on TLC plate and

carry out thin layer chromatography. Develop, dry and scan the plate as described in preceding paragraph for calibration curve of *gallic acid*. Calculate the amount of *gallic acid in* the test solution from the calibration curve of *gallic acid*.

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: K¾aya (pthisis), Ku¾ºha (diseases of skin), Atisāra (diarrhoea), Prameha (urinary disorder), Śvāsa (dyspnoea/asthma), Kāsa (cough).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

BALĀRI½¯A
(AFI, Part-I, 1: 9)

Definition:

Balāri¾°a is a fermented liquid preparation, made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Balā API	*Sida cordifolia*	Rt.	4.8 kg
2	Aśvagandhā API	*Withania somnifera*	Rt.	4.8 kg
3	Jala API for decoction	Water		49.152 l
	reduced to			12.288 l
4	Gu²a API	Jaggery		14.4 kg
5	Dhātakī API	*Woodfordia fruticosa*	Fl.	768 g
Prak¾epa dravyas:				
6	Payasyā (K¾īra vidārī API)	*Ipomea digitata*	Sub. Rt.	96 g
7	Pa®cā¬gula (Era´²a API)	*Ricinus communis*	Rt.	96 g
8	Rāsnā API	*Pluchea lanceolata*	Lf.*/Rt.	48 g
9	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	48 g
10	Prasāra´ī API	*Paederia foetida*	Pl.	48 g
11	Devapu¾pa (Lava¬ga API)	*Syzgyium aromaticum*	Fl. Bd.	48 g
12	Uśīra API	*Vetiveria zizanioides*	Rt.	48 g
13	Śvada¼¾°rā (Gok¾ura API)	*Tribulus terrestris*	Fr.	48 g

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 and 2 *(Kvātha dravya)* of the formulation composition.
Clean, dry and powder the ingredients numbered 6 to 13 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add specified amount of water to the *Kvātha dravya*, soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.
Add the ingredient number 4 and 5 of the formulation composition to the *Kvātha*, allow to dissolve and filter through *muslin cloth*.
Transfer the filtrate to a clean container; add ingredient number 5 and other finely powdered *Prak¾epa dravyas* and seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean *muslin cloth*.
Pack in air tight containers and allow for maturation.

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* Actual part used in the formulation.

Description:

Clear brown liquid without frothing and significant sedimentaton; with aromatic odour and sweet taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 10 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 20 µl of test solution prepared as above and 5 µl of marker solution prepared by dissolving 1 mg of *gallic acid* in 1 ml of *methanol*, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.25 (light yellow), 0.40 (blue, corresponding to *gallic acid)*, 0.58 (sky blue) and at 0.62 (blue).

Physico-chemical parameters:

Total phenolic content:	0.095 to 0.105 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 22.0 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.05 to 1.20,	Appendix 3.2
*p*H*:*	3.4 to 4.6,	Appendix 3.3
Reducing sugars:	Not less than 14.0 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 1.0 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Agnimāndya (digestive impairment), Daurbalya (weakness), Vātajaroga (diseases due to vāta do¾a), Kārśya (emaciation).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

DAŚAMŪLĀRI½¯A
(AFI, Part-I, 1: 18)

Definition:

Daśamūlāri¾°a is a fermented liquid preparation, made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Bilva API	*Aegle marmelos*	St. Bk	48 g
2	Śyonāka API	*Oroxylum indicum*	St. Bk	48 g
3	Gambhārī API	*Gmelina arborea*	St. Bk	48 g
4	Pā°alā API	*Stereospermum suaveolens*	St. Bk	48 g
5	Agnimantha API	*Premna mucronata* (Official substitute)	St. Bk	48 g
6	Śālapar´ī API	*Desmodium gangeticum*	Pl.	48 g
7	P¨śnipar´ī API	*Uraria picta*	Pl.	48 g
8	B¨hatī API	*Solanum indicum*	Pl.	48 g
9	Ka´°akārī API	*Solanum xanthocarpum*	Pl.	48 g
10	Gok¾ura API	*Tribulus terrestris*	Pl.	48 g
11	Citraka API	*Plumbago zeylanicum*	Rt.	240 g
12	Pau¾kara (Pu¾kara API)	*Inula racemosa*	Rt.	240 g
13	Lodhra API	*Symplocos racemosa*	St. Bk.	192 g
14	Gu²ūcī API	*Tinospora cordifolia*	St.	192 g
15	Dhātrī (Āmalakī API)	*Emblica officinalis*	P.	154 g
16	Durālabhā (Dhanvayāsa API)	*Fagonia cretica*	Pl.	115 g
17	Khadira API	*Acacia catechu*	Ht. Wd.	77 g
18	Bījasāra API	*Pterocarpus marsupium*	Ht. Wd.	77 g
19	Pathyā (Harītakī API)	*Terminalia chebula*	P.	77g
20	Ku¾°ha API	*Saussurea lappa*	Rt.	19 g
21	Ma®ji¾°hā API	*Rubia cordifolia*	Rt.	19 g
22	Devadāru API	*Cedrus deodara*	Ht. Wd.	19 g
23	Vi²a¬ga API	*Embelia ribes*	Fr.	19 g
24	Madhuka API	*Glycyrrhiza glabra*	Rt.	19 g
25	Bhār¬gī API	*Clerodendrum serratum*	Rt.	19 g
26	Kapittha API	*Feronia limonia*	Fr.P.	19 g
27	Bibhītaka API	*Terminalia bellirica*	P.	19 g
28	Punarnavā (Rakta Punarnavā API)	*Boerhavia diffusa*	Rt.	19 g
29	Cavya API	*Piper retrofractum*	St.	19 g
30	Mā¼sī (Ja°āmā¼sī API)	*Nardostachys jatamansi*	Rz.	19 g
31	Priya¬gu API	*Callicarpa macrophylla*	Fl.	19 g
32	Śārivā API	*Hemidesmus indicus*	Rt.	19 g
33	K¨¾´a Jīraka API	*Carum carvi*	Fr.	19 g
34	Triv¨tā (Triv¨t API)	*Operculina turpethum*	Rt.	19 g
35	Re´ukā API	*Vitex negundo*	Sd.	19 g

36	Rāsnā API	*Pluchea lanceolata*	Lf.	19 g
37	Pippalī API	*Piper longum*	Fr.	19 g
38	Kramuka (Pūga API)	*Areca catechu*	Sd.	19 g
39	Śa°hī (Śa°ī API)	*Hedychium spicatum*	Rz.	19 g
40	Haridrā API	*Curcuma longa*	Rz.	19 g
41	Śatapu¾pā (Śatāhvā API)	*Anethum sowa*	Fr.	19 g
42	Padmaka API	*Prunus cerasoides*	St.	19 g
43	Nāgakeśara API	*Mesua ferrea*	Stmn.	19 g
44	Mustā API	*Cyperus rotundus*	Rz.	19 g
45	Indrayava API	*Holarrhena antidysenterica*	Sd.	19 g
46	Ś¨¬gī (Karka°a ś¨¬gī API)	*Pistacia integerrima*	Gl.	19 g
47	Jīvaka API	*Pueraria tuberosa* (Official substitute)	Rt.Tr.	19 g
48	§¾abhaka API	*Microstylis wallichii*	Rt.Tr.	19 g
49	Medā API	*Polygonatum cirrhifolium*	Rt.Tr.	19 g
50	Mahāmedā API	*Asparagus racemosus* (Official substitute)	Rt.Tr.	19 g
51	Kākolī API	*Withania somnifera* (Official substitute)	Sub.Rt.	19 g
52	K¾īrakākolī API	*Withania somnifera* (Official substitute)	Sub.Rt	19 g
53	§ddhi API	*Dioscorea bulbifera* (Official substitute)	Sub.Rt. Tr.	19 g
54	V¨ddhi API	*Dioscorea bulbifera* (Official substitute)	Sub.Rt. Tr.	19 g
55	Jala API for decoction reduced to	Water		20 l 5 l
56	Drāk¾ā API	*Vitis vinifera*	Dr.Fr.	600 g
57	Jala API for decoction reduced to	Water		2.45 l 1.84 l
58	Madhu API	Honey		307 g
59	Gu²a API	Jaggery		3.8 kg
60	Dhātakī API	*Woodfordia fruticosa*	Fl.	290 g
61	Ka¬kola API	*Piper cubeba*	Fr.	19 g
62	Jala (Hrīvera API)	*Coleus vettiveroides*	Rt.	19 g
63	Candana (Śveta candana API)	*Santalum album*	Ht. Wd.	19 g
64	Jātīphala API	*Myristica fragrans*	Sd.	19 g
65	Lava¬ga API	*Syzygium aromaticum*	Fl. Bud	19 g
66	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	19 g
67	Elā (Śūk¾mailā API)	*Elettaria cardamomum*	Sd.	19 g
68	Patra (Tejpatra API)	*Cinnamomum tamala*	Lf.	19 g
69	Keśara (Nāgakeśara API)	*Mesua ferrea*	Stmn.	19 g
70	Pippalī API	*Piper longum*	Fr.	19 g
71	Kataka Phala (Kataka API)	*Strychnos potatorum*	Sd.	QS

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 and 54 *(Kvātha dravya)* of the formulation composition individually and pass through the sieve number 44 to obtain coarse powder. Add specified amount of water (Number 55), soak overnight, heat, reduce to half and filter through *muslin cloth* to obtain *Kvātha*.
Wash and crush the ingredient numbered 56 *(Kvātha dravya)* of the formulation composition. Add specified amount of water (Number 57), soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.
Collect the two *Kvāthas* into one clean container and mix to form a homogenous liquid.
Clean, dry and powder the ingredients numbered 61 to 70 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add the ingredient number 59 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the muslin cloth.
Transfer the filtrate to a clean container; add *Madhu*, *Dhātakī* and other finely powdered *Prak¾epa dravyas* and seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean muslin cloth.
Pack in air tight containers and allow for maturation.

Description:

Clear dark brown liquid without frothing and significant sedimentaton; with aromatic odour and bitter taste.

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3), and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract in vacuum and weigh. Take 20 mg of ethyl acetate extract and dissolve in 1 ml of *methanol*.
Apply 3 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (3 : 3 : 0.8 : 0.2) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent*, dry and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.08 (yellow), 0.15 (dark blue), 0.37(light blue), 0.44 (blue), 0.55 (light blue) and 0.63 (light blue).

Physico-chemical parameters:

Total phenolic content:	0.2 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	24 - 54 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.09 – 1.1 g/ml,	Appendix 3.2

*p*H*:*	3.6 – 3.7,	Appendix 3.3
Reducing sugars:	14 -24 per cent w/v,	Appendix 5.1.3
Non-reducing sugars	Not more than 1 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 - 7 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Arśa (piles), Bhagandara (fistula in-ano), Pā´²u (anaemia), Kāmalā (jaundice), Udara (diseases of abdomen), Mūtravibandha (retention of urine), Agnimāndya (dyspepsia), Aruci (anorexia), Chardī (emesis), Graha´ī (malabsorption syndrome), Gulma (abdominal lump), Kāsa (cough), Śvāsa (asthma), K¾aya (pthisis), Dhātuk¾aya (tissue wasting), Vātavyādhi (disorder due to vātado¾a), Ku¾°ha (disease of skin), Meha (excessiue flow of urine), Śarkarā (gravel in urine), Aśmarī (calculus), Vandhyatva (infertility), Kārśya (emaciation), Śukrak¾aya (deficiency of semen), Daurbalya (weakness).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

DRĀK½ĀRI½¯A

(AFI, Part-I, 1:20)

Definition:

Drāk¾āri¾°a is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Drāk¾ā API	*Vitis vinifera*	Dr. Fr.	2.4 kg
2	Jala API for decoction	Water		49.152 l
	reduced to			12.288 l
3	Gu²a API	Jaggery		9.6 kg
Prak¾epa dravyas:				
4	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	48 g
5	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	48 g
6	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	48 g
7	Keśarā (Nāgakeśara API)	*Mesua ferrea*	Stmn.	48 g
8	Priya¬gu API	*Callicarpa macrophylla*	Fl.	48 g
9	Marica API	*Piper nigrum*	Fr.	48 g
10	K¨¾´ ā (Pippalī API)	*Piper longum*	Fr.	48 g
11	Vi²a¬ga API	*Embelia ribes*	Fr.	48 g
12	Dhātakī API	*Woodfordia fruticosa*	Fl.	384 g

Method of preparation:

Take the raw materials of pharmacopoeial quality.

Wash and crush the ingredient numbered 1 *(Kvātha dravya)* of the formulation composition.

Clean, dry and powder the ingredients numbered 4 to 11 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.

Add specified amount of water to the *Kvātha dravya*, soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.

Add the ingredient number 3 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the *muslin cloth*.

Transfer the filtrate to a clean container; add *Dhātakī* and other finely powdered *Prak¾epa dravyas.* Seal the mouth of the container.

Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.

Filter the fermented material through a clean *muslin cloth*.

Pack in air tight containers and allow for maturation.

Description:

Clear brown liquid without frothing and significant sedimentaton; with aromatic odour and sweet taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 10 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 5 µl of test solution prepared as above and 3 µl of marker solution prepared by dissolving 1 mg of *gallic acid* in 1 ml of *methanol*, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultra violet light (366 nm). It shows spots at R_f 0.19 (light blue), 0.37 (blue, corresponding to *gallic acid*), 0.44 (yellow) and R_f 0.64 (light green).

Physico-chemical parameters:

Total phenolic content:	0.028 to 0.082 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 28.00 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.08 to 1.20,	Appendix 3.2
*p*H:	3.5 to 4.5,	Appendix 3.3
Reducing sugars:	Not less than 14.0 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.80 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other Requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Agnimāndya (digestive impairment), Kāsa (cough), Śvāsa (dyspnoea/ asthma), K¾aya (pthisis), Ura^{a}k¾ata (chestwound), Malaśodhaka (laxative), Galaroga (diseases of throat) and Daurbalya (weakness).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

DRĀK½ĀSAVA
(AFI, Part-II, 1: 1)

Definition:

Drāk¾āsava is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Drāk¾ā API	*Vitis vinifera*	Dr. Fr.	4.8 kg
2	Jala API for decoction reduced to	Water		49.152 l 12.288 l
3	Śarkarā (Gu²a śarkarā API)	Jaggery		4.8 kg
4	Madhu API	Honey		4.8 kg
Prak¾epa dravyas:				
5	Dhātakī API	*Woodfordia fruticosa*	Fl.	336 g
6	Jātī API	*Jasminum officinale*	Fl.	24 g
7	Lava¬ga API	*Syzygium aromaticum*	Fl. Bud	24 g
8	Kakkola (Ka¬kola API)	*Piper cubeba*	Fr.	24 g
9	Lavalīphala API	*Cicca acida*	Fr.	24 g
10	Candana (Śveta candana API)	*Santalum album*	Ht. Wd.	24 g
11	K¨¾´ā (Pippalī API)	*Piper longum*	Fr.	24 g
12	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	24 g
13	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	24 g
14	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	24 g

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash and crush the ingredient numbered 1 *(Kvātha dravya)* of the formulation composition.
Clean, dry and powder the ingredients numbered 6 to 14 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add specified amount of water to the *Kvātha dravya*, soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha.*
Add the ingredient number 3 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the *muslin cloth*.
Transfer the filtrate to a clean container; add *Madhu, Dhātakī* and other finely powdered *Prak¾epa dravyas*. Seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean *muslin cloth*.
Pack in air tight containers and allow for maturation.

Description:

Clear brown liquid without frothing and significant sedimentaton; with aromatic odour and sweet taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 20 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 2µl of test solution prepared as above and 1µl of marker solution prepared by dissolving 1 mg of *gallic acid in* 1 ml of *methanol*, on TLC plate. Develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.01 (light blue), 0.44 (blue, corresponding to *gallic acid*), 0.65 (light green) and at R_f 0.80 (green).

Physico-chemical parameters:

Total phenolic content:	0.049 to 0.085 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 25.0 per cent w/v,	Appendix 3.8
Specific gravity (at 25°):	1.08 to 1.20,	Appendix 3.2
*p*H*:*	4.0 to 4.5,	Appendix 3.3
Reducing sugars:	Not less than 16.0 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.80 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Arśa (piles), Aruci (tastelessness), H¨droga (heart disease), Pā´²u (anaemia), Raktapitta (bleeding disorder), Udararoga (diseases of abdomen), K¾a°a (wound), Śo¾a (cachexia), Jvara (fever).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

JĪRAKĀDYARI½¯A
(AFI, Part-I, 1: 16)

Definition:

Jīrakādyari¾°a is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Jīraka (Śveta jīraka API)	*Cuminum cyminum*	Fr.	9.6 kg
2	Jala API for decoction	Water		49.152 l
	reduced to			12.288 l
3	Gu²a API	Jaggery		14.4 kg
Prak¾epa dravyas:				
4	Dhātakī API	*Woodfordia fruticosa*	Fl.	768 g
5	Śu´°hī API	*Zingiber officinale*	Rz.	48 g
6	Jātīphala API	*Myristica fragrans*	Sd.	48 g
7	Mustaka (Mustā API)	*Cyperus rotundus*	Rz.	48 g
8	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	48 g
9	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	48 g
10	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	48 g
11	Nāgakeśara API	*Mesua ferrea*	Stmn.	48 g
12	Yamānikā (Yavānī API)	*Trachyspermum ammi*	Fr.	48 g
13	Kakkola (Ka¬kola API)	*Piper cubeba*	Fr.	48 g
14	Devapu¾pa (Lava¬ga API)	*Syzygium aromaticum*	Fl. Bud	48 g

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and crush the ingredient numbered 1 *(Kvātha dravya)* of the formulation composition.
Clean, dry and powder the ingredients numbered 5 to 14 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add specified amount of water to the *Kvātha dravya*, soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.
Add the ingredient number 3 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the *muslin cloth*.
Transfer the filtrate to a clean container; add *Dhātakī* and other finely powdered *Prak¾epa dravyas*. Seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean *muslin cloth*.
Pack in air tight containers and allow for maturation.

Description:

Clear dark brown liquid without frothing and significant sedimentaton; with aromatic odour and bitter taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 2 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 5 µl of test solution prepared as above and 5 µl each of marker solution prepared by dissolving 1 mg each of *luteolin* and *apigenin* in 1 ml each of *methanol* separately, on TLC plate. Develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.40 (orange, corresponding to *luteolin*), 0.51 light green, and at R_f 0.64 (parrot green, corresponding to *apigenin*).

Physico-chemical parameters:

Total phenolic content:	0.154 to 0.189 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 22.0 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.08 to 1.20,	Appendix 3.2
*p*H*:*	3.5 to 4.5,	Appendix 3.3
Reducing sugars:	Not less than 14.00 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 1.00 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Sūtikāroga (puerperal disease), Agnimāndya (digestive impairment), Atisāra (diarrhoea), Graha´ī (malabsorption syndrome).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

KANAKĀSAVA

(AFI, Part-I, 1: 9)

Definition:

Kanakāsava is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Kanaka (Dhattūra API)	*Datura metel*	Pl.	192 g
2	V¨¾amūla (Vāsā API)	*Adhatoda vasica*	Rt.	192 g
3	Madhuka (Ya¾ºī API)	*Glycyrrhiza glabra*	Rt.	96 g
4	Māgadhī (Pippalī API)	*Piper longum*	Fr.	96 g
5	Vyāghrī (Ka´ºakārī API)	*Solanum xanthocarpum*	Pl.	96 g
6	Keśara (Nāgakeśara API)	*Mesua ferrea*	Stmn.	96 g
7	Viśvabhe¾aja (Śu´ºhī API)	*Zingiber officinale*	Rz.	96 g
8	Bhār¬gī API	*Clerodendrum serratum*	Rt.	96 g
9	Tālīsapatra API	*Abies webbiana*	Lf.	96 g
10	Dhātakī API	*Woodfordia fruticosa*	Fl.	768 g
11	Drāk¾ā API	*Vitis vinifera*	Dr. Fr.	960 g
12	Jala API	Water		24.576 l
13	Śarkarā API	Sugar		4.8 kg
14	K¾audra (Madhu API)	Honey		2.4 kg

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 to 9 of the formulation composition and pass through the sieve number 44 to obtain coarse powder.
Wash and clean the ingredients numbered 10 and 11 of the formulation composition.
Add specified amount of water to the ingredient number 13 of the formulation composition, allow to dissolve and filter through the *muslin cloth*.
Transfer the filtrate to a clean container; add *Dhātakī, Drāk¾ā* and coarsely powdered other drugs. Seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean *muslin cloth*.
Pack in air tight containers and allow for maturation.

Description:

Clear dark yellow colour liquid without frothing and significant sedimentaton; with aromatic odour and acrid taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 40 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 10 µl of test solution prepared as above and 5 µl each of marker solutions prepared by dissolving 1 mg each of *gallic acid and ethyl gallate* in 1 ml each of *methanol* separately, on TLC plate. Develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (3 : 3 : 0.8 : 0.2) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultra violet light (366 nm). It shows spots at R_f 0.06 (light yellow), 0.09 (dark yellow), 0.43 (light blue), 0.47 (blue, corresponding to *gallic acid),* 0.58 (light blue, corresponding to *ethyl gallate*), and 0.65 (light green).

Physico-chemical parameters:

Total phenolic content:	0.054 to 0.085 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 11.50 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.01 to 1.15,	Appendix 3.2
*p*H*:*	3.5 to 4.2,	Appendix 3.3
Reducing sugars:	Not less than 6.5 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.50 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Kāsa (cough); Śvāsa (asthma); Rājayak¾mā (tuberculosis); K¾ata k¾īna (debility due to chest injury).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

KHADIRĀRI½¯A
(AFI, Part I, 1:14)

Definition:

Khadirāri¾°a is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Khadira API	*Acacia catechu*	Ht. Wd.	2.4 kg
2	Devadāru API	*Cedrus deodara*	Ht. Wd.	2.4 kg
3	Bākucī API	*Psoralea corylifolia*	Sd.	576 g
4	Dārvī (Dāruharidrā API)	*Berberis aristata*	St.	960 g
5	Harītakī API	*Terminalia chebula*	P.	960 g
6	Bibhītaka API	*Terminalia belerica*	P.	960 g
7	Āmalakī API	*Emblica officinalis*	P.	960 g
8	Jala API for decoction	Water		98.304 l
	reduced to			12.288 l
9	Mākṣika (Madhu API)	Honey		9.6 kg
10	Śarkarā API	Cane sugar		4.8 kg
Prak¾epa dravyas:				
11	Dhātakī API	*Woodfordia fruticosa*	Fl.	960 g
12	Ka¬kola API	*Piper cubeba*	Fr.	48 g
13	Nāgakeśara API	*Mesua ferrea*	Stmn.	48 g
14	Jātīphala API	*Myristica fragrans*	Sd.	48 g
15	Lavaṅga API	*Syzygium aromaticum*	Fl. Bd.	48 g
16	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	48 g
17	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	48 g
18	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	48 g
19	K¨¾´ā (Pippalī API)	*Piper longum*	Fr.	192 g

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 to 7 *(Kvātha dravya)* of the formulation composition and pass through the sieve number 44 to obtain coarse powder.
Clean, dry and powder the ingredients numbered 12 to 19 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add specified amounts of water to the *Kvātha dravya*, soak overnight, heat, reduce to one eighth and filter through *muslin cloth* to obtain *Kvātha*.
Add the ingredient number 10 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the *muslin cloth* in to a clean container.
Add *Dhātakī*, *Madhu* and other finely powdered *Prak¾epa dravyas*. Seal the mouth of the container.

Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean muslin cloth.
Pack in air tight containers and allow for maturation.

Description:

Clear, dark brown liquid without frothing and significant sedimentaton; with astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 25 ml *water* and partition with *chloroform* (25 ml x 3). Filter and concentrate the *chloroform* extract in vacuum and weigh. Dissolve 10 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 15 µl of test solution prepared as above and 0.2 µl each of *berberine* and *palmatine* solutions, prepared by dissolving 1 mg each in 1 ml of *methanol* separately, on TLC plate and develop to a distance of 8 cm using *n-butano: ethyl acetate: formic acid: water* (3 : 5 : 1 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.45 (light green, corresponding to *palmatine*) and 0.55 (light green, corresponding to *berberine*).
Apply separately 15 µl of test solution prepared as above and 15 µl marker solution prepared by dissolving 0.1 mg of *angelicine* in 1 ml of *methanol*, on TLC plate and develop the plate to a distance of 8 cm using *n-hexane: ethyl acetate* (7 : 3) as mobile phase. After development, allow the plate to dry in air. Spray the plate with 10 % *ethanolic potassium hydroxide*, dry and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.38 (parrot green, corresponding to *angelicine*) and R_f 0.45 (blue).

Physico-chemical parameters:

Total phenolic content:	0.070 to 0.091 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 11.50 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.01 to 1.15,	Appendix 3.2
*p*H*:*	3.50 to 4.2,	Appendix 3.3
Reducing sugars:	Not less than 6.5 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.50 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Mahāku¾°ha (skin diseases), H¨droga (heart diseases), Pā´²u (anaemia), Arbuda (tumor), Gulma (abdominal lump), Granthi (cysts), K¨mi (worm infestation), Kāsa (cough), Śvāsa (asthma), Plīhodara (splenomegaly).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

KUMĀRYĀSAVA (B)

(AFI, Part-I, 1:13)

Definition:

Kumāryāsava (B) is a fermented liquid preparation made with ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Kumārī rasa (Kumārī API)	*Aloe barbadensis*	Lf.	12.288 l
2	Gu²a API	Jaggery		4.8 kg
3	Vijayā (Harītakī API)	*Terminalia chebula*	P.	1.2 kg
4	Jala API for decoction	Water		12.288 l
	reduced to			3.072 l
5	Madhu API	Honey		3.072 kg
6	Dhātakī API	*Woodfordia fructicosa*	Fl.	768 g
7	Jātīphala API	*Myristica fragrans*	Sd.	48 g
8	Lava¬ga API	*Syzygium aromaticum*	Fl. Bd.	48 g
9	Ka¬kola API	*Piper cubeba*	Fr.	48 g
10	Ja°ilā (Ja°āmā¼sī API)	*Nardostachys jatamansi*	Rz.	48 g
11	Kabābaka API	*Piper cubeba*	Fr.	48 g
12	Cavya API	*Piper retrofractum*	St.	48 g
13	Citra (Era´²a API)	*Ricinus communis*	Rt.	48 g
14	Jātīpatrī (Jātīphala API)	*Myristica fragrans*	Ar.	48 g
15	Karka°a (Karka°aś¨¬gī API)	*Pistacia integerrima*	Gl.	48 g
16	Akṣa (Bibhītaka API)	*Terminalia belerica*	P.	48 g
17	Pu¾karamūla (Pu¾kara API)	*Inula racemosa*	Rt.	48 g
18	M¨ta śulva (Tāmra API) bhasma	*Calcined Tāmra*		48 g
19	M¨ta loha (Lauha API) bhasma	*Calcined Loha*		24 g

Method of preparation:

Take the raw materials of pharmacopoeial quality.

Wash, clean and extract juice from the ingredient number 1 of the formulation composition.

Wash, dry and powder the ingredient numbered 3 *(Kvātha dravya)* of the formulation composition and pass through the sieve number 44 to obtain coarse powder.

Clean, dry and powder the ingredients numbered 7 to 17 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.

Prepare *Bhasma* of the ingredients numbered 18 and 19 of the formulation composition.

Add specified amounts of water to the *Kvātha dravya*, soak overnight, heat, reduce to one eighth and filter through *muslin cloth* to obtain *Kvātha*.

Add the ingredient number 2 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the *muslin cloth* in to a clean container.

Add *Kumari rasa, Tāmra Bhasma, Loha Bhasma, Madhu*, *Dhātakī* and other finely powdered *Prak¾epa dravyas*. Seal the mouth of the container.

Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean *muslin cloth*.
Pack in air tight containers and allow for maturation.

Description:

Clear, dark brown liquid without frothing and significant sedimentaton; with astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve l mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 1.5 µl of the test solution prepared as above and 2 µl of marker solution prepared by dissolving 1 mg of *gallic acid* in 1 ml of *methanol*, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.31 (blue, corresponding to *gallic acid)* and at R_f 0.54 (light blue).

Physico-chemical parameters:

Total phenolic content:	0.061 to 0.079 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 13.0 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.01 to 1.10,	Appendix 3.2
*p*H*:*	3.50 to 4.2,	Appendix 3.3
Reducing sugars:	Not less than 7.5 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.30 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Gulma (abdominal lump); Kāsa (cough); Śvāsa (asthma); Arśa (piles); Vātavyādhi (neurological diseases); Apasmāra (epilepsy); K¾aya (pthisis); Udara (abdominal diseases); Manyāroga (diseases of neck region); Agnimāndya (digestive impairement); Ko¾°haśūla (abdominal pain) Na¾°a pu¾pa (menopause).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

KU¯AJĀRI½¯A

(AFI, Part-I, 1: 11)

Definition:

Kuºajāri¾°a is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Kuºajamūla (Kuºaja API)	*Holarrhena antidysenterica*	St. Bk.	4.8 kg
2	M¨dvīkā (Drāk¾ā API)	*Vitis vinifera*	Dr. Fr.	2.8 kg
3	Madhūka pu¾pa (Madhūka API)	*Madhuca indica*	Fl.	480 g
4	Kāśmarī (Gambhārī API)	*Gmelina arborea*	St. Bk.	480 g
5	Jala API for decoction	Water		49.152 l
	reduced to			12.288 l
6	Gu²a API	Jaggery		4.8 kg
7.	Dhātakī API	*Woodfordia fruticosa*	Fl.	960 g

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 and 4 *(Kvātha dravya)* of the formulation composition.
Wash and clean the ingredients numbered 2 and 3 *(Kvātha dravya)* of the formulation composition.
Add specified amount of water to the *Kvātha dravya*, soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.
Add the ingredient number 6 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the *muslin cloth*.
Transfer the filtrate to a clean container; add *Dhātakī* and seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean *muslin cloth*.
Pack in air tight containers and allow for maturation.

Description:

Clear dark brown liquid without frothing and significant sedimentaton; with aromatic odour and bitter taste

Identification:

Thin Layer Chromatography:

Partition 50 ml of the formulation with *chloroform* (50 ml x 3) and discard the chloroform extract. Adjust the pH of the aqueous layer to 8.5 with *ammonium hydroxide* and again partition with *chloroform* (50 ml x 3). Filter and concentrate the chloroform extract in vacuum and weigh. Dissolve 20 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 3 µl of test solution prepared as above and 10 µl of marker solution prepared by dissolving 1 mg of *conessine* in 1 ml of *methanol*, on TLC plate. Develop the plate to a distance of 8 cm using *ethyl acetate:* n-*hexane: triethylamine* (7.5 : 2.4 : 0.6) as mobile phase. After development, allow the plate to dry in air and derivatise with *modified Dragendorff's reagent* and examine under ultraviolet light 560 nm after drying. It shows spots at R_f 0.40 (mustard yellow, corresponding to *conessine*) and at R_f 0.54 (yellow).

Physico-chemical parameters:

Total phenolic content:	0.119 to 0.201 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 16.0 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.04 to 1.12,	Appendix 3.2
*p*H*:*	3.5 to 4.5,	Appendix 3.3
Reducing sugars:	Not less than 7.50 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.90 per cent w/v,	Appendix 5.1.3
Alcohol content:	4 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Assay:

The sample contains 0.003 to 0.01 percent w/v of *conessine*, when assayed by the following method.

Estimation of conessine: Apply separately 4 µl to 12 µl (8 data point) of *conessine* solution prepared under thin layer chromatography on TLC plate and develop the plate to a distance of 8 cm using *ethyl acetate:* n-*hexane: triethylamine* (7.5 : 2.4 : 0.6) as mobile phase and dry. Derivatise the plate with *modified Dragendorff's reagent* and dry in a current of cold air and scan in the TLC scanner at 560 nm. Note the peak area under curve for the peak corresponding to *conessine* and prepare the calibration curve by plotting peak area *vs* concentration of *conessine*.
Process 50 ml of the formulation partitioned under thin layer chromatography.
Apply 3 µl of the test solution on TLC plate. Develop, dry and scan the plate as described in preceding paragraph for calibration curve of *conessine*. Calculate the amount of *conessine* in the test solution from the calibration curve of *conessine*.

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protected from light and moisture.

Therapeutic uses: Graha´ī (malabsorption syndrome); Pravāhikā (dysentery); Raktātisāra (diarrhoea with blood); Jvara (fever).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

LOHĀSAVA
(AFI, Part-I, 1:32)

Definition:

Lohāsava is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Loha cūr´a-Śodhita (Lauha API)	Iron dust		192 g
2.	Śu´ºhī API	*Zingiber officinale*	Rz.	192 g
3	Marica API	*Piper nigrum*	Fr.	192 g
4	Pippalī API	*Piper longum*	Fr.	192 g
5	Harītakī API	*Terminalia chebula*	P.	192 g
6	Bibhītaka API	*Terminalia bellierica*	P.	192 g
7	Āmalakī API	*Emblica officinalis*	P.	192 g
8	Yavānika (Yavānī API)	*Trachyspermum ammi*	Fr.	192 g
9	Vi²a¬ga API	*Embelia ribes*	Fr.	192 g
10	Mustaka (Mustā API)	*Cyperus rotundus*	Rz.	192 g
11	Citra (Era´²a API)	*Ricinus communis*	Rt.	192 g
12	Dhātakī API	*Woodfordia fruticosa*	Fl.	960 g
13	K¾audra (Madhu API)	Honey		3.072 kg
14	Gu²a API	Jaggery		4.80 kg
15	Jala API	Water		24.576 l

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 2 to 11 of the formulation composition and pass through the sieve number 44 to obtain coarse powder.
Add specified amount of water to the ingredient number 14 of the formulation composition, allow to dissolve and filter through the *muslin cloth*.
Transfer the filtrate to a clean container; add *Lauha Bhasma*, *Madhu, Dhātakī* and coarsely powdered other drugs. Seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean *muslin cloth*.
Pack in air tight containers and allow for maturation.

Description:

Clear, dark brown liquid without frothing and significant sedimentaton; with astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 20 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 5 µl of test solution prepared as above and 3 µl each of marker solutions prepared by dissolving 1 mg each of *gallic acid and* ethyl gallate in 1 ml each of *methanol* separately, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.25 (light yellow), 0.40 (blue, corresponding to *gallic acid),* 0.39 (blue), and 0.53 (light blue, corresponding to *ethyl gallate*).

Physico-chemical parameters:

Total phenolic content:	0.062 to 0.075 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 3.0 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.00 to 1.20,	Appendix 3.2
*p*H*:*	3.4 to 4.5,	Appendix 3.3
Reducing sugars:	Not less than 14.0 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than .80 per cent w/v,	Appendix 5.1.3
Alcohol content:	4 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Assay:

The sample contains 0.1 to 0.5 per cent w/v of *gallic acid* and 0.09 to 0.1 per cent w/v of *ethyl gallate,* when assayed by the following method.
Estimation of gallic acid and *ethyl gallate*: Dissolve 1 mg each of *gallic acid* and *ethyl gallate* in 1 ml each of *methanol* separately.
Apply separately 1.0 to 8.0 µl each of (5 data point) of above solutions on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) acid as mobile phase. Derivatise the plate with *Natural product reagent* and dry in a current of cold air and scan in the TLC scanner at a wavelength of 366 nm. Note the peak areas under curve for the peaks corresponding to *gallic acid and ethyl gallate* and prepare the calibration curve by plotting peak area *vs* concentration of *gallic acid* and *ethyl gallate* separately.
Process vacuum-dried 50 ml of the formulation under thin layer chromatography. Apply 5 µl of the test solution on TLC plate. Develop, dry and scan the plate as described in

preceding paragraph for calibration curve of *gallic acid* and *ethyl gallate*. Calculate the amount of *gallic acid and ethyl gallate* in the test solution from the calibration curves of *gallic acid and ethyl gallate* respectively.

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protected from light and moisture.

Therapeutic uses: Ja°hara (weak digestion), Pā´²u (anaemia), Śvayathu (oedema), Gulma (abdominal lump), Arśa (piles), Agnimāndya (digestive impairment), Plīhā roga (splenic disease), Ku¾°ha (disease of skin), Kāsa (cough), Śvāsa (asthma), Bhagandara (fistula-in-ano), Aruci (tastelessness), Graha´ī (malabsorption syndrome), H¨droga (disease of heart).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

MUSTAKĀRI½¯A
(AFI, Part-I, 1: 26)

Definition:

Mustakāri¾°a is a fermented liquid preparation, made with ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation Composition:

1.	Mustaka (Mustā API)	*Cyperus rotundus*	Rz.	2.4 kg
2.	Jala for decoction	Water		12.2880 l
	reduced to			3.072 l
3.	Gu²a API	Jaggery		3.6 kg
4.	Dhātakī API	*Woodfordia fruticosa.*	Fl.	192 g
5.	Yamānī (Yavānī API)	*Trachyspermum ammi*	Fr.	24 g
6.	Viśvabhe¾aja (Śu´°hī API)	*Zingiber officinale*	Rz.	24 g
7.	Marica API	*Piper longum*	Fr.	24 g
8.	Lava¬ga (Devapu¾pa API)	*Syzygium aromaticum*	Fl. Bd.	24 g
9.	Methī API	*Trigonella foenum-graecum*	Sd.	24 g
10.	Vahni (Citraka API)	*Plumbago zeylanica*	Rt.	24 g
11.	Jīraka (Śveta jīraka API)	*Cuminum cyminum*	Fr.	24 g

Method of Preparation:

Take the raw materials of Pharmacopoeial quality.
Wash, dry and crush the ingredient numbered 1 *(Kvātha dravya)* of the formulation composition and pass through the sieve number 44 to obtain coarse powder.
Clean, dry and powder the ingredients numbered 5 to 11 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add specified amount of water to the *Kvātha dravya*, soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.
Add the ingredient number 3 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the *muslin cloth*.
Transfer the filtrate to a clean container; add *Dhātakī* and other finely powdered *Prak¾epa dravya*. Seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean *muslin cloth*.
Pack in air tight containers and allow for maturation.

Description:

Clear dark brown liquid without frothing and significant sedimentaton; with aromatic odour and bitter taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water*, shake and partition successively with n-*hexane* (100 ml x 3), *chloroform* (100 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 20 mg of residue in 1 ml of *methanol* and carry out the thin layer chromatography.
Apply 5 µl of the solution prepared above and 5 µl of marker solution prepared by dissolving 1 mg of *gallic acid* in 1 ml of *methanol* separately, on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *formic acid*: *methanol* (3.3 : 0.8 : 0.2) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *anisaldehyde-sulphuric acid reagent*, followed by heating at 105^0 for about 10 min and examine at 560 nm. It shows major spots at R_f 0.06 (yellow), 0.10 (dark yellow), 0.21 (orange), 0.27 (yellow), 0.32 (light blue), 0.42 (sky blue), 0.51 (dark blue, corresponding to *gallic acid)*, 0.62 (white), 0.65 (orange) and 0.68 (light blue).

Physico-chemical parameters:

Total phenolic content:	Not less than 0.06 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	20 to 30 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.1 to 1.25,	Appendix 3.2
*p*H*:*	3.02 to 4.5,	Appendix 3.3
Reducing sugars:	30 to 45 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 5 per cent w/v,	Appendix 5.1.3
Alcohol content:	3.0 to 7.5 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other Requirements:

Microbial load:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic Uses: Ajīr´a (dyspepsia); Agnimāndya (digestive impairment), Graha´ī (malabsorption syndrome); Visūcikā (gastro-enteritis with piercing pain).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

PĀRTHĀDYĀRI½¯A

(AFI, Part-I, 1: 21)

Definition:

Pārthādyāri¾°a is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1.	Pārtha (Arjuna API)	*Terminalia arjuna*	St. Bk.	4.8 kg
2.	M¨idvīkā (Drāk¾ā API)	*Vitis vinifera*	Fr.	2.4 kg
3.	Madhupu¾pa (Madhūka API)	*Madhuca indica*	Fl.	960 g
4.	Jala API for decoction	Water		49.152 l
	reduced to			12.288 l
5.	Dhātakī API	*Woodfordia fruticosa*	Fl.	960 g
6.	Gu²a API	Jaggery		4.8 kg

Method of preparation:

Take the raw materials of pharmacopoeial quality.

Wash, dry and powder the ingredient numbered 1 *(Kvātha dravya)* of the formulation composition and pass through the sieve number 44 to obtain coarse powder. Wash and clean the ingredient number 4 and 5 *(Kvātha dravya)* of the formulation composition.

Add specified amount of water to the *Kvātha dravya*, soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.

Add the ingredient number 6 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the muslin cloth.

Transfer the filtrate to a clean container; add *Dhātakī* and seal the mouth of the container.

Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.

Filter the fermented material through a clean muslin cloth.

Pack in air tight containers and allow for maturation.

Description:

Clear brown liquid without frothing and significant sedimentaton; with aromatic odour and astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 1 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 15 µl of test solution prepared as above and 5 µl each of marker solutions prepared by dissolving 1 mg each of *gallic acid* and *ethyl gallate* in 1 ml each of *methanol* separately, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid* (3 : 3 : 08) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.13 (brilliant blue), 0.31 (blue), 0.45 (blue, corresponding to *gallic acid)* and at R_f 0.56 (light blue, corresponding to *ethyl gallate*).

Physico-chemical parameters:

Total phenolic content:	0.095 to 0.110 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 10.0 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.02 to 1.05,	Appendix 3.2
*p*H*:*	4.0 to 4.6,	Appendix 3.3
Reducing sugars:	Not less than 5.5 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.30 per cent w/v,	Appendix 5.1.3
Alcohol content:	6 to 12 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: H¨droga (heart disease), Phuphphusa roga (lung disease), Balak¾aya (loss of strength/ immunity), Vīryak¾aya (azoospermia).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

PIPPALYĀDYĀSAVA

(AFI, Part-I, 1: 22)

Definition:

Pippalyādyāsava is a fermented liquid preparation, made with ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1.	Pippalī API	*Piper longum*	Fr.	8 g
2.	Marica API	*Piper nigrum*	Fr.	8 g
3.	Haridrā API	*Curcuma longa*	Rz	8 g
4.	Cavya API	*Piper chaba*	Rz.	8 g
5.	Citraka API	*Plumbago zeylanica*	Rt.	8 g
6.	Ghana (Mustā API)	*Cyperus rotundus*	Rt.	8 g
7.	Vi²a¬ga API	*Embelia ribes*	Fr.	8 g
8.	Kramuka (Pūga API)	*Areca catechu*	Sd	8 g
9.	Lodhra API	*Symplocos racemosa*	St. Bk.	8 g
10.	Pā°hā API	*Cissampelos pareira*	Rt.*/Pl.	8 g
11.	Dhātrī (Āmalakī API)	*Emblica officinale*	P.	8 g
12.	Elavāluka API	*Prunus avium*	St. Bk.	8 g
13.	Uśīra API	*Vetiveria zizanioides*	Rt.	8 g
14.	Candana (Śveta candana API)	*Santalum album*	St. Bk.	8 g
15.	Ku¾°ha API	*Saussurea lappa*	Rt.	8 g
16.	Lava¬ga API	*Syzygium aromaticum*	Fl.bd	8 g
17.	Tagara API	*Valeriana wallichii*	Rz.	8 g
18.	Ja°āmā¼sī API	*Nardostachys jatamansi*	Rz.	8 g
19.	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	8 g
20.	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	8 g
21.	Patra(Tejapatra API)	*Cinnamomum tamala*	Lf.	8 g
22.	Priya¬gu API	*Callicarpa macrophylla*	Fl.	8 g
23.	Nāgakeśara API	*Mesua ferrea*	Stmn.	8 g
24.	Jala API	Water		8.1 l
25.	Gu²a	Jaggery		4.8 kg
26.	Dhātakī API	*Woodfordia fruticosa*	Fl.	160 g
27.	Drāk¾ā API	*Vitis vinifera Linn*	Dr.Fr.	2.880 kg

Method of Preparation:

Take the raw materials of pharmacopoeial quality.

Wash, dry and powder the ingredients numbered 1 to 23 of the formulation composition individually and pass through the sieve number 44 to obtain coarse powder.

Wash and clean the ingredient number 27 of the formulation composition.

Add specified amount of water to the ingredient number 25 of the formulation composition, allow to dissolve and filter through the muslin cloth.

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* Actual part used in the forumulation.

Transfer the filtrate to a clean container; add *Drāk¾ā, Dhātakī* and coarsely powdered other drugs. Seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean muslin cloth.
Pack in air tight containers and allow for maturation.

Description:

Clear dark brown liquid without frothing and significant sedimentaton; with aromatic odour and acrid taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water*, shake and partition successively with n-*hexane* (50 ml x 3) and *chloroform* (50 ml x 3). Filter and concentrate the *chloroform* extract under vacuum and weigh. Dissolve 20 mg of residue in 1 ml of *chloroform* and carry out the thin layer chromatography.
Apply 10 µl of the solution prepared above and 5 µl of marker solution prepared by dissolving 1 mg of *piperine* in 1 ml of *chloroform* separately, on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *acetic acid* (8 : 2 : 0.3) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (254 nm). It shows major spots at R_f 0.13 (light black), 0.22 (light black), 0.30 (dark black, corresponding to *piperine)* and 0.66 (light black).
Apply 10 µl of the solution prepared above and 5 µl each of marker solutions prepared by dissolving 1 mg each of *gallic acid and caffeic acid* in 1 ml each of *methanol* separately, on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *formic acid*: *methanol* (3: 3: 0.8: 0.2)) as mobile phase. After development spray the plate with *Natural product reagent* and dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.08 (light yellow), 0.13 (light black), 0.13 (light blue), 0.22 (light black), 0.30 (dark black, corresponding to *piperine*), 0.48 (dark blue, corresponding to *gallic acid*), 0.60 (light blue, corresponding to *caffeic acid*).

Physico-chemical parameters:

Total phenolic content:	Not less than 0.1 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	20 to 30 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.0 to 1.25,	Appendix 3.2
*p*H*:*	4.0 to 5.0,	Appendix 3.3
Reducing sugars:	10 to 25 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.5 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 7.5 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other Requirements:

Microbial load:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic Uses: Graha´ī (malabsorption syndrome); Gulma (abdominal lump); Kārśya (emaciation); K¾aya (pthisis); Arśa (piles); Udara (urticaria); Pā´²u (anaemia).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

PUNARNAVĀDYĀRI½¯A
(AFI, Part-II, 1:2)

Definition:

Punarnavādyari¾°a is a fermented liquid preparation, made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Śveta punarnavā API	*Boerhavia verticillata*	Rt.	144 g
2	Rakta punarnavā API	*Boerhavia diffusa*	Rt.	144 g
3	Balā API	*Sida cordifolia*	Rt.	144 g
4	Atibalā API	*Abutilon indicum*	Rt.	144 g
5	Pā°hā API	*Cissampelos pareira*	Rt.	144 g
6	Vāsā API	*Adhatoda vasica*	Rt.	144 g
7	Gu²ūcī API	*Tinospora cordifolia*	St.	144 g
8	Citraka API	*Plumbago zeylanica*	Rt.	144 g
9	Nidigdhikā (Ka´°akārī API)	*Solanum surattense*	Pl.	144 g
10	Jala API for decoction	Water		12.288 l
	reduced to			6.144 l
11	Gu²a API	Jaggery		9.6 kg
12	Madhu API	Honey		768 g
Prak¾epa dravyas:				
13	Hema (Nāgakeśara API)	*Mesua ferrea*	Stmn.	24 g
14	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	24 g
15	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	24 g
16	Marica API	*Piper nigrum*	Fr.	24 g
17	Ambu (Hrīvera API)	*Coleus vettiveroides*	Rt.	24 g
18	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	24 g

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 to 9 *(Kvātha dravya)* of the formulation composition individually and pass through the sieve number 44 to obtain coarse powder.
Clean, dry and powder the ingredients numbered 13 to 18 *(Prak¾epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.
Add specified amount of water to the *Kvātha dravya*, soak overnight, heat, reduce to half and filter through *muslin cloth* to obtain *Kvātha*.
Add the ingredient number 11 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the muslin cloth.
Transfer the filtrate to a clean container; add *Madhu,* finely powdered *prak¾epa dravyas* and seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.

Filter the fermented material through a clean muslin cloth.
Pack in air tight containers and allow for maturation.

Description:

Clear, dark brown liquid without frothing and significant sedimentaton; with astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 10 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 5 µl each of test solution prepared as above and marker solution prepared by dissolving 0.2 mg of *gallic acid* in 1 ml of *methanol* separately, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.21 (light blue), 0.56 (light green, corresponding to *gallic acid*) and 0.61(light blue).

Physico-chemical parameters:

Total phenolic content:	0.052 to 0.083 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 11.50 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.02 to 1.3,	Appendix 3.2
*p*H*:*	3.5 to 4.5,	Appendix 3.3
Reducing sugars:	Not less than 5.8 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.90 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage:

Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Śotha (inflammatory diseases), Udara roga (abdominal diseases), Plīhāroga (splenic disorders), Amlapitta (hyperacidity), Gulma (abdominal lump) and Jvara (fever).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

PUNARNAVĀSAVA

(AFI, Part-I, 1: 23)

Definition:

Punarnavāsava is a fermented liquid preparation, made with the ingredients of the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1.	Śu´°hī API	*Zingiber officinale*	Rz.	16 g
2.	Marica API	*Piper nigrum*	Fr.	16 g
3.	Pippalī API	*Piper longum*	Fr.	16 g
4.	Harītakī API	*Terminalia chebula*	Fr.P	16 g
5.	Bibhītaka API	*Terminalia belerica*	Fr.P	16 g
6.	Āmalakī API	*Emblica officinalis.*	Fr.P	16 g
7.	Dārvī (Dāruharidrā API)	*Berberis aristata*	St.	16 g
8.	Śvada¼¾trā (Gok¾ura API)	*Tribulus terrestris*	Fr.	16 g
9.	B¨hatī API	*Solanum indicum*	Rt.	16 g
10.	Ka´°akārī API	*Solanum xanthocarpum*	Pl.	16 g
11.	Vāsāmūla (Vāsā API)	*Adhatoda vasica*	Rt.	16 g
12.	Era´²amūla (Era´²a API)	*Ricinus communis*	Rt.	16 g
13.	Ka°ukī API	*Picrorrhiza kurroa*	Rt./Rz.	16 g
14..	Gajapippalī API	*Scindapsus officinalis*	Fr.	16 g
15.	Śothaghnī (Punarnavā API)	*Boerhaavia diffusa*	Rt.	16 g
16.	Picumarda (Nimba API)	*Azadirachta indica*	St. Bk.	16 g
17.	Gu²ūcī API	*Tinospora cordifolia*	St.	16 g
18.	Su¾ka Mūlaka (Mūlaka API)	*Raphanus sativus*	Rt.	16 g
19.	Durālabhā API	*Fagonia cretica*	Rt.	16 g
20.	Pa°ola API	*Trichosanthes dioica*	Lf.	16 g
21.	Dhātakī API	*Woodfordia fruticosa*	Fl.	256 g
22.	Drāk¾ā API	*Vitis vinifera*	Dr. Fr.	320 g
23.	Sitā API	Sugar		1.6 kg
24.	Māk¾ika (Madhu API)	Honey		800 g
25.	Jala API	Water		8.19 l

Method of Preparation:

Take the raw materials of pharmacopoeial quality.

Wash, dry and powder the ingredients numbered 1 to 20 of the formulation composition individually and pass through the sieve number 44 to obtain coarse powder.

Wash and clean the ingredient number 22 of the formulation composition.

Add specified amount of water to the ingredient number 23 of the formulation composition, allow to dissolve and filter through the muslin cloth.

Transfer the filtrate to a clean container; add *Madhu*, *Drāk¾ā*, *Dhātakī* and coarsely powdered other drugs. Seal the mouth of the container.

Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean muslin cloth.
Pack in air tight containers and allow for maturation.

Description:

Clear dark brown liquid without frothing and significant sedimentaton; with aromatic odour and acrid taste

Identification:

Thin Layer Chromatography:

Dry 400 ml of the formulation in vacuum to remove the self generated alcohol. Add 100 ml *water*, shake and partition successively with n-*hexane* (100 ml x 3) and *chloroform* (100 ml x 3). Filter and concentrate the chloroform extract under vacuum and weigh. Dissolve 10 mg of residue in 1 ml of *methanol* and carry out the thin layer chromatography.
Apply 40 µl of the solution prepared above and 5 µl each of marker solutions prepared by dissolving 1 mg each of *berberine* and *palmatine* in 1 ml of *chloroform* separately, on TLC plate and develop the plate to a distance of 8 cm using n-*butanol: ethyl acetate: formic acid: water* (3 : 5 : 1 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.39 (parrot green, corresponding to *palmatin*), 0.48 (parrot green, corresponding to *berberine*) and 0.55 (light blue).
Apply 10 µl of the test solution prepared above and 5 µl of marker solution prepared by dissolving 1 mg of *gallic acid* in 1 ml of *methanol* on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (3 : 3 : 0.8 : 0.2) as mobile phase. After development spray the plate with *Natural Product reagent* and dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.38 (sky blue), 0.43 (dark blue, corresponding to *gallic acid),* 0.49 (dark green), 0.57 (light blue), 0.62 (orange) and 0.64(light green).

Physico-chemical parameters:

Total phenolic content:	Not less than 0.04 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	10 to 20 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.0 to 1.1,	Appendix 3.2
*p*H*:*	3.5 to 4.5,	Appendix 3.3
Reducing sugars:	7.5 to 12.5 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 1.0 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Assay:

The formulation contains 0.01 to 0.02 per cent w/v of *berberine*, when assayed by the following method:

Estimation of berberine: Apply 1.0 to 8.0 µl of (5 data point) *berberine* solution prepared under thin layer chromatography on TLC plate and develop the plate to a distance of 8 cm using n-*butanol: ethyl acetate: formic acid : water* (3 : 5 : 1 : 1) as mobile phase. After development allow the plate to dry in a current of cold air and scan in the TLC scanner at a wavelength of 366 nm. Note the peak areas under curve for the peak corresponding to *berberine* and prepare the calibration curve by plotting peak area *vs* concentration of *berberine.*

Process vacuum-dried 400 ml of the formulation under thin layer chromatography.

Apply 1 µl of the test solution on TLC plate. Develop, dry and scan the plate for calibration curve of *berberine*. Calculate the amount of *berberine* in the test solution from the calibration curve of *berberine*.

Other Requirements:

Microbial load:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Śotha (inflammation conditions), Udara roga (eight type of abdominal disorders), Plīhā (splenic disease); Amlapitta (hyperacidity); Yak¨t (disease of liver); Gulma (abdominal lump); Jvara (fever); K¨cchra Sādhya roga (related to difficult conditions to manage).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

ROHĪTAKĀRI½¯A

(AFI, Part-I, 1:31)

Definition:

Rohītakāri¾°a is a fermented liquid preparation made with the ingredients in Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Rohītaka API	*Tecomella undulata*	St. Bk	4.8 kg
2	Jala for decoction reduced to	Water		49.152 l 12.288 l
3	Gu²a API	Jaggery		9.6 kg
Prak¼epa dravyas:				
4	Dhātakī API	*Woodfordia fruticosa*	Fl.	768 g
5	Pippalī API	*Piper longum*	Fr.	48 g
6	Pippalīmūla API	*Piper longum*	St.	48 g
7	Cavya API	*Piper retrofractum*	St.	48 g
8	Citraka API	*Plumbago zeylanica*	Rt.	48 g
9	Śu´°hī API	*Zingiber officinale*	Rz.	48 g
10	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	48 g
11	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	48 g
12	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	48 g
13	Harītakī API	*Terminalia chebula*	P.	48 g
14	Bibhītaka API	*Terminalia belerica*	P.	48 g
15	Āmalakī API	*Emblica officinalis*	P.	48 g

Method of preparation:

Take the raw materials of pharmacopoeial quality.

Wash, dry and powder the ingredients numbered 1 *(Kvātha dravya)* of the formulation composition and pass through the sieve number 44 to obtain coarse powder.

Clean, dry and powder the ingredients numbered 5 to 15 *(Prak¼epa dravya)* of the formulation composition individually and pass through the sieve number 85 to obtain fine powder.

Add specified amounts of water to the *Kvātha dravya*, soak overnight, heat, reduce to one fourth and filter through *muslin cloth* to obtain *Kvātha*.

Add the ingredient number 3 of the formulation composition to the *Kvātha*, allow to dissolve and filter through the muslin cloth.

Transfer the filtrate to a clean container; add *Dhātakī* and other finely powdered *prak¼epa dravyas*. Seal the mouth of the container.

Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.

Filter the fermented material through a clean muslin cloth.

Pack in air tight containers and allow for maturation.

Description:

Clear, dark brown liquid without frothing and significant sedimentaton; with astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 10 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 6 µl of the test solution prepared as above and 5 µl of marker solution prepared by dissolving 1 mg each of *gallic acid* and *ethyl gallate* in 1 ml each of *methanol*, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (3 : 3 : 0.8 : 0.2) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.34 (brilliant blue), 0.45 (blue, corresponding to *gallic acid)*, 0.57 (blue, corresponding to *ethyl gallate*) and 0.63 (light blue).

Physico-chemical parameters:

Total phenolic content:	0.060 to 0.071 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 16.0 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.05 to 1.14,	Appendix 3.2
*p*H*:*	3.8 to 4.7,	Appendix 3.3
Reducing sugars:	Not less than 11.0 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.70 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Plīhāroga (splenic disease), Gulma (abdominal lump), Udara roga (disease of abdomen), A¾°hīlā (prostatic hypertrophy), Arśa (piles), Kāmalā (jaundice), Ku¾°ha (disease of skin).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

SĀRIVĀDYĀSAVA

(AFI, Part-I, 1: 37)

Definition:

Sārivādyāsava is a fermented liquid preparation made with the ingredients in the Formulation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Sārivā (Śveta sārivā API)	*Hemidesmus indicus*	Rt.	192 g
2	Mustaka (Mustā API)	*Cyperus rotundus*	Rz.	192 g
3	Lodhra API	*Symplocos racemosa*	St. Bk.	192 g
4	Nyagrodha API	*Ficus bengalensis*	St. Bk.	192 g
5	Pippala (Aśvattha API)	*Ficus religiosa*	Fr.	192 g
6	Śa°ī API	*Hedychium spicatum*	Rz.	192 g
7	Anantā (Śveta sārivāAPI)	*Hemidesmus indicus*	Rt.	192 g
8	Padmaka API	*Prunus cerasoides*	St.	192 g
9	Bāla (Hrīvera API)	*Coleus vettiveroides*	Rt.	192 g
10	Pā°hā API	*Cissampelos pareira*	Rt.	192 g
11	Dhātrī (Āmalakī API)	*Emblica officinalis*	P.	192 g
12	Gu²ūcikā (Gu²ūcī API)	*Tinospora cordifolia*	St.	192 g
13	Ūśīra API	*Vetiveria zizanioides*	Rt.	192 g
14	Śveta candana API	*Santalum album*	Ht. Wd.	192 g
15	Rakta candana API	*Pterocarpus santalinus*	Ht. Wd.	192 g
16	Yamānī (YavānīAPI)	*Trachyspermum ammi*	Fr.	192 g
17	Kaṭurohi´ī (Ka°ukā API)	*Picrorhiza kurroa*	Rz.	192 g
18	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	192 g
19	Sthūlailā API	*Amomum subulatum*	Sd.	192 g
20	Sūk¾mailā API	*Elettaria cardamomum*	Sd.	192 g
21	Ku¾°ha API	*Saussurea lappa*	Rt.	192 g
22	Svar´apatrī API	*Cassia angustifolia*	Lf.	192 g
23	Harītakī API	*Terminalia chebula*	P.	192 g
24	Jala	Water		24.576 l
25	Gu²a API	Jaggery		14.4 kg
26	Dhātakī API	*Woodfordia fruticosa*	Fl.	480 g
27	Drāk¾ā API	*Vitis vinifera*	Dr. Fr.	2.8 kg

Method of preparation:

Take the raw materials of pharmacopoeial quality.

Wash, dry and powder the ingredients numbered 1 to 23 of the formulation composition and pass through the sieve number 44 to obtain coarse powder.

Wash and clean the ingredient numbered 27 of the formulation composition.

Add specified amount of water to the ingredient number 25 of the formulation composition, allow to dissolve and filter through the muslin cloth.

Transfer the filtrate to a clean container; add *Dhātakī, Drāk¾ā* and other coarsely powdered drugs. Seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean muslin cloth.
Pack in air tight containers and allow for maturation.

Description:

Clear, dark brown liquid without frothing and significant sedimentaton; with astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 20 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 5 µl of test solution prepared as above and 3 µl of marker solution prepared by dissolving 1 mg of *gallic acid* in 1 ml of *methanol*, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.31 (blue, corresponding to *gallic acid*), 0.51 (light blue) and 0.62 (brilliant blue).

Physico-chemical parameters:

Total phenolic content :	0.037 to 0.078 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 24.0 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.10 to 1.15,	Appendix 3.2
*p*H*:*	3.0 to 4.0,	Appendix 3.3
Reducing sugars:	Not less than 15.0 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.75 per cent w/v,	Appendix 5.1.3
Alcohol content:	5 to 10 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Vātarakta (gout), Meha (excessive flow of urine), Prameha (increased frequency and turbidity of urine), Pi²akā (carbuncle), Upada¼śa (syphilis/soft chancre), Bhagandara (fistula-in-ano), Rakta vikāra (disorders of blood), Daurbalya (weakness), Agnimāndya (digestive impairment).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

UŚĪRĀSAVA
(AFI, Part-I, 1:8)

Definition:

Uśīrāsava is a fermented liquid preparation, made with the ingredients in the Formulalation composition given below. It contains not more than 10 per cent, and not less than 5 per cent of alcohol that is self generated in the preparation over a period of time.

Formulation composition:

1	Uśīra API	*Vetiveria zizanioides*	Rt.	48 g
2	Bālaka (Hrīveṛa API)	*Coleus vettiveroides*	Rt.	48 g
3	Padma API	*Nelumbo nucifera*	Fl.	48 g
4	Kāśmarya (Gambhārī API)	*Gmelina arborea*	St. Bk.	48 g
5	Nīlotpala (Utpala API)	*Nymphaea stellata*	Fl.	48 g
6	Priya¬gu API	*Callicarpa macrophylla*	Fl.	48 g
7	Padmaka API	*Prunus cerasoides*	St.	48 g
8	Lodhra API	*Symplocos racemosa*	St. Bk.	48 g
9	Ma®ji¾ºhā API	*Rubia cordifolia*	Rt.	48 g
10	Dhanvayāsaka API	*Fagonia cretica*	Pl.	48 g
11	Pāºhā API	*Cissampelos pareira*	Rt. /Pl.	48 g
12	Kirātatikta API	*Swertia chirata*	Pl.	48 g
13	Nyagrodha API	*Ficus benghalensis*	St. Bk.	48 g
14	Udumbara API	*Ficus racemosa*	St. Bk.	48 g
15	Śaºī API	*Hedychium spicatum*	Rz.	48 g
16	Parpaºa API	*Fumaria parviflora*	Pl.	48 g
17	Pu´darīka (Kamala API)	*Nelumbo nucifera*	Fl.	48 g
18	Paºola API	*Trichosanthes dioica*	Lf./Pl.	48 g
19	Kā®canāraka (Kā®canāra API)	*Bauhinia variegata*	St. Bk.	48 g
20	Jambu API	*Syzygium cumini*	St. Bk.	48 g
21	Śālmalī niryāsa (Śālmalī API)	*Salmalia malabarica*	Exd.	48 g
22	Drāk¾ā API	*Vitis vinifera*	Dr. Fr.	960 g
23	Dhātakī API	*Woodfordia fruticosa*	Fl.	q.s. for dhupana
24	Jala API	Water		24.576 l
25	Śarkarā	Jaggery		768 g
26	K¾audra (Madhu API)	Honey		4.8 kg
28.	Marica API	*Piper nigrum*	Fr.	

Method of preparation:

Take the raw materials of pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 to 21 of the formulation composition and pass through the sieve number 44 to obtain coarse powder.
Wash and clean the ingredient number 22.
Add specified amount of water to the ingredient number 25 of the formulation composition, allow to dissolve and filter through the muslin cloth.

Transfer the filtrate to a clean container; add *Madhu, Drāk¾ā, Dhātakī* and coarsely powdered other drugs. Seal the mouth of the container.
Shift the container to the fermentation room and constantly check for the signs of completion of fermentation process.
Filter the fermented material through a clean muslin cloth.
Pack in air tight containers and allow for maturation.

Description:

Clear, dark brown liquid without frothing and significant sedimentaton; with astringent taste

Identification:

Thin Layer Chromatography:

Dry 50 ml of the formulation in vacuum to remove the self generated alcohol. Add 50 ml *water* to dissolve the extract and partition successively with n-*hexane* (50 ml x 3), *chloroform* (50 ml x 3) and *ethyl acetate* (50 ml x 3). Filter and concentrate the ethyl acetate extract under vacuum and weigh. Dissolve 20 mg of residue in 1 ml of *methanol* and carry out thin layer chromatography.
Apply separately 10 µl of test solution prepared as above and 3 µl of marker solution prepared by dissolving 1 mg of *gallic acid* in 1 ml of *methanol* separately, on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. After development, allow the plate to dry in air and derivatise with *Natural product reagent* and examine under ultraviolet light (366 nm). It shows spots at R_f 0.28 (blue, corresponding to *gallic acid*), 0.43 (light blue) and 0.61(light blue).

Physico-chemical parameters:

Total phenolic content:	0.036 to 0.51 per cent w/v equivalent to tannic acid,	Appendix 5.1.1
Total solids:	Not less than 7.00 per cent w/v,	Appendix 3.8
Specific gravity (at 25^0):	1.02 to 1.15,	Appendix 3.2
*p*H*:*	3.5 to 4.5,	Appendix 3.3
Reducing sugars:	Not less than 5.00 per cent w/v,	Appendix 5.1.3
Non-reducing sugars:	Not more than 0.65 per cent w/v,	Appendix 5.1.3
Alcohol content:	4 to 9 per cent v/v,	Appendix 3.17
Methanol:	Absent,	Appendix 2.8

Assay:

Contains not less than 0.1 to 0.5 per cent w/v of *gallic acid* when assayed by the following method:

Estimation of gallic acid : Apply 1.0 to 8.0 µl of (5 data point) *gallic acid* solution prepared under Thin layer chromatography on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: acetic acid* (5 : 4 : 1) as mobile phase. Derivatise the plate with *Natural product reagent* and dry in a current of cold air and scan

in the TLC scanner at a wavelength of 366 nm. Note the peak areas under curve for the peak corresponding to *gallic acid and* prepare the calibration curve by plotting peak area *vs* concentration of *gallic acid.*

Process vacuum-dried 50 ml of the formulation under thin layer chromatography.

Apply 5 µl of the test solution on TLC plate. Develop, dry and scan the plate for calibration curve of *gallic acid.* Calculate the amount of *gallic acid in* the test solution from the calibration curve of *gallic acid.*

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured bottle, protect from light and moisture.

Therapeutic uses: Raktapitta (bleeding disorders); Pā´²u (aneamia), Ku¾ºha (skin diseases); Prameha (urinary disorders); Arśa (piles); K¨mi (worm infestation); Śotha (inflammatory diseases).

Dose: 15 – 30 ml orally with equal amount of water after meals twice a day.

AVALEHA

General Description:

Avaleha or *Lehya* is a semi-solid preparation of drugs, prepared with addition of jaggery, sugar or sugar-candy and boiled with prescribed juices or decoction.

These preparations generally have

(1) *Ka¼āya* or other liquids,
(2) Jaggery, sugar or sugar-candy,
(3) Powders or pulps of certain drugs,
(4) Ghee or oil and
(5) Honey.

Jaggery, sugar or sugar-candy is dissolved in the liquid and strained to remove the foreign particles. This solution is boiled over a moderate fire. When pressed between two fingers if *pāka* becomes thready (*Tantuvat*), or when it sinks in water without getting easily dissolved, it should be removed from the fire. Fine powders of drugs are then added in small quantities and stirred continuously to form a homogenous mixture. Ghee or oil, if mentioned, is added while the preparation is still hot and mixed well. Honey, if mentioned is added when the preparation becomes cool and mixed well.

The *Lehya* should neither be hard nor a thick fluid. When pulp of the drugs is added and ghee or oil is present in the preparation, this can be rolled between the fingers. When metals are mentioned, the *bhasmas* of the metals are used. In case of drugs like *Bhallātaka,* purification process is to be followed.

The *Lehya* should be kept in glass or porcelain jars. It can also be kept in a metal container which does not react with it. Normally, *Lehyas* should be used within one year.

DAŚAMŪLA HARĪTAKĪ

(AFI, Part-I, 3:14)

Definition:

Daśamūla Harītakī is a semisolid preparation made with the ingredients in the Formulation composition given below.

Formulation composition:

1.	Daśamūla ka¾āya	Decoction of Daśamūla Kvātha Cūr´a		3.072 l
(a.)	Bilva API	*Aegle marmelos*	Rt./St. Bk.	
(b.)	Agnimantha API	*Premna mucronata (Official substitute)*	Rt./St. Bk.	
(c.)	Śyonāka API	*Oroxylum indicum*	Rt./St. Bk.	
(d.)	Kāśmarī (Gambhārī API)	*Gmelina arborea*	Rt./St. Bk.	
(e.)	Pā°alā API	*Stereospermum suaveolens*	Rt./St. Bk.	
(f.)	Śālapar´ī API	*Desmodium gangeticum*	Pl.	
(g.)	P¨¾nipar´ī API	*Uraria picta*	Pl.	
(h.)	Śvada¼¾trā (Gok¾ura API)	*Tribulus terrestris*	Pl.	
(i.)	B¨hatī API	*Solanum indicum*	Pl.	
(j.)	Kā´°akārī API	*Solanum surattense*	Pl.	
	Jala for decoction reduced to	Water		12.288 l 3.072 l
2.	Pathyā (Harītakī API)	*Terminalia chebula*	Fr. P.	100 in number
3.	Gu²a API	Jaggery		4.8 kg
4.	Tvak API	*Cinnamomum verum (=C. zeylanicum)*	St. Bk.	48 g
5.	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	48 g
6.	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	48 g
7.	Śu´°hī API	*Zingiber officinale*	Rz.	48 g
8.	Marica API	*Piper nigrum*	Fr.	48 g
9.	Pippalī API	*Piper longum*	Fr.	48 g
10.	Yava¾ūkāja (Yavak¾āra API)	*Hordeum vulgare*	Water soluble ash of Pl.	12 g
11.	K¾audra (Madhu API)	Honey		384 g

Method of Preparation:

Take all ingredients of pharmacopoeial quality.

Take the powders of *Daśamūla* ingredients in a steel vessel, mix well to make a uniform mixture, add water and soak it overnight.

Filter the decoction (*ka¾āya*) through muslin cloth.

Heat the above mixture to about 100^0, till the water reduces to one fourth the volume and *Harītakī* becomes soft.
Remove the bundle of *Harītakī* from *Daśamūla ka¾āya*, separate the pulp of the boiled *Harītakī* and pulverize in a grinder to make a homogenous paste.
Cut *Gu²a* into thin flakes and add to the above *Daśamūla ka¾āya* in a steel vessel and heat, maintaining the temperature between 80^0 and 90^0. After the *Gu²a* dissolves, filter the hot syrup through muslin cloth.
Add the paste of *Harītakī* to the syrup, mix well and heat the mixture with continuous stirring maintaining the temperature between 100^0 to 106^0. Observe the mixture for formation of soft bolus, which does not disperse in water. Stop heating and allow to cool to 50^0.
Add powders of ingredients numbered 7 to 10 in it and mix well.
On cooling to room temperature add powders of ingredients numbered 4 to 6, followed by honey and mix well to obtain a homogenous mixture.
Pack it in tightly closed containers to protect from light and moisture.

Description:

Brown semi solid, sticky paste, with spicy odour and sweet, pungent taste

***Identification*:**

Microscopy:

Take about 5 g of the sample, wash with water three times, each time pouring off the supernatant and adding fresh water. Take a small quantity of the washed sediment, and warm with adequate quantity of chloral hydrate solutions, on water bath. Wash with water to remove chloral hydrate and mount in glycerin. Take another small quantity of sediment and mount in iodine water. Observe the following characteristics.
Epidermal tissues showing thin walled cells, slightly beaded, with occasional cross, long fibres with blunt or pegged tips, wide lumen **(Harītakī**).; fragments of fibres with narrow lumen not over 600 µ long or over 45 µ midwidth, stone cells lignified on three sides only, parenchyma cells containing minute acicular crystals of calcium oxalate (**Tvak)**; selereids for testa, long fibre light cells with very thin walls from aril, perispern cells with bulbus projection and orange coloured sclerenchymatous cells (**Sūk¾mailā)**; groups of angular epidermal parenchyma with sunken stomata, and unicellular to bicellular brichomes **(Tejapatra)**; large oval starch grains up to 75 µ in size, hilun eccentric lamellae distinct, yellow color oleoresin cells, non lignified septate fibres **(Śu´°hī);** fragments of hypodermis in surface view, stone cells of various stages and size, in groups, interspersed among parenchyma tissue **(Marica);** stone cells with broad lumen in groups of two to eight **(Pippalī).**

Thin-layer Chromatography:

Extract 5 g of formulation with 25 ml *methanol* under reflux on a water bath for 30 min, Filter, and concentrate the extract to 10 ml and carry out the thin layer chromatography. Apply 10 µl of the extract on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid* (3 : 3 : 0.5) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (366nm). It shows major fluorescent spots at R_f 0.42, 0.59 and 0.71 (all blue).

Physicochemical parameters:

Total Ash:	Not more than 2.0 per cent,	Appendix 2.2.3
Acid insoluble ash:	Not more than 0.13 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 74 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 70 per cent,	Appendix 2.2.8
Reducing sugar:	25 to 35 per cent,	Appendix 5.1.3.1
Non-reducing sugar:	20 to 30 per cent,	Appendix 5.1.3.1
*p*H *(5 % aqueous solution):*	3.96 to 4.08,	Appendix 3.3

Assay:

Daśamūla Harītakī contains 4.5 to 5.0 % w/w *gallic acid* when assayed by the following method:

Estimation of gallic acid: Dissolve about 10 mg of accurately weighed *gallic acid* in 100 ml of *methanol* in a volumetric flask. From this stock solution, prepare standard solutions of 15 to 75 µg / ml by transferring aliquots (1.5 to 7.5 ml) of stock solution to 10 ml-volumetric flasks and adjusting the volume to 10 ml with *methanol*.
Apply 10 µl each of the standard solutions corresponding to 150 ng to 750 ng of *gallic acid* on a TLC plate. Develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (3 : 3 : 0.8 : 0.2) as mobile phase. After development, dry the plate and scan in TLC scanner at a wavelength of 280 nm. Note the area under the curve for peak corresponding to *gallic acid* and prepare the calibration curve by plotting peak area *vs* amount of *gallic acid.*
Hydrolyze about 5 g, accurately weighed, avaleha by refluxing with 50 ml of 2N *hydrochloric acid* on a water-bath. Filter, add equal amount of *water*, transfer to a separating funnel and extract with *diethyl ether* (20 ml x 4). Collect the *diethyl ether* layers and dry the combined extract over *anhydrous sodium sulphate* to remove the solvent. Dissolve the residue in 25 ml of *methanol*. Apply 10 µl on a TLC plate and develop, dry and scan the plate as described in the preceding paragraph for calibration curve of *gallic acid*. Note area under the curve for a peak corresponding to *gallic acid*. Calculate the amount of *gallic acid* in the test solution from the calibration curve of *gallic acid* .

Other requirements:

Microbial Limits:	Appendix 2.4.
Aflatoxins:	Appendix 2.7.

Storage: Store in a cool place in tightly closed amber coloured containers, to protect from light and moisture.

Therapeutic uses: Śopha (oedema); Arocaka (tastelessness); Gara-udararoga (abdominal disorder due to slow/accumulated poison); Gulma (abdominal lump); Plīhāroga (splenic disease); Vaivar´ya (discoloration); Mūtrak¨cchra (dysuria); Śukrado¾a (vitiation of semen); Śvāsa (asthma); Jvara (fever); Meha (excessive flow of urine); Kārśya (emaciation); Raktapitta (bleeding disoder); Āmavāta (rheumatism).

Dose: 6 to 12 g twice a day.

Anupāna: water, milk

DRĀK½ĀVALEHA
(AFI, Part-I, 3:15)

Definition:

Drāk¾āvaleha is a semisolid preparation made with the ingredients in the Formulation composition given below.

Formulation Composition:

1.	Drāk¾ā API	*Vitis vinifera*	Dr. Fr.	768 g
2.	Ka´ā (Pippalī API)	*Piper longum*	Fr.	768 g
3.	Śarkarā	Sugar		2.800 kg
4.	Madhuka (Ya¾°ī API)	*Glycyrrhiza glabra*	Rt.	96 g
5.	Śu´°hī API	*Zingiber officinale*	Rz.	96 g
6.	Tvak¾īrī (Va¼śa API)	*Bambusa arundinacea*	S.C.	96 g
7.	Dhātrī (Āmalakī API) Phala rasa	*Embelica officinalis*	P.	12.288 l
8.	Madhu	Honey		768 g

Method of preparation:

Take all ingredients of pharmacopoeial quality.
Wash the *Drāk¾ā* with fresh water, till it becomes clean and drain the water completely. Remove the seeds and crush to a fine paste.
Clean, dry the ingredients numbered 2, 4 and 5 of the formulation composition, powder separately and pass through sieve number 85.
Clean the ingredient number 6 of the formulation composition, powder and pass through sieve number 120.
Wash, clean the fresh *Āmalakī* fruits, grind it, squeeze the juice and filter it through *muslin cloth* to obtain *Svarasa*.
Crush *Drāk¾ā* to make a pulp and pass through sieve number 44.
Add sugar to *Svarasa* and heat, maintaining the temperature between 80^0 and 90^0. After the sugar dissolves, filter the hot syrup through muslin cloth.
Heat the filtered syrup mildly to make 'two-thread sugar syrup'.
Add the *Drāk¾ā* pulp to the above syrup, heat with constant stirring maintaining temperature between 90^0 and 100^0 and observe the mixture till the formation of a soft bolus, which does not disperse in water. Stop heating and allow to cool to 50^0.
Add fine powders of *Prak¾epa dravyas* and mix thoroughly to prepare a homogeneous blend.
Allow to cool to room temperature and add *Madhu*.
Pack it in tightly closed amber coloured containers to protect from light and moisture.

Description:

Semi solid, malleable, dark brown, sticky preparation, with a spicy odour, sour and pungent, sweet taste

Identification:

Microscopy:

Weigh 5 g of the sample, and mix with 50 ml of water in a beaker with gentle warming, till the sample gets completely dispersed in water. Centrifuge the mixture and decant the supernatant. Wash the sediment with distilled water and centrifuge again. Decant the supernatant and mount the sediment in glycerine. Take another small quantity of sediment and mount in iodine water. Observe the following characters.

Broad xylem vessels with spiral thickening, septate fibres, wide lumen with oblique tips, sac shaped simple large starch grains with hilum at narrow end and showing eccentric striations, parenchymatous cells filled with yellowish-brown droplets of oleoresin (**Śu´°hī**); perisperm cells packed with minute starch grains; elongated, spindle shaped, wide lumened lignified cells associated with spirally thickened narrow vessels. (**Pippalī**); cells from pericarp filled with pink colour pigment, acicular needles of calcium oxalate (**Drāk¾ā**); crystal fibres, group of tracheids with bordered pits and slit like openings, fragments of xylem vessels with bordered pits (**Ya¾°ī**); angular fragments, glass like, visible in the microscope, but becoming invisible between crossed polars in a polarizing microscope **(Va¼śa)**.

Thin-layer chromatography:

Extract 5 g of formulation with 25 ml *methano*l under reflux on a water bath for 30 min, filter, and concentrate the extract to 10 ml and carry out the thin layer chromatography. Apply 20 µl of the extract on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (3 : 3 : 0.8 : 0.2) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (254 nm). It shows major fluorescent spots at R_f 0.10, 0.21, 0.48, 0.60, 0.74, 0.80 and 0.84 (all blue).

Physico-chemical parameters:

Total Ash:	Not more than 2.5 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 0.8 per cent,	Appendix 2.2.4
Alcohol -soluble extractive:	Not less than 55.0 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 65.0 per cent,	Appendix 2.2.8
Reducing sugar:	37 to 40 per cent,	Appendix 5.1.3.1
Non-reducing sugar:	4.7 to 6.3 per cent,	Appendix 5.1.3.1
pH (5 % aqueous solution):	3.35 to 3.75,	Appendix 3.3

Assay:

Drāk¾āvaleha contains 5.0 to 5.75 per cent *gallic acid* when assayed by the following method:

Estimation of gallic acid: Dissolve 10 mg of *gallic acid in* 100 ml of *methanol* in a volumetric flask. From this stock solution, prepare standard solutions of 15 to 75 µg / ml by transferring aliquots (1.5 to 7.5 ml) of stock solution to 10 ml-volumetric flasks and adjusting the volume 10 ml with *methanol*.
Apply 10 µl of each standard solution corresponding to 150 ng to 750 ng of *gallic acid on* a TLC plate. Develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (3: 3: 0.8: 0.2) as mobile phase. After development, dry the plate and scan in TLC scanner at wavelength of 280 nm. Note the area under the curve for peak corresponding to *gallic acid and* prepare the calibration curve by plotting peak area *vs* amount of *gallic acid.*
Hydrolyze about 5 g, accurately weighed avaleha by refluxing with 50 ml of 2N *hydrochloric acid* on a water-bath. Filter, add equal amount of *water*, transfer to a separating funnel and extract with *diethyl ether* (20 ml x 4). Collect the *diethyl ether* layers and dry over *anhydrous sodium sulphate* to remove the solvent. Dissolve the residue in 25 ml of *methanol*. Apply 10 µl on a TLC plate and develop, dry and scan the plate as described in the preceding paragraph for calibration curve of *gallic acid*. Note area under the curve for a peak corresponding to *gallic acid*. Calculate the amount of *gallic acid in* the test solution from the calibration curve of *gallic acid.*

Other requirements:

Microbial Limits:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed amber coloured containers to protect from light and moisture.

Therapeutic uses: Pā´²u (anemia); Kāmalā (jaundice); Halīmaka (chronic obstructive Jaundice/chlorosis/advanced stage of jaundice).

Dose: 6 to 12 gm twice a day

Anupāna: water, milk

ELĀDYA MODAKA

(AFI, Part-I, 3:3)

Definition:

Elādya Modaka is a semisolid preparation made with the ingredients in the Formulation composition given below.

Formulation Composition:

1.	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	1 part
2.	Madhūka API	*Madhuca indica*	Fl.	1 part
3.	Agni (Citraka) API	*Plumbago zeylanica*	Rt.	1 part
4.	Haridrā API	*Curcuma longa*	Rz.	1 part
5.	Dāruharidrā API	*Berberis aristata*	St.	1 part
6.	Harītakī API	*Terminalia chebula*	P.	1 part
7.	Bibhītaka API	*Terminalia belerica*	P.	1 part
8.	Āmalakī API	*Emblica officinalis*	P.	1 part
9.	Raktaśāli (ŚāliAPI)	*Oryza sativa*	Sd.	1 part
10.	Ka´ā (Pippalī API)	*Piper longum*	Fr.	1 part
11.	Drāk¾ā API	*Vitis vinifera*	Dr. Fr.	1 part
12.	Kharjūra API	*Phoenix sylvestris*	Fr.	1 part
13.	Tila API	*Sesamum indicum*	Sd.	1 part
14.	Yava API	*Hordeum vulgare*	Sd.	1 part
15.	Vidārī API	*Pueraria tuberosa*	Rt. Tr.	1 part
16.	Gok¾ura bīja (Gok¾ura API)	*Tribulus terrestris*	Fr.	1 part
17.	Triv¨tā (Triv¨t API)	*Ipomoea turpethum*	Rt.	1 part
18.	Śatāvarī API	*Asparagus racemosus*	Rt.	1 Part
19.	Sitā API	Sugar candy		36 part
20.	Jala API	Water		12 part

Method of Preparation:

Take all ingredients of pharmacopoeial quality.

Wash, clean, dry ingredients numbered 1 to 18 in formulation composition, powder separately and pass through sieve number 85.

Add sugar to water in a stainless steel vessel and heat, maintaining the temperature between 80^0 and 90^0. After the sugar dissolves, filter the hot syrup through muslin cloth.

Heat the filtered syrup until it becomes thick syrup of optimum consistency. Stop heating and allow to cool to 50^0.

Add the fine powders of *Prak¾epa dravyas* with constant stirring to form a homogeneous mixture. Roll the mixture into *Modaka* of approximately 6 g each while warm.

Pack in tightly closed containers to protect from light and moisture.

Description:

Brown soft balls; initially bitter followed by slightly sweet and pungent taste and faintly flavoured with Ela

Identification:

Thin-layer chromatography:

Extract 25 g of formulation with *methanol: chloroform: ether* (1 : 1 : 1) under reflux on a water bath for 30 min, filter and concentrate the extract to 10 ml and carry out the thin-layer chromatography.
Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (6 : 6 : 0.4 : 1.6) as mobile phase. After development allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.33 (black), 0.45 (black), 0.65 (blue), 0.71 (yellow), 0.75 (fluoresent blue). Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows spots at R_f 0.15 (brown), 0.45 (black), 0.62 (brown), 0.71 (bluish-black), 0.75 (green), 0.85 (blue) and 0.91 (pink) under ultraviolet light (366 nm) and spots at R_f 0.45 (light-brown); 0.65 (brown, α-pinene) and 0.71 (brick red, *curcumin*), in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 1.47 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 0.19 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 40.0 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 70.0 per cent,	Appendix 2.2.8
Reducing sugar:	11 to 16 per cent,	Appendix 5.1.3.1
Non-reducing sugar:	70 to 72 per cent,	Appendix 5.1.3.1
*p*H *(5 % aqueous solution):*	4.3 to 4.6,	Appendix 3.3

Other requirements:

Microbial Limits:	Appendix-2.4
Aflatoxins:	Appendix-2.7

Storage: Store in cool place in tightly closed amber coloured containers, protect from light and moisture.

Therapeutic uses: Agnimāndya (digestive impairment); Chardi (emesis); Madātyaya (alcoholism); Madyāpānaja vikāra (alcholism disorder).

Dose: 6 to 12 gm twice a day

Anupāna: Fresh milk, Mudga Yū¾a.

MADHUSNUHĪ RASĀYANA

(AFI, Part-I, 3:19)

Definition:

Madhusnuhī Rasāyana is a semisolid Avaleha preparation made with the ingredients in the Formulation composition given below.

Formulation Composition :

1.	Śu´°hī API	*Zingiber officinale*	Rz.	6 g
2.	Maricā API	*Piper nigrum*	Fr.	6 g
3.	Pippalī API	*Piper longum*	Fr.	6 g
4.	Harītakī API	*Terminalia chebula*	P.	6 g
5.	Bibhītaka API	*Terminalia belerica*	P.	6 g
6.	Āmalakī API	*Emblica officinalis*	P.	6 g
7.	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	6 g
8.	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	6 g
9.	Patra (Tejapatra API)	*Cinnamomum zeylanicum*	Lf.	6 g
10.	Jātīphala API	*Myristica fragrans*	Sd.	6 g
11.	Jātīpatrī (Jātīphala API)	*Myristica fragrans*	Ar.	6 g
12.	Agni (Citraka API)	*Plumbago zeylanica*	Rt.	6 g
13.	Varālā (Lava¬ga API)	*Syzigium aromaticum*	Fl. Bd.	6 g
14.	Dhānyaka API	*Coriandrum sativum*	Fr.	6 g
15.	Śveta jīraka API	*Cuminum cyminum*	Fr.	6 g
16.	K¨¾´a jīraka API	*Carum carvi*	Fr.	6 g
17.	Vi²a¬ga API	*Embelia ribes*	Fr.	6 g
18.	Cavya API	*Piper chaba*	St.	6 g
19.	Ku¾°ha API	*Saussuera lappa*	Rt.	6 g
20.	Triv¨tā (Triv¨t API)	*Ipomoea turpethum*	Rt.	6 g
21.	Granthika (Pipplīmūla API)	*Piper longum*	Rt.	6 g
22.	Vājigandhikā (Aśvagandhā API)	*Withania somnifera*	Rt.	6 g
23.	Bhār¬gī API	*Clerodendrum serratum*	Rt.	6 g
24.	Tejovatī-bīja API	*Zanthoxylum alatum*	Sd.	6 g
25.	Keśara (Nāgakeśara API)	*Mesua ferrea*	Stmn.	6 g
26.	Śuddha gandha (Gandhaka API)	Sulphur		192 g
27.	Mahi¾āk¾a guggulu-śodhita API	*Commiphora wightii*	O. R.	192 g
28.	Madhusnuhī API	*Smilax china*	Rt. Tr.	192 g
29.	Gh¨ta (Goghrta API)	Clarified butter from cow's milk		576 g
30.	Sitā API	Sugar candy		576 g
31.	Madhu API	Honey		768 g

Method of Preparation:

Take raw materials of pharmacopoeial quality.
Clean, dry the ingredients number 1 to 26 and 29 (*Prak¾epa dravya*) of the formulation composition, powder separately and pass through sieve number 85.
Treat *Guggulu* to prepare *Śodhita Guggulu* (Appendix 6.2.7.4).
Treat *Gandhaka* to prepare *Śodhita Gandhaka* (Appendix 6.2.7.3).
Powder *Suddha Gandhaka* and pass through sieve number 120.
Add two times water to the sugar in a stainless steel vessel and heat, maintaining the temperature between 80^0 and 90^0. After the sugar dissolves, filter the hot syrup through muslin cloth.
Heat the filtered syrup mildly to make two thread sugar syrup. Stop heating and allow to cool to 60^0.
Add warm *Gh¨ta* and mix well.
Add *Sodhita Guggulu*, followed by fine powders of ingredients number 1 to 26 and 29, followed by *Śuddha Gandhaka*. Mix thoroughly each time to prepare a homogeneous blend.
Allow to cool it to room temperature and add *Madhu*.
Pack in tightly closed container to protect from light and moisture.

Description:

Solid, brown, sweet semi solid with smell characteristic of coconut

Identification:

Thin-layer chromatography:

Extract 5 g of formulation with 25 ml *methanol* under reflux on a water bath for 30 min, Filter and concentrate the extract to 10 ml and carry out the TLC. Apply 20 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid: methanol* (6 : 5 : 0.8 : 0.2) as mobile phase. After development allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.34 (black), 0.48 (black), 0.53 (blue), 0.57 (blue), 0.63 (blue), 0.72 (blue), 0.75 (greenish-blue), 0.85 (light blue). Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.34 (brown), 0.48 (brown), 0.66 (light violet), 0.68 (light yellow), 0.69 (light violet), 0.72 (blue), 0.77 (blue), 0.81 (light violet), 0.89 (grey) in visible light.

Physico-chemical parameters

Total Ash:	Not more than 1.4 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 0.23 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 40.0 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 47.5 per cent,	Appendix 2.2.8
Total sugar:	29.86 to 35.14 per cent,	Appendix 5.1.3.2
Reducing sugar:	25 to 30 per cent,	Appendix 5.1.3.1
Non-reducing sugar:	4.78 to 5.14 per cent,	Appendix 5.1.3.1
*p*H *(5 % aqueous solution):*	4.02 to 4.17,	Appendix 3.3

Other requirements:

Microbial Limits:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed containers, protect from light and moisture.

Therapeutic uses: Pramehapi²aka (diabetic carbuncle); Arbuda (tumour); Ga´²amālā (cervical lymphadenitis); Bhagandara (fistula-in-ano); Guhyavra´a (ulcer in genitalia); Vātarakta (gout); Ku¾ha (diseases of skin); Kilāsa (vitiligo) Arśa (piles); Prameha (increased frequency and turbidity of urine); Ka´²ū (itching). Used as rasāyana.

Dose: 6 to 12 gm twice a day

Anupāna: warm water

CŪR³A

General Descripition:

Drugs according to the formulation composition of the particular c*ūr´a* are collected, dried, powdered individually and passed through sieve number 85 to prepare a fine powder. They are mixed in the specified proportion and stored in well closed container.

The term c*ūr´a* may be applied to the powder prepared by a single drug or a combination of more drugs.

Raja and *K¾oda* are the synonyms for c*ūr´a*. *Cūr´as* may be of plant origin, or mixed with other ingredients. The following points are to be noted.

If metals / minerals are used, prepare *bhasma* or *sindūra* of the minerals unless otherwise mentioned.

In cases where *pārada* and *gandhaka* are mentioned, prepare *Kajjalī* and add other drugs, one by one, according to the formula.

In general the aromatic drugs like *Hi¬gu* [Asafoetida] etc. should be fried before they are converted to fine powders.

Specific care should be taken in case of Salts and Sugars. Formulations with hygroscopic components should not usually be prepared during rainy seasons. If so, specific precautions should be taken during storage.

C*ūr´as* should be stored in air tight containers. Polyethylene and foil packing also provides damp proof protection.

Special precaution for storage should be taken in cases of formulations with salts, sugars and *Kṣāras*.

BHĀSKARALAVA³A CŪR³A

(Lava´abhāskara Cūr´a)

(AFI, Part-I, 7:27)

Definition:

Bhāskaralava´a Cūr´a is a powder preparation made with the ingredients in the Formulation composition given below.

Formulation composition:

1.	Sāmudra lava´a API	Sea salt		96 g
2.	Sauvarcala lava´a API			60 g
3.	Vi²a lava´a API			24 g
4.	Saindhava lava´a API	Rock salt		24 g
5.	Dhānyaka API	*Coriandrum sativum*	Fr.	24 g
6.	Pippalī API	*Piper longum*	Fr.	24 g
7.	Pippalī mūla API	*Piper longum*	Rt.	24 g
8.	K¨¾´a jīraka API	*Carum carvi*	Fr.	24 g
9.	Patraka (Tvak patra API)	*Cinnmomum tamala*	Lf.	24 g
10.	Nāgakeśara API	*Mesua ferrea*	Stmn.	24 g
11.	Tālīsa API	*Abies webbiana*	Lf.	24 g
12.	Amlavetasa API	*Garcinia pedunculata*	Fr.	24 g
13.	Marica API	*Piper nigrum*	Fr.	12 g
14.	Jīraka (Śveta jīraka API)	*Cuminum cyminum*	Fr.	12 g
15.	Viśva (Śu´°hī API)	*Zingiber officinale*	Rz.	12 g
16.	Dā²ima Bīja (Dā²ima API)	*Punica granatum*	Dr.Sd.	48 g
17.	Tvak API	*Cinnmomum zeylanicum*	St. Bk.	6 g
18.	Elā (Sūk¾mailā API)	*Eletteria cardamomum*	Sd.	6 g

Methods of preparation:

Take all ingredients of pharmacopoeial quality.

Wash and dry the ingredients numbered 5 to 18.

Roast coarsely powdered *Samudra lava´a, Sauvarcala lava´a, Saindhava lava´a* and *Vi²a lava´*a individually in a stainless steel pan on low flame till free from moisture, powder separately and pass through sieve number 85**.**

Powder the ingredients 5 to 18. The powders should completely pass through sieve number 44 and not less than 50 per cent through sieve number 85.

Weigh each ingredient separately and mix together. Pass the *cūr´a* through sieve number 44 to obtain a homogenous blend and pack in an air-tight container.

Description:

Creamish-brown coloured, smooth powder with a characteristic odour of *Vi²a lava´a* and salty taste. The powder completely passes through sieve number 44 and not less than 50 per cent through sieve number 85.

Identification:

Thin Layer Chromatography:

Extract 4 g of formulation with 25 ml *alcohol* under reflux on a water bath for 30 min, filter and concentrate the extract to 10 ml and carry out the thin layer chromatography. Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate* (5:3) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light. It shows major spots at R_f 0.13 (greenish blue), 0.23 (blue), 0.44 (pale blue), 0.59 (pale blue), 0.72 (greenish blue), 0.74 (pale blue), 0.82 (greenish blue) and 0.92 (blue) under 254 nm and 0.10 (violet), 0.48 (pale blue), 0.77 (pale blue) and 0.85 (pink) under 366 nm. Spray the plate with *vanillin-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.13 (orange), 0.23 (light orange), 0.38 (light orange), 0.51 (light grey), 0.64 (dark brown), 0.72 (pink) and 0.95 (black) in visible light.

Test for Chlorides:
Dissolve 1 g of sample in 10 ml *deionised water* and filter. Acidify the filtrate with *dilute nitric acid*, add 5 per cent w/v *silver nitrate solution*. A curdy white precipitate shows the presence of chlorides.

Test for Magnesium:
Dissolve 1 g of sample in 10 ml *deionised water* and filter. Add 1 ml of *dilute hydrochloric acid*, 1 drop of *Magneson II reagent* and 3 ml of *dilute sodium hydroxide solution*. A blue precipitate shows the presence of magnesium.

Test for Sulphates:
Dissolve 1 g of sample in 10 ml *deionised water* and filter. Add 2 ml of 2 per cent *barium chloride solution*. A white precipitate shows the presence of sulphates.

Test for Sulphides:
Dissolve 1 g of sample in 10 ml *deionised water* and filter. Add 4 ml of *silver nitrate solution*. A black precipitate shows the presence of sulphides.

Physico-chemical parameters:

Loss on drying at 105^0:	Not more than 7 per cent,	Appendix 2.2.10.
Total ash:	Not more than 50 per cent,	Appendix 2.2.3.
Acid-insoluble ash:	Not more than 3 per cent,	Appendix 2.2.4.
Alcohol-soluble extractive:	Not less than 12 per cent,	Appendix 2.2.7.
Water-soluble extractive:	Not less than 47 per cent,	Appendix 2.2.8.
*p*H *(10% aqueous solution):*	4.0 to 4.7,	Appendix 3.3.

Assay:

Sodium:	Not less than 14 per cent w/w,	Appendix 5.29

Other requirements:

Microbial limits:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed containers, protect from light and moisture.

Therapeutic uses: Agnimāndya (digestive impairment); Śūla (pain); Graha´ī (mal absorption syndrome); Vāta kaphaja gulma (tumor due to Vāta do¾a and Kapha do¾a); Plīha (splenic disease); Udara (disease of abdomen); Arśa (piles); K¾aya (pthisis); Ku¾°ha (disease of skin); Vibandha (constipation); Bhagandara (fistula-in-ano); Śopha (oedema); Śūla (pain); Śvāsa (asthma); Kāsa (cough); Āmavāta (rhumatism); H¨druja (angina pectoris); Ajīr´a (dyspepsia).

Dose: 2-5 g in divided doses.

Anupāna: Mastu, Takra, Āsava, Warm water.

GOMŪTRA HARĪTAKĪ

(AFI, Part-I, 7:8)

Definition:

Gomūtra Harītakī is a powder preparation made with the ingredients in the Formulation composition given below.

Formulation composition:

1.	Gomūtra	Cow urine		4 parts
2.	Pathyā (Harītakī API)	*Terminalia chebula*	P.	1 part
3.	Jala kvātha (Hrīvera API)	*Coleus vettiveroides*	Rt.	1 part
4.	Miśi kvātha (Miśreyā API)	*Foeniculum vulgare*	Fr.	1 part
5.	Ku¾ºha API Kvātha	*Saussurea lappa*	Rt.	1 part

Method of preparation:

Take all ingredients of pharmacopoeial quality.
Wash and dry the ingredients numbered 2 to 5.
Boil the *Harītakī* in *Gomūtra* till all the *Gomūtra* is absorbed.
Boil coarsely powdered *Hrīvera* in potable water till it reduces to eighth part, filter and collect the decoction of *Hrīvera* in a stainless steel vessel.
Soak the boiled *Harītakī* in the decoction of *Hrīvera* and dry it under sun light till all the decoction gets absorbed by the *Harītakī*.
Boil coarsely powdered *Miśreyā* in potable water till it reduces to eighth part. Filter and collect the decoction of *Miśreyā*.
Soak the *Harītakī* in the *Miśreyā* decoction and dry under sun light till all the decoction gets absorbed by the *Harītakī*.
Boil coarsely powdered *Ku¾ha* in potable water till it reduces to eighth part, filter and collect the decoction.
Soak the *Harītakī* in *Ku¾ha Kvātha* and dry under sunlight till all the decoction gets absorbed by the *Harītakī*.
Dry under sunlight and powder the dried *Harītakī* in a pulverizer and pass through sieve number 85 and pack in an air tight container.

Description:

Brown coloured, smooth powder with a characteristic odour of *Gomūtra* and a slightly astringent and salty taste. The powder completely passes through sieve number 44 and not less than 50 per cent through sieve number 85.

Identification:

Microscopy:

Take about 2 g of *Cūr´a*, and wash it thoroughly without loss of *Cūr´a*; warm a few mg of *Cūr´a* with *chloral hydrate*, wash and mount in *glycerin*; wash a few mg of *Cūr´a* in plain water and mount in *glycerin*; treat a few mg of *Cūr´a* with *iodine* in *potassium iodide* solution and mount in *glycerin*; heat a few mg of Cūr´a in 2% *potassium hydroxide*, wash in water and mount in *glycerin*. Observe the following characters in the different mounts. Groups of elongated thick walled sclereids with pits and broad lumen, criss-cross thin walled fibres with broad lumen and pegged tips, thin walled parenchyma cells, rosette crystals of calcium oxalate upto 25 µ in size; polygonal epidermal cells with slightly beaded wall; stone cells with wide lumen and pits **(Harītakī);** cork cells in surface view; fragments of reticulate and pitted vessels; pitted parenchyma; thin walled broad lumen lignified fibres with oblique pointed ends upto 450 µ in length **(Hrīvera)**; endosperm cells with oil globules and aluerone grains; reticulate vessels; fragments of vittae; epidermis with stomata and tracheids with wide lumen and pits **(Miśreyā);** groups of elongated polygonal parenchymatous cells, xylem vessels with scalariform and spiral thickening; storage parenchyma with inulin: fibres with thin walled broad lumen with sharp end tips upto 300 µ in length; positive test for Inulin, when a few mg of *Cūrna* is treated with *α- naphthol* and *conc. sulphuric acid*, warmed gently, and observed under microscope; development of a dark violet colour in the storage parenchyma indicates the presence of inulin **(Ku¾ºha).**

Thin Layer Chromatography:

Extract 4 g of formulation with 25 ml *alcohol* under reflux on a water bath for 30 min, filter and concentrate the extract to 10 ml and carry out the thin layer chromatography. Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *chloroform: methanol: formic acid* (9 : 1 : 0.1) as mobile phase. After development, allow it to dry in air and examine under ultraviolet light. It shows major spots at R_f 0.13 (green), 0.53 (green), 0.66 (bluish green) and 0.89 (light green) under 254 nm; and 0.11 (violet), 0.24 (blue), 0.58 (blue), 0.68 (blue), 0.89 (pale blue) under 366 nm. Spray the plate with *vanillin-sulphuric acid reagent* followed by heating at 105^0 for about 10 minutes. It shows major spots at R_f 0.16 (grey), 0.55 (blue), 0.84 (grey) in visible light.

Physico-chemical parameters:

Loss on drying at 105^0:	Not more than 10 per cent,	Appendix 2.2.10.
Total ash:	Not more than 10 per cent,	Appendix 2.2.3.
Acid-insoluble ash:	Not more than 0.95 per cent,	Appendix 2.2.4.
Alcohol-soluble extractive:	Not less than 28 per cent,	Appendix. 2.2.7.
Water-soluble extractive:	Not less than 49 per cent,	Appendix 2.2.8.
pH (10% aqueous solution):	5.0 to 6.0,	Appendix 3.3.

Other requirements:

Microbial limits:	Appendix 2.4
Aflatoxin:	Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Mukha roga (disease of mouth)

Dose: 2 to 4 g daily in divided doses.

Anupāna: Water

JĀTĪPHALĀDYA CŪR³A
(AFI, Part-I, 7:12)

Definition:

Jātīphalādya Cūr´a is a powder preparation made with the ingredients in the Formulation composition given below.

Formulation composition:

1.	Jātīphala API	*Myristica fragrans*	Sd.	1 part
2.	Lava¬ga API	*Syzygium aromaticum*	Fl.Bd.	1 part
3.	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	1 part
4.	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	1 part
5.	Tvak API	*Cinnamomum zeylanicum*	St.Bk.	1 part
6.	Nāgakeśara API	*Mesua ferrea*	Stmn.	1 part
7.	Karpūra API	*Cinnamomum camphora*	Sub.Ext	1 part
8.	Candana (Śveta candana API)	*Santalum album*	Ht.Wd.	1 part
9.	Tila API	*Sesamum indicum*	Sd.	1 part
10.	Tvak¾īrī (Va¼sa API)	*Bambusa bambos*	S.C	1 part
11.	Tagara API	*Valeriana wallichii*	Rt.	1 part
12.	Āmala (ĀmalakīAPI)	*Emblica officinalis*	P.	1 part
13.	Tālīsa API	*Abies webbiana*	Lf.	1 part
14.	Pippalī API	*Piper longum*	Fr.	1 part
15.	Pathyā (Harītakī API)	*Terminalia chebula*	P.	1 part
16.	Sthūlajīraka(Upakuñcikā API)	*Nigella sativa*	Sd.	1 part
17.	Citraka API	*Plumbago zeylanica*	Rt.	1 part
18.	Śu´°hī API	*Zingiber officinale*	Rz.	1 part
19.	Vi²a¬ga API	*Embelia ribes*	Fr.	1 part
20.	Marica API	*Piper nigrum*	Fr.	1 part
21.	Bha¬gā (Vijayā API) Śuddha	*Cannabis sativa*	Lf.	20 parts
22.	Śarkarā API	Cane sugar		40 parts

Methods of preparation:

Take all ingredients of pharmacopoeial quality.
Treat *Bha¬gā* to prepare *Śuddha Bha¬gā*.(Appendix 6.2.7.15)
Wash and dry the ingredients numbered 1 to 6, 8, 9 and 11 to 21.
Powder the ingredients 1 to 22. The powders should completely pass through sieve number 44 and not less than 50 per cent through sieve number 85. Weigh each ingredient and mix together in required quantity. Pass the *Cūr´a* through sieve number 44 to obtain a homogenous blend and pack in an air-tight container.

Description:

Greenish brown, smooth powder, odour characteristic of camphor, tastes sweet and faintly pungent. The powder completely passes through sieve number 44 and not less than 50 per cent through sieve number 85.

Identification:

Thin Layer Chromatography:

Extract 4 g of formulation with 25 ml *alcohol* under reflux on a water bath for 30 min, filter and concentrate the extract to 10 ml and carry out the thin layer chromatography. Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate* (5 : 1.5) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *vanillin-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.27 (light yellow), 0.41 (light pink), 0.49 (light violet), 0.54, 0.64 (both bluish grey), 0.81 (light violet) and 0.95 (violet) in visible light.

Physico-chemical Parameters:

Loss on drying at 105^0:	Not more than 6.0 per cent,	Appendix 2.2.10
Total ash:	Not more than 7.5 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 2.8 per cent,	Appendix 2.2.4
Alcoho-soluble extractive:	Not less than 16.0 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 41.0 per cent,	Appendix 2.2.8
*p*H *(10% aqueous solution):*	6.0 to 7.0,	Appendix 3.3
Total sugar:	Not less than 36.0 per cent,	Appendix.5.1.3.2

Other requirements:

Microbial limits:	Appendix 2.4
Aflatoxin:	Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Aruci (tastelessness) Atisāra (diarrhoea); Graha´ī (malabsorption syndrome); Pravāhikā (dysentery); Kāsa (cough); Śvāsa (dyspnoea/asthma); Vātaśle¾ma Pratiśyāya (rhinitis due to vāta do¾a and śle¾ma do¾a).

Dose: 2-5 g in divided doses.

Anupāna: Honey, Water, Takra (Butter milk).

NĀRASI»HA CŪR³A
(AFI, Part-I, 7:18)

Definition:

Nārasi¼ha Cūr´a is an electuary prepared with the ingredients in the Formulation composition given below.

Formulation composition:

1.	Śatāvarī raja (Śatāvarī API)	*Asparagus racemosus*	Rt. Tr.	768 g
2.	Gok¾ura API	*Tribulus terrestris*	Fr.	768 g
3.	Vārāhī API	*Dioscorea bulbifera*	Rz.	960 g
4.	Gu²ūcī API	*Tinospora cordifolia*	St.	1.200 kg
5.	Bhallātaka API –Śuddha	*Semecarpus anacardium*	Fr.	1.536 kg
6.	Citraka API	*Plumbago zeylanica*	Rt.	480 g
7.	Tila API	*Sesamum indicum*	Sd.	768 g
8.	Śu´°hī API	*Zingiber officinale*	Rz.	128 g
9.	Marica API	*Piper nigrum*	Fr.	128 g
10.	Pippalī API	*Piper longum*	Fr.	128 g
11.	Śarkarā API	Cane sugar		3.360 kg
12.	Māk¾ika (Madhu API)	Honey		1.680 kg
13.	Gh¨ta (Gogh¨ta API)	Clarified butter from cow's milk		840 g
14.	Vidārī kanda raja (Vidārī API)	*Pueraria tuberosa*	Rt. Tr.	768 g

Methods of preparation:

Take all ingredients of pharmacopoeial quality.
Treat *Bhallātaka* to prepare *Bhallātaka Śuddha* (Appendix 6.2.7.7).
Wash and dry the ingredients numbered 1 to 4, 6 to 10 and 14, powder individually in a pulverizer. The powders should completely pass through sieve number 44 and not less than 50 per cent through sieve number 85. Weigh separately each ingredient, mix together and pass through sieve number 44 to obtain a homogenous blend. Add *Madhu* and *Gh¨ta* to the mixture and mix thoroughly till it spreads evenly to give a moist granular powder.
Store the *Cū¨ña* in a ceramic jar smeared with ghee in its inner surface.

Description:

Brown-coloured, moist, granular powder, slightly pungent to taste with the characteristic smell of Bhallātaka

Identification:

Thin Layer Chromatography:

Extract 4 g of formulation with 25 ml *alcohol* under reflux on a water bath for 30 min, filter and concentrate the extract to 10 ml and carry out the thin layer chromatography. Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: formic acid* (5 : 1.5 : 0.5) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light. It shows major spots at R_f 0.33, 0.55, 0.60, 0.73 (all green), 0.78 (light green), 0.85 (green), 0.93 (greenish blue) under 254 nm; and 0.23, 0.33 (both pink), 0.53 (pale blue), 0.60 (light violet), 0.70 (pale blue), 0.80 (light pink), 0.85 (violet) under 366nm. Spray the plate with *vanillin-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.33 (brown), 0.48 (light blue), 0.68 (light blue), 0.78 (bluish brown) in visible light.

Physico-chemical parameters:

Loss on drying at 105^0:	Not more than 9 per cent,	Appendix 2.2.10
Total ash:	Not more than 4.0 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 1.2 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 28 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 34 per cent,	Appendix 2.2.8
*p*H *(10 % aqueous solution):*	5.0 to 5.4,	Appendix 3.3.
Total sugar:	Not less than 5 per cent,	Appendix 5.1.3.1
Reducing sugar:	Not less than 5 per cent,	Appendix 5.1.3.1

Other requirements:

Microbial limits:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage:

Store the *Cū¨na* in a ceramic jar smeared with ghee on its inner surface and protect from light and moisture.

Therapeutic uses: Kāsa (cough); K¾aya (pthisis); Śukra k¾aya (deficiency of semen); Jarā (senility); Rujā (pain); Valī (wrinkles in the skin); Palita (graying of hair); Khālitya (alopecia); Meha (excessive flow of urin); Pā´²u (anaemia); Ā²hyavāta (gout); Pīnasa (chornic rhinitis); Ku¾°ha (disesase of skin); Udara (disease of abdomen); Bhagandara (fistula-in–ano); Mūtrak¨cchra (dysuria); G¨dhrasī (sciatica); Halīmaka (chronic obstructive jaundice); Vātavikāra (discorder due to Vāta do¾a); Pittavikāra (disorder of pitta do¾a); Arśa (piles); Ślesmavikāra (disorder due to kapha do¾a).

Dose: 2-5 g in divided doses.

Anupāna: Milk, Ghee, Honey.

GH§TA

General Description:

Gh¨tas are preparations in which the *Gh¨ta* is boiled with prescribed liquid [*Svarasa*/*Ka¼ãya* etc.] and fine paste [*Kalka*] of the drugs specified in the formulation composition. Unless specified otherwise *Gh¨ta* means *Go Gh¨ta.*

General Method of Preparation:

1. There are usually three essential components in the manufacture of *Gh¨ta Kalpanã*.

    a. *Drava* [Any liquid medium as prescribed in the composition]
    b. *Kalka* [Fine paste of the specified drugs]
    c. *Sneha dravya* [Fatty media - *Gh¨ta*]
    and, occasionally.
    d. *Gandha dravya* [Perfuming agents]

2. Unless otherwise specified in the verse, if *Kalka* is one part by weight, *Gh¨ta* should be four parts and the *Drava dravya* should be sixteen parts.

3. There are a few exceptions for the above general rule:

    a. Where *Drava dravya* is either *Kvãtha* or *Svarasa*, the ratio of *Kalka* should be one-sixth and one-eighth respectively to that of *Gh¨ta.*
    If the *Drava dravya* is either *K¼îra* or *Dadhi* or *Ma¼ísa rasa* or *Takra*, the ratio of *Kalka* should be one-eighth to that of *Gh¨ta.*
    b. When flowers are advised for use as *Kalka*, it should be one-eighth to that of *Gh¨ta.*
    c. Where the numbers of Drava-dravya are four or less than four, the total quantity should be four times to that of *Gh¨ta.*
    d. Where the number of *Drava-dravyas* is more than four, each *drava* should be equal to that of *Gh¨ta.*
    e. If, *Kalka dravya* is not prescribed in a formulation, the drugs specified for the *Drava-dravya* [*Kvãtha* or *Svarasa*] should be used for the preparation of *Kalka*.
    f. Where no *Drava dravya* is prescribed in a formulation, four parts of water should be added to one part of *Gh¨ta*.

4. In general, the *Gh¨ta* should be subjected to *Mürcchana* process, followed by addition of increments of *Kalka* and *Drava-dravya* in specified ratio. The contents are to be stirred continuously thoroughout the process in order to avoid charring.

5. The process of boiling is to be continued till the whole amount of moisture gets evaporated and characteristic features of *Gh¨ta* appear.

6. The whole process of *Pãka* should be carried out on a mild to moderate flame.

7. Three stages of *Pāka* are specified for therapeutic purposes.

    a. *M¨du Pāka*: In this stage, the *Kalka* looks waxy and when rolled between fingers, it rolls like lac without sticking. The *Gh¨ta* obtained at this stage is used for *Nasya* [Nasal instillation].

    b. *Madhyama Pāka*: In this stage, the *Kalka* becomes harder and rolls into *Varti*. It burns without crackling sounds when exposed to fire and *phena* [froth] will disappear in *Gh¨ta.* The *Gh¨ta* obtained at this stage is used for *Pāna* [Internal administration] and *Vasti* [Enema].

    c. *Khara Pāka:* Further heating of the *Gh¨ta,* leads to *Khara paka*. *Kalka* becomes brittle when rolled between fingers. The *Gh¨ta* obtained at this stage is used only for *Abhyanga* [External application].

8. The period of *Pāka* depends upon the nature of liquid media used in the process.

    a. *Takra* or *Āranala* — 5 Nights
    b. *Svarasa* — 3 Nights
    c. *K¨ra* — 2 Nights

9. *Pātra Pāka:* It is the process by which the *Gh¨ta* is augmented or flavored by certain prescribed substances. The powdered drugs are suspended in a vessel containing warm, filtered *Gh¨ta.*

    The medicated *Gh¨ta* will have the odour, colour and taste of the drugs used in the process. If a considerable amount of milk is used in the preparation, the *Gh¨ta* will become thick and may solidify in cold seasons.

    Gh¨tas are preserved in good quality of glass, steel or polythene containers. These medicated preparations retain the therapeutic efficacy for sixteen months.

DĀ±IMĀDI GH§TA – A

(AFI, Part-I, 6:19)

Definition:

Dā²imādi gh¨ta is a medicated preparation made with the ingredients in the Formulation composition given below with Gh¨ta as the basic ingredient.

Formulation Composition:

1.	Dā²ima API	*Punica granatum*	Dr. Sd.	192 g
2.	Dhānya (Dhānyaka API)	*Coriandrum sativam*	Fr.	96 g
3.	Citraka API	*Plumbago zeylanica*	Rt.	48 g
4.	Ś¨¬gavera (Śu´°hī API)	*Zingiber officinale*	Rz.	48 g
5.	Pippalī API	*Piper nigrum*	Fr.	24 g
6.	Gh¨ta (Go gh¨ta API)	Clarified butter from cow's milk		960 g
7.	Jala API	Water		3.072 l

Method of Preparation:

Take all ingredients of pharmacopoeial quality.
Wash, clean, dry the ingredients numbered 2 to 5 of the formulation composition, powder separately and pass through sieve number 85 (*Kalka dravyas*).
Transfer the *Kalka dravyas* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend (*Kalka*).
Clean *Dadima* seeds and crush to prepare a paste.
Take *Gh¨ta* in a stainless steel vessel and heat mildly to remove moisture if any.
Add increments of *Kalka* and *Dadima* paste. Stir thoroughly while adding water.
Heat for 3 h with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Stop heating and allow to stand overnight.
Start the heating next day and observe the boiling mixture for subsidence of froth *(phena śānti)* and constantly check the *Kalka* for formation of *varti (madhyama pāka lak¾a´a).*
Expose the *varti* to flame and confirm the absence of crackling sound indicating absence of moisture. Stop heating when the *Kalka* forms a *varti* and the froth subsides. Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
Pack it in tightly closed glass containers to protect from light and moisture.

Description:

A green-coloured, soft, low melting medicated fat, unctuous to touch with pleasant sweetish odour and ghee like taste

Identification:

Thin layer chromatography:

Extract 25 ml of formulation with *methanol* (25 ml x 3) under reflux on a water bath, filter and concentrate the extract to 10 ml and carry out the thin layer chromatography. Apply 10 µl of the extract on TLC plate and develop the plate to a distance of 8 cm using *toluene:*

diethyl ether (1 : 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots under ultraviolet light (366 nm) at R_f 0.28 (blue), 0.35 (green), 0.48 (blue), 0.57 (violet), 0.63 (pink); and major spots at R_f 0.14 (light pink); 0.37 (grey), 0.48 (blue), 0.50 (violet), 0.63 (purple) in visible light.

Physicochemical parameters:

Refractive index at 40^0:	1.470 to1.468,	Appendix -3.1
Specific gravity at 40^0:	0.959-0.969,	Appendix -3.1.
Acid value:	Not more than 0.9,	Appendix -3.12
Saponification value:	236 to 242,	Appendix - 3.10
Iodine value:	69 to 70,	Appendix -3.11
Peroxide value:	Not more than 6.5,	Appendix - 3.13
Congealing point:	28^0 to18^0,	Appendix - 3.4.2

Other requirements:

Mineral oil:	Absent,	Appendix -3.15
Microbial limits:		Appendix -2.4
Aflatoxins:		Appendix- 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Pā´²u (anemia); Gulma (abdominal lump); Plīharoga (splenic disease); H¨droga (heart disease); Arśa (piles); Pari´āma śūla (duodenal ulcer); Garbhi´ī roga (diseases during pregnancy); Vātakapha roga (disease due to Vāta do¾a and Kapha do¾a); Agnimāndya (digestive impairment); Śvāsa (asthma); Kāsa (cough); Mū²havāta (obstructed movement of Vāta do¾a); Vandhyatva (infertility); Du^{a}kha prasava (difficult labour).

Dose: 6 to 12 gm twice a day

Anupāna: Warm water

DĀ±IMĀDI GH§TA -B

(AFI, Part-I, 87, 6:19)

Definition:

Dā²imādi gh¨ta is a medicated preparation made with the ingredients in the Formulation composition given below, with Mūrcchita Gh¨ta as the basic ingredient.

Formulation Composition:

1.	Dā²ima API	*Punica granatum*	Dr. Sd.	192 g
2.	Dhānya (Dhānyaka API)	*Coriandrum sativam*	Fr.	96 g
3.	Citraka API	*Plumabago zeylanica*	Rt.	48 g
4.	Ś¨¬gavera (Śu´ºhī API)	*Zingiber officinale*	Rz.	48 g
5.	Pippalī API	*Piper longum*	Fr.	24 g
6.	Mūrcchita Gh¨ta (Gogh¨ta API)	Clarified butter from Cow's milk		960 g
7.	Jala API	Water		3.072 l

Method of Preparation:

Take all ingredients of pharmacopoeial quality.
Treat Gh¨ta to prepare *Mūrcchita Gh¨ta* (Appendix 6.2.8.2)
Wash, clean, dry the ingredients numbered 2 to 5 of the formulation composition powder separately and pass through sieve number 85 (*Kalka dravyas*).
Transfer the *Kalka dravyas* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend (*Kalka*).
Clean *Dadima* seeds and crush to prepare a paste.
Take Gh¨ta in a stainless steel vessel and heat mildly.
Add increments of *Kalka* and *Dadima* paste. Stir thoroughly while adding water.
Heat for 3 h with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Stop heating and allow to stand overnight.
Start the heating next day and observe the boiling mixture for subsidence of froth *(phena śānti)* and constantly check the *Kalka* for formation of *varti (madhyama pāka lak¾a´a).*
Expose the *varti* to flame and confirm the absence of crackling sound indicating absence of moisture. Stop heating when the *Kalka* forms a *varti* and the froth subsides. Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
Pack it in tightly closed glass containers to protect from light and moisture.

Description:

A green-coloured, soft, low melting medicated fat, unctuous to touch with pleasant sweetish odour and bitter taste

Identification:

Thin layer chromatography:

Extract 25 ml of formulation with 25 ml *methanol* under reflux on a water bath, filter and concentrate the extract to 10 ml and carry out the thin layer chromatography.
Apply 10 µl of the extract on a TLC plate and develop the plate to a distance of 8 cm using *toluene: diethyl ether* (1 : 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0

for about 10 min. It shows major spots at R_f 0.33 (yellow), 0.50 (blue), 0.61 (pink), 0.74 (pink), 0.78 (pink) and 0.88 (pink) under ultraviolet light (366 nm); and major spots at R_f 0.35 (brown), 0.51 (violet), 0.63 (purple) and 0.7 (yellow) in visible light.

Physicochemical parameters:

Refractive index at 40^0:	1.468 to 1.470,	Appendix 3.1
Specific gravity at 40^0:	0.955 to 0.969,	Appendix 3.1
Acid value:	Not more than 0.33,	Appendix 3.12
Saponification value:	236 to 242,	Appendix 3.10
Iodine value:	70 to 90,	Appendix 3.11
Peroxide value:	Not more than 6.5,	Appendix 3.13
Congealing point:	28^0 to18^0,	Appendix 3.4.2

Other requirements:

Mineral oil:	Absent,	Appendix 3.15
Microbial limits:		Appendix 2.4
Aflatoxins:		Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Pā´²u (anemia); Gulma (abdominal lump); Plīhāroga (splenic disease); H¨droga (heart disease); Arśa (piles); Pari´āma śūla (duodenal ulcer); Garbhinī roga (disease during pregnancy); Vātakapha roga (disease due to Vāta Do¾a and Kapha do¾a); Agnimāndya (digestive impairment); Śvāsa (asthma); Kāsa (cough); Mū²havāta (obstructed movment of Vāta do¾a); Vandhyatva (infertility); Du^{a}kha prasava (difficult labour).

Dose: 6 to 12 gm twice a day

Anupāna: warm water.

INDUKĀNTA GH§TA - A

(AFI, Part-I, 6 : 5)

Definition:

Indukānta gh¨ta is a medicated preparation made with the ingredients in Formulation composition given below, with Gh¨ta as basic ingredient.

Formulation Composition:

1.	Pūtīka (Cirabilva API)	*Holoptelea integrifolia*	St. Bk.	256 g
2.	Dāru (Devadāru API)	*Cedrus deodara*	Ht. Wd.	256 g
3.	Bilva API	*Aegle marmelos*	St. Bk.	25.6 g
4.	Agnimantha API	*Premna integrifolia*	St. Bk.	25.6 g
5.	Śyonāka API	*Oroxylum indicum*	St. Bk.	25.6 g
6.	Gambhārī API	*Gmelina arborea*	St. Bk.	25.6 g
7.	Pā°alā API	*Stereospermum suveolance*	St. Bk.	25.6 g
8.	Śālapar´ī API	*Desmodium gangeticum*	Pl.	25.6 g
9.	P¨¾nipar´ī API	*Uraria picta*	Pl.	25.6 g
10.	B¨hatī API	*Solanum indicum*	Pl.	25.6 g
11.	Ka´°akārī API	*Solanum xanthocarpum*	Pl.	25.6 g
12.	Gok¾ura API	*Tribulus terrestris*	Pl.	25.6 g
13.	Jala for decoction reduced to	Water		12.288 l 3.072 l
14.	K¾īra API (Go dugdha)	Cow milk		768 ml
15.	Gh¨ta API (Go gh¨ta)	Clarified butter from Cow's milk		768 g
16.	Pippalī API	*Piper longum*	Fr.	48 g
17.	Pippalīmula (Pippalī API)	*Piper longum*	Rt.	48 g
18.	Cavya API	*Piper chaba*	St.	48 g
19.	Citraka API	*Plumbago zeylanica*	Rt.	48 g
20.	Śu´°hī API	*Zingiber officinale*	Rz.	48 g
21.	Yava k¾āra API (Yava)	*Hordeum vulgare*	Water soluble ash of Pl.	48 g

Method of Preparation:

Take all ingredients of pharmacopoeial quality.

Wash, clean and dry the ingredients numbered 1 to 12 of the formulation composition, powder separately and pass through sieve number 44 *(Kvātha dravya)*.

Wash, clean, dry the ingredients numbered 16 to 21 of the formulation composition, powder separately and pass through sieve number 85 (*Kalka dravyas*).

Add water for decoction to the *Kvātha dravyas* and soak for four hours, heat and reduce the volume to one-fourth. Filter with *muslin cloth* to obtain *Kvātha*.

Transfer the *Kalka dravyas* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend.

Take *Gh¨ta* in a stainless steel vessel and heat mildly to remove moisture if any.

Add increments of *Kalka*. Stir thoroughly while adding *Kvātha* and *Godugdha*.

Heat for 3 h with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Stop heating and allow to stand overnight.
Start the heating next day and observe the boiling mixture for subsidence of froth *(phena śānti)* and constantly check the *Kalka* for formation of *varti (madhyama pāka lak¾a´a).*
Expose the *varti* to flame and confirm the absence of crackling sound indicating absence of moisture. Stop heating when the *Kalka* forms a *varti* and the froth subsides. Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
Pack it in tightly closed glass containers to protect from light and moisture.

Description:

A green-coloured, soft, low melting medicated fat, unctuous to touch with bitter odour and slightly bitter taste

Identification:

Thin layer chromatography:

Extract 25 ml of formulation with 25 ml *methanol* under reflux on a water bath, filter and concentrate the extract to 10 ml and carry out the thin layer chromatography.
Apply 10 µl of the extract on TLC plate and develop the plate to a distance of 8 cm using *toluene: diethyl ether* (1 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light. It shows major spots at R_f 0.11, 0.44, 0.52 under 254 nm; and fluorescent spots at R_f 0.11 (pink), 0.16, 0.18, 0.24, 0.30, 0.39, 0.48 and 0.65 (all blue) under 366 nm. Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.12, 0.20 (both grey); 0.23 (blue), 0.30 (green), 0.37, 0.45, 0.53, 0.65 and 0.71 (all blue) under ultraviolet light (366 nm); and major spots at R_f 0.12 (purple), 0.20 (yellow), 0.32, 0.38, 0.53, 0.65 (all blue) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.469 to1.473,	Appendix 3.1
Specific gravity at 40^0:	0.957 to 0.962,	Appendix 3.1.
Acid value:	Not more than 1.53,	Appendix 3.12
Saponification value:	229 to 231,	Appendix 3.10
Iodine value:	85 to 90,	Appendix 3.11
Peroxide value:	Not more than 11.0,	Appendix 3.13
Congealing point:	28^0 to18^0,	Appendix 3.4.2

Other requirements:

Mineral oil:	Absent,	Appendix 3.15
Microbial limits:		Appendix 2.4
Aflatoxins:		Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Śūla (pain/colic); Gulma (abdominal lump); Udara (disease of abdomen); Vi¾amajvara (intermittent fever); Vātaroga (disease due to vāta do¾a); K¾aya (pthisis); Daurbalya (weakness).

Dose: 6 to 12 gm twice a day

Anupūna: warm milk, warm water, Gu²ūcī svarasa.

INDUKĀNTA GH§TA -B

(AFI, Part-I, 6:5)

Definition:

Indukānta gh¨ta is a medicated preparation made with the ingredients in Formulation composition given below, with Mūrcchita Gh¨ta as the main basic ingredient.

Formulation Composition:

1.	Pūtīka (Cirabilva API)	*Holoptelea integrifolia*	St. Bk.	256 g
2.	Dāru (Devadāru API)	*Cedrus deodara*	Ht. Wd.	256 g
3.	Bilva API	*Aegle marmelos*	St. Bk.	25.6 g
4.	Agnimantha API	*Premna integrifolia*	St. Bk.	25.6 g
5.	Śyonāka API	*Oroxylum indicum*	St. Bk.	25.6 g
6.	Gambhārī API	*Gmelina arborea*	St. Bk.	25.6 g
7.	Pā°alā API	*Stereospermum suaveolance*	St. Bk.	25.6 g
8.	Śālapar´ī API	*Desmodium gangeticum*	Pl.	25.6 g
9.	P¨śnipar´ī API	*Uraria picta*	Pl.	25.6 g
10.	B¨hatī API	*Solanum indicum*	Pl.	25.6 g
11.	Ka´°akārī API	*Solanum xanthocarpum*	Pl.	25.6 g
12.	Gok¾ura API	*Tribulus terrestris*	Pl.	25.6 g
13.	Jala for decoction reduce to	Water		12.288 l 3.072 l
14.	K¾īra (Go dugdha API)	Cow's milk		768 ml
15.	Gh¨ta (Go gh¨ta API)	Clarified butter from Cow's milk		768 g
16.	Pippalī API	*Piper longum*	Fr.	48 g
17.	Pippalī mūla (Pippalī API)	*Piper longum*	Rt.	48 g
18.	Cavya API	*Piper chaba*	St.	48 g
19.	Citraka API	*Plumbago zeylanica*	Rt.	48 g
20.	Śu´°hī API	*Zingiber officinale*	Rz.	48 g
21.	Yava ksāra (Yava API)	*Hordeum vulgare*	Water soluble ash of Pl.	48 g

Method of Preparation:

Take all ingredients of pharmacopoeial quality.
Treat *Gh¨ta* to prepare *Mūrcchita Gh¨ta* (Appendix 6.2.8.2).
Wash, clean and dry the ingredients numbered 1 to 12 of the formulation composition, powder separately and pass through sieve number 44 *(Kvātha dravya).*
Wash, clean, dry the ingredients numbered 16 to 21 of the formulation composition powder separately and pass through sieve number 85 (*Kalka dravyas*).

Add water for decoction to the *Kvātha dravyas* and soak for four hours, heat and reduce the volume to one-fourth. Filter with *muslin cloth* to obtain *Kvātha*.
Transfer the *Kalka dravyas* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend.
Take *Gh ̈ta* in a stainless steel vessel and heat mildly.
Add increments of *Kalka*. Stir thoroughly while adding *Kvātha* and *Godugdha*.
Heat for 3 h with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Stop heating and allow to stand overnight.
Start the heating next day and observe the boiling mixture for subsidence of froth *(phena śānti)* and constantly check the *Kalka* for formation of *varti (madhyama pāka lak¾a ´a).*
Expose the *varti* to flame and confirm the absence of crackling sound indicating absence of moisture. Stop heating when the *Kalka* forms a *varti* and the froth subsides. Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
Pack it in tightly closed glass containers to protect from light and moisture.

Description:

A green-coloured, soft, low melting medicated fat, unctuous to touch, slightly pungent odour and slightly bitter taste

Identification:

Thin layer chromatography:

Extract 25 ml of formulatin with 25 ml *methanol* under reflux on a water bath, filter and concentrate the extract to 10 ml and carry out the thin layer chromatography. Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: diethyl ether* (1 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light. It shows major spots at R_f 0.11, 0.22, 0.24, 0.34, 0.39, 0.54, 0.88 under 254 nm; and fluorescent spots at R_f 0.11 (brown), 0.16, 0.24 (both blue), 0.35 (yellow), 0.48 and 0.65 (both blue) under 366 nm. Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.12, 0.20 (both grey), 0.23 (blue), 0.30 (green), 0.37, 0.45, 0.53, 0.65, 0.71 (all blue) and 0.88 (brown) under ultraviolet light (366 nm); and major spots at R_f 0.12 (purple); 0.20 (yellow), 0.32 (brown), 0.38, 0.53, 0.65 (all blue) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.468 to 1.473,	Appendix 3.1
Specific gravity at 40^0:	0.952 to 0.962,	Appendix 3.1.
Acid value:	Not more than 1.44,	Appendix 3.12
Saponification value:	229 to 231,	Appendix 3.10
Iodine value:	85 to 92,	Appendix 3.11
Peroxide value:	Not more than 11.0,	Appendix 3.13
Congealing point:	28^0 to18^0,	Appendix 3.4.2

Other requirements:

Mineral oil:	Absent,	Appendix 3.15
Microbial limits:		Appendix 2.4
Aflatoxins:		Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Śūla (pain/colic); Gulma (abdominal lump); Udara (disease of abdomen); Vi¾amajvara (intermittent fever); Vātaroga (disease due to vāta do¾a); K¾aya (pthisis); Daurbalya (weakness).

Dose: 6 to 12 gm twice a day

Anupāna: warm milk, warm water, Gu²ūcī svarasa

MAHĀ TRIPHALĀDYA GHṚTA

(AFI, Part- I, 6:35)

Definition:

Ś¨¬gavera

Mahā Triphalādya ghṛta is a medicated semisolid preparation made with the ingredients in the Formulation composition given below, with Gh¨ta as the basic ingredient.

Formulation composition:

1.	Triphalārasa (Triphalā API)-kvātha	*Terminalia belerica* *Terminalia chebula* *Emblica officinalis*	P. P. P.	768 ml
2.	Bh¨¬ga rasa (Bh¨¬garāja API)	*Eclipta alba*	Pl.	768 ml
3.	V¨¾a rasa (Vāsā API)	*Adhatoda vasica*	Lf.	768 ml
4.	Śatāvarī rasa (Śatāvarī API)	*Asparagus racemosus*	Rt. Tr.	768 ml
5.	Ajā k¾īra	Goat Milk		768 ml
6.	Gu²ūcī rasa (Guḍūcī API)	*Tinospora cordifolia*	St.	768 ml
7.	Āmalakī API rasa	*Emblica officinalis*	P.	768 ml
8.	Ka´ā (Pippalī API)	*Piper longum*	Fr.	8.72 g
9.	Sitā API	Sugar candy		8.72 g
10.	Drāk¾ā API	*Vitis vinifera*	Dr. Fr.	8.72 g
11.	Harītakī API	*Terminalia chebula*	P.	8.72 g
12.	Bibhītaka API	*Terminalia belerica*	P.	8.72 g
13.	Āmalakī API	*Emblica officinalis*	P.	8.72 g
14.	Nīlotpala (Utpala API)	*Nymphaea stellata*	Fl.	8.72 g
15.	Madhuka (Ya¾ṭī API)	*Glycyrrhiza glabra*	Rt.	8.72 g
16.	K¾īra kākolī API	*Fritillaria roylei*	Sub. Rt.	8.72 g
17.	Madhupar´ī (Gu²ūcī API)	*Tinospora cordifolia*	St.	8.72 g
18.	Nidigdhikā (Ka´°akārī API)	*Solanum xanthocarpum*	Pl.	8.72 g
19.	Gh¨ta (Gogh¨ta API)	Clarified butter from Cow's milk		768 g

Method of preparation:

Take all ingredients of pharmacopoeial quality.

Take fresh *Bh¨¬garāja, Śatāvarī, Guḍūcī* and *Āmalakī* and wash thoroughly with water. Grind and filter with *muslin cloth* to obtain *svarasa*.

Take fresh *Vāsā* leaves and obtain juice by *pu°apāka* method (Appendix 6.1.4.)

Soak the coarse *Triphalā* powder in potable water in the specified ratio for overnight, boil it till the volume is reduced to one fourth of its original volume, cool the *Kvātha* and filtere through muslin cloth. (Appendix 6.1.2.)

Treat *Ghṛta* to prepare *Mūrcchita Ghṛta* (Appendix 6.2.8.2.).

Wash, dry the ingredients number 8 to 18 of the formulation composition, powder separately and pass through sieve number 85. Transfer the powdered ingredients to the wet grinder and grind with sufficient quantity of water to prepare a homogenous blend (*Kalka dravya*).

Take *Mūrcchita Ghṛta* in a stainless steel vessel and heat to make it moisture free.
Add increments of *Kalka*, stir thoroughly while adding *Triphalā Kvātha*, *Bh¨¬garāja, Śatāvarī, Guḍūcī, Āmalakī* and *Vāsā Svarasa* in the specified ratio.
Heat with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Stop heating and allow to stand overnight.
Start the heating next day and observe the boiling mixture for subsidence of froth (*phena śānti*) and constantly check the *Kalka* for the formation of *varti* (*madhyama pāka lak¾a´a*).
Expose the *Gh¨ta* and *varti* to flame and confirm the absence of crackling sound indicating absence of moisture.
Stop heating when the *Kalka* forms a *varti* and the froth subsides.
Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
Pack it in tightly closed glass containers to protect from light and moisture.

Description*:*

A low melting *Ghṛta*, greenish cream in colour, unctuous to touch, no specific odour and taste bitter

Identification:

Thin layer chromatography:

Extract 5 g of the formulation with 25 ml n-*hexane* under reflux on a water bath for 30 min, filter and concentrate the extracts to 10 ml and carry out the thin-layer chromatography. Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using n-*hexane: ethyl acetate* (8.5 : 1.5) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.31 (purple), 0.34 (pink), 0.41, 0.65 (both blue), 0.78 (greyish blue) and 0.92 (blue) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4531 to 1.4534,	Appendix 3.1
Saponification value:	0.2100 to 0.2147,	Appendix 3.10
Acid value:	Not more than 2.9,	Appendix 3.12
Peroxide value:	Not more than 15.8,	Appendix 3.13

Other requirements:

Mineral oil:	Absent,	Appendix 3.15
Microbial Limits:		Appendix 2.4
Aflatoxins:		Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Naktāndhya (night blindness); Timira (cataract); Kāca (cataract); Nīlikā (mole); Pa°ala Arbuda (growth in the layers of eyes); Netrābhi¾yanda (conjunctivitis); Adhimantha (glaucoma); Pak¾makopa (trichiasis/entropion); Netraroga (disease of eyes); Ad¨¾°i (blindness); Mandadr¾°¡i (diminished vision); Netrasrāva (chronic

dacrocystitis/epiphora); Netraka´²ū (itching in eyes); Dūrad¨¾i (hypermetropia); Samīpa d¨¾i (myopia).

Dose: 6 to 12 gm twice a day

Anupāna: Warm milk, warm water.

TIKTAKA GHṚTA -A

(AFI, Part I, 6:13)

Definition:

Tiktaka Gh¨ta is a gh¨ta prepation made with the ingredients in the Formulation composition given below with Gh¨ta as the basic ingredient.

Formulation Composition:

1.	Pa°ola API	*Tricosanthes dioica*	Pl.	48 g
2.	Nimba API	*Azadirachta indica*	St. Bk.	48 g
3.	Ka°ukā API	*Picrorhiza kurroa*		48 g
4.	Dārvī (Dāruharidrā API)	*Berberis aristata*	St.	48 g
5.	Pā°hā API	*Cissampelos pareira*	Rt.	48 g
6.	Durālabhā (Dhanvayāsa API)	*Fagonia cretica*	Pl.	48 g
7.	Parpa°a API	*Fumaria parviflora*	Pl.	48 g
8.	Trāyamā´ā API	*Gentiana kurroo*	Pl.	48 g
9.	Jala for decoction reduced to	Water		6.144 l 768 ml
10.	Trāyantī (Trāyamā´ā API)	*Gentiana kurroo*	Pl.	12 g
11.	Musta (Mustā API)	*Cyperus rotundus*	Rz.	12 g
12.	Bhūnimba (Kirātatikta API)	*Swerita chirata*	Pl.	12 g
13.	Kali¬ga (Indrayava API)	*Holarrhena antidysenterica*	Sd.	12 g
14.	Ka´ā (Pippalī API)	*Piper longum*	Fr.	12 g
15.	Candana (Śveta candana API)	*Santalum album*	Ht. Wd.	12 g
16.	Sarpi (Go gh¨ta)	Clarified butter from Cow's milk		576 g

Method of Preparation:

Take all ingredients of pharmacopoeial quality.
Wash, clean and dry the ingredients numbered 1 to 8 of the formulation composition, powder separately and pass through sieve number 44 *(Kvātha dravyas).*
Wash, clean, dry the ingredients numbered 10 to 15 of the formulation composition powder separately and pass through sieve number 85 (*Kalka dravyas*).
Add water for decoction to the *Kvātha dravyas* and soak for four hours, heat and reduce the volume to one-eighth. Filter with *muslin cloth* to obtain *Kvātha*.
Transfer the *Kalka dravyas* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend.
Take *Gh¨ta* in a stainless steel vessel and heat mildly to remove moisture if any.
Add increments of *Kalka*. Stir thoroughly while adding *Kvātha*.
Heat for 3 h with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Stop heating and allow to stand overnight.
Start the heating next day and observe the boiling mixture for subsidence of froth *(phena śānti)* and constantly check the *Kalka* for formation of *varti (madhyama pāka lak¾a´a).*

Expose the *varti* to flame and confirm the absence of crackling sound indicating absence of moisture. Stop heating when the *Kalka* forms a *varti* and the froth subsides. Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
Pack it in tightly closed glass container to protect from light and moisture.

Description:

A light green-coloured, soft, low melting medicated fat, unctuous to touch with specific odour and bitter taste

Identification:

Thin layer chromatography:

Extract 25 ml of formulation with 25 ml *methanol* under reflux on a water bath, filter and concentrate the extract to 10 ml and carry out the thin layer chromatography.
Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: diethyl ether* (1 : 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.11 (purple), 0.30 (green), 0.38, 0.50 (both blue), 0.65 (pink) and 0.73 (purple) under ultraviolet light (366 nm); and major spots at R_f 0.11 (purple), 0.23 (bluish grey), 0.29 (blue), 0.50 (violet) and 0.66 (purple) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.467 to 1.468,	Appendix 3.1
Specific gravity at 40^0:	0.965 to 0.968,	Appendix 3.1.
Acid value:	Not more than 1.9,	Appendix 3.12
Saponification value:	240 to 255,	Appendix 3.10
Iodine value:	85 to100,	Appendix 3.11
Peroxide value:	Not more than 6.5	Appendix 3.13
Congealing point:	28^0 to18^0,	Appendix 3.4.2

Other requirements:

Mineral oil:	Absent,	Appendix - 3.15
Microbial limits:		Appendix - 2.4
Aflatoxins:		Appendix - 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: T¨¾´ā (thirst); Bhrama (vertigo); Dāha (burning sensation); Parīsarpa (erysipelas); Pi²akā (carbuncle); Pittaja ku¾ºha (diseases of skine due to pitta do¾a); Ka´²u (itching); Pā´²uroga (anemia); Ga´²a (cervical lymphadenitis); Nā²īvra´a (sinus); Apacī (chronic lymphadenopathy/scrofula); Visphota (blisterous erupation); Vidradhi (abscess); Gulma (abdominal lump); Śopha (oedema); Unmāda (mania/psychosis); Meda (adipose tissue); H¨droga (heart disease); Timira (cataract); Vya¬ga (dark shade on face due to

stress and excessive exercise/localized hyper pigmentation of skin); Grahaˊī (malabsorption syndrome); Śvitra (leucoderma/Vitiligo); Kāmalā (jaundice); Bhagandara (fistula-in-ano); Udara (diseases of abdomen); Apasmāra (epilepsy); Pradara (excessive vaginal discharge); Gara (slow/accumulated poison); Arśa (piles); Raktapitta (bleeding disorder).

Dose: 6 to 12 gm twice a day

Anupāna: warm water

TIKTAKA GHṚTA - B

(AFI, Part I, 6:13)

Definition:

Tiktaka Gh¨ta is a gh¨ta preparation made with the ingredients in the Formulation composition given below with Mūrchit Gh¨ta as the basic ingredient.

Formulation Composition:

1.	Paᵒola API	*Tricosanthes dioica*	Pl.	48 g
2.	Nimba API	*Azadirachta indica*	St. Bk.	48 g
3.	Kaᵒukā API	*Picrorhiza kurroa*	Rz.	48 g
4.	Dārvī (Dāruharidrā API)	*Berberis aristata*	St.	48 g
5.	Pāᵒhā API	*Cissampelos pareira*	Rt.	48 g
6.	Durālabhā (Dhanvayāsa API)	*Fagonia cretica*	Pl.	48 g
7.	Parpaᵒa API	*Fumaria parviflora*	Pl.	48 g
8.	Trāyamā´ā API	*Gentiana kurroo*	Pl.	48 g
9.	Jala for decoction reduced to	Water		6.144 l 768 ml
10.	Trāyantī (Trāyamā´ā API)	*Gentiana kurroo*	Pl.	12 g
11.	Musta (Mustā API)	*Cyperus rotundus*	Rz.	12 g
12.	Bhūnimba (Kirātatiktā API)	*Swerita chirata*	Pl.	12 g
13.	Kali¬ga (Indrayava API)	*Holarrhena antidysenterica*	Sd.	12 g
14.	Ka´ā (Pippalī API)	*Piper longum*	Fr.	12 g
15.	Candana (Śveta candana API)	*Santalum album*	Ht. Wd.	12 g
16.	Sarpi Mūrchit (Go ghṛta)	Clarified butter from cow's milk		576 g

Method of Preparation:

Take all ingredients of pharmacopoeial quality.
Treat *Gh¨ta* to prepare *Mūrcchita Gh¨ta* (Appendix 6.2.8.2).
Wash, clean and dry the ingredients numbered 1 to 8 of the formulation composition, powder separately and pass through sieve number 44 *(Kvātha dravya).*
Wash, clean, dry the ingredients numbered 10 to 15 of the formulation composition, powder separately and pass through sieve number 85 (*Kalka dravyas*).
Add water for decoction to the *Kvātha dravyas* and soak for four hours, heat and reduce the volume to one-eighth. Filter with *muslin cloth* to obtain *Kvātha*.
Transfer the *Kalka dravyas* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend.
Take *Gh¨ta* in a stainless steel vessel and heat mildly.
Add increments of *Kalka*. Stir thoroughly while adding *Kvātha*.
Heat for 3 h with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Stop heating and allow to stand overnight.

Start the heating next day and observe the boiling mixture for subsidence of froth *(phena śānti)* and constantly check the *Kalka* for formation of *varti (madhyama pāka lak¾a ´a).* Expose the *varti* to flame and confirm the absence of crackling sound indicating absence of moisture. Stop heating when the *Kalka* forms a *varti* and the froth subsides. Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
Pack it in tightly closed glass containers to protect from light and moisture.

Description:

A dark green-coloured, soft, low melting medicated fat, unctuous to touch with slightly characteristic odour and bitter taste

Identification:

Thin layer chromatography:

Extract 25 ml of formulation with 25 ml *methanol* under reflux on a water bath, filter and concentrate the extracts to 10 ml and carry out the thin layer chromatography.
Apply 10 µl of the extract on TLC plate and develop the plate to a distance of 8 cm using *toluene: diethyl ether* (1 : 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.11 (purple), 0.35 (yellow), 0.48 (blue), 0.64 (pink), 0.73 (purple), 0.77 (pink) under ultraviolet light (366 nm); and major spots at R_f 0.10, 0.37 (both blue), 0.50 (violet), 0.65, 0.76 (both purple) and 0.89 (yellow) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.467 to1.470,	Appendix 3.1
Specific gravity at 40^0:	0.961 to 0.968,	Appendix 3.1.
Acid value:	Not more than 0.56,	Appendix 3.12
Saponification value:	230 to 232,	Appendix 3.10
Iodine value:	86 to 100,	Appendix 3.11
Peroxide value:	Not more than 2.2,	Appendix 3.13
Congealing point:	28^0 to18^0,	Appendix 3.4.2

Other requirements:

Mineral oil:	Absent,	Appendix - 3.15
Microbial limits:		Appendix - 2.4
Aflatoxins:		Appendix - 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: T¨¾´ā (thirst); Bhrama (vertigo); Dāha (burning sensation); Parīsarpa (erysipelas); Pi²akā (carbuncle); Pittaja ku¾°ha (diseases of skine due to pitta do¾a); Ka´²¦ (itching); Pā´²uroga (anemia); Ga´²a (cervical lymphadenitis); Nā²i vra´a (sinus); Apacī (chronic lymphadenopathy/scrofula); Vispho°a (blisterous erupation); Vidradhi (abscess); Gulma (abdominal lump); Śopha (oedema); Unmāda (mania/ psychosis); Meda (adipose tissue); H¨droga (heart disease); Timira (cataract); Vya¬ga (dark shade on face due to stress and excessive exercise/localized hyper pigmentation of skin); Graha´ī (malabsorption syndrome); Śvitra (leucoderma/vitiligo); Kāmalā (jaundice); Bhagandara (fistula-in-ano); Udara (diseases of abdomen); Apasmāra (epilepsy); Pradara (excessive vaginal discharge); Gara (slow/accumulated poison); Arśa (piles); Raktapitta (bleeding disorder).

Dose: 6 to 12 gm twice a day

Anupāna: Warm water

GUGGULU

General Description:

Guggulu is an oleoresin *(Niryāsa)* obtained from the plant *Commiphora wightii.* Preparations having the exudates as main effective ingredient are known as *Guggulu*. There are five different varieties of *Guggulu* described in the Ayurvedic texts. However two of the varieties, namely, *Mahi¾āk¾a* and *Kanaka Guggulu* are usually preferred for medicinal preparations. *Mahi¾āk¾a Guggulu* is dark greenish brown and *Kanaka Guggulu* is yellowish brown in color.

Before using, *Guggulu* is cleaned in the following manner:

1. Sand, stone, plant debris, glass etc. are first removed.
2. It is then broken into small pieces.
3. It is thereafter bundled in a piece of cloth and boiled in *Dola Yantra* containing any one of the following fluids.
    a. *Gomūtra*,
    b. *Triphalā ka¾āya,*
    c. *Nirgu´²ipatra Svarasa* with *Haridrā Cūr´a*,
    d. *Vāsāpatra Ka¾āya,*
    e. *Vāsāpatra Svarasa* and
    f. *Dugdha*.

The boiling of *Guggulu* in *Dolā Yantra* is carried on until all the *Guggulu* passes into the fluid through the cloth. By pressing with fingers, much of the fluid that can pass through is taken out. The residue in the bundle is discarded. The fluid is filtered and again boiled till it forms a mass. This mass is dried and then pounded with a pestle in a stone mortar, adding ghee in small quantities till it becomes waxy.

Guggulu cleaned as above, is soft, waxy and brown in color. Characteristics of preparations of *Guggulu* vary depending on the other ingredients added to the preparations.

Guggulu is kept in glass or porcelain jars free from moisture and stored in a cool place. The potency is maintained for two years when prepared with ingredients of plant origin and indefinitely when prepared with metals and minerals.

Note: *Guggulu* formulations can also be prepared in a tablet dosage form, without the use of excipients, but they should comply the general tests for tablets.

GOK½URĀDI GUGGULU

(AFI, Part-I, 5:3)

Definition:

Gok¾urādi Guggulu va°ī is a preparation made with the ingredients in the Formulation composition given below with *Guggulu* as the basic ingredient.

Formulation composition:

1.	Gok¾ura API	*Tribulus terrestris*	Fr.	1.344 kg
2.	Jala for decoction	Water		8.064 l
	reduced to			4.032 l
3.	Guggulu API - Śuddha	*Commiphora wightii*	O.R.	336 g
4.	Śu´°hī API	*Zingiber officinale*	Rz.	48 g
5.	Marica API	*Piper nigrum*	Fr.	48 g
6.	Pippalī API	*Piper longum*	Fr.	48 g
7.	Harītakī API	*Terminalia chebula*	P.	48 g
8.	Bibhītaka API	*Terminalia belerica*	P.	48 g
9.	Āmalakī API	*Emblica officinalis*	P.	48 g
10.	Mustā API	*Cyperus rotundus*	Rz.	48 g

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.

Wash, dry and powder the ingredients number 4 to 10 of the formulation composition separately and pass through sieve number 85, weigh them separately in the required quantities and mix.

Crush weighed quantity of *Guggulu- Śuddha.*

Wash, dry and powder the *Gok¾ura* and pass through sieve number 40. Soak the coarse powder of *Gok¾ura* in 8 times of potable water for 12 h. Gently heat the mixture to boil and continue the boiling to reduce the volume of the mixture to half of its original volume.

Stop the boiling and filter while still warm through a *muslin cloth*.

Boil the filtrate (*Kvātha*) in an iron vessel. Add *Śuddha Guggulu* to *Kvātha* and concentrate to *Gu²apāka* (semi-solid) condition.

Add fine powder of mixed ingredients with continuous stirring. Pound the mixture to a semi-solid uniformly mixed mass of suitable plasticity. Use *Gh¨ta* for smooth pounding.

Expel the pounded mass through *va¢ī* machine fitted with a suitable die and cut the *va¢īs* to a desired weight.

Roll the *va¢īs* on flat surface to round them by circular motion of palm covered with a glove and smeared with *Gh¨ta* or use suitable mechanical device.

Dry the rounded *va¢īs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.

Pack it in tightly closed containers to protect from light and moisture.

Description:

Spherical pills, black in colour with pleasant odour and bitter taste.

Identification:

Microscopy:

Take about 5 g of the sample, powder it and add n-*hexane* (20 ml) stir for 10 min thoroughly over a water-bath; pour out n-*hexane*. Repeat the process thrice adding fresh quantities of n-*hexane*; discard n-*hexane* washings. Wash thoroughly the sediment in hot water. Take a few mg of washed material, stain with *iodine solution* and mount in 50 per cent *glycerine*. Clarify a few mg with *chloral hydrate* and mount in 50 per cent *glycerine*. Observe the following characters in different mounts.

Fragments of testa in surface view showing thick-walled cells with beaded walls and striations, prismatic crystals of calcium oxalate (**Gok¼ura**); oval to elliptical, crescent-shaped, simple or 2 to 3 compound starch grains with distinct hilum **(Śu´ºhī**); fragment of thick-walled epicarp cells in surface view several with beaded walls, and thin cross walls, long fibres with blunt or pegged tips (**Harītakī**); simple, unicellular or bicellular trichomes with a swollen basal cell (**Bibhītaka**); fragments of parenchyma cells with corner thickenings, minute rosette crystals of calcium oxalate **(Āmalakī**); dagger or spindle shaped stone cells with wide lumen associated with annular vessels (**Pippalī**); iso diametric or square thick walled stone cells from testa, and hypodermis tissue with group of stone cells among parenchyma **(Marica)**; fibre sclerids from scale leaves in packed rows **(Musta)**; Abundant stone cells of various shapes and sizes and abundant perisperm cells and minute starch grains in general.

Thin layer chromatography:

Extract 5 g of formulation powder in 75 ml of n-*hexane* under reflux on a water-bath for 30 min. Filter and concentrate the extract to 25 ml and carry out the thin layer chromatography.
Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: acetone* (9 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.19, 0.37, 0.44 and 0.59 (all fluorescent blue). Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.37, 0.44 and 0.59 (all pink changing to purple) under visible light.

Physico-chemical parameters:

Loss on drying:	Not more than 15 per cent,	Appendix 2.2.10
Total ash:	Not more than 5 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 1 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 22 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 29 per cent,	Appendix 2.2.8
*p*H *(1% aqueous solution):*	4.42 to 4.79,	Appendix 3.3

Other requirements:

Microbial Limit:	Appendix-2.4
Aflatoxins:	Appendix-2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Prameha (increased frequency and turbidity of urine); Mūtrak¨cchra (dysuria); Mūtrāghata (urinary obstruction); Aśmarī (calculus); Pradara (excessive vaginal discharge); Vātarakta (gout); Vātaroga (disease due to vāta do¾a/neurological disease); Śukrado¾a (vitiation of semen).

Dose: 2 - 3 g daily in divided doses.

Anupāna: Mustā kvātha, Pā¾ā´ abheda kvātha, Uśīra kvātha.

KÃ¿CANĀRA GUGGULU
(AFI, Part-I, 5:1)

Definition:

Kã®canāra Guggulu vaºī is a preparation made with the ingredients in the Formulation composition given below with *Guggulu* as the basic ingredient.

Formulation composition:

1.	Kã®canāra API	*Bauhinia variegata*	St. Bk.	480 g
2.	Harītakī API	*Terminalia chebula*	P.	96 g
3.	Bibhītaka API	*Terminalia bellerica*	P.	96 g
4.	Āmalakī API	*Phyllanthus emblica*	P.	96 g
5.	Śu´ºhī API	*Zingiber officinale*	Rz.	48 g
6.	Marica API	*Piper nigrum*	Fr.	48 g
7.	Pippalī API	*Piper longum*	Fr.	48 g
8.	Varu´a API	*Crataeva nurvala*	St. Bk.	48 g
9.	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	12 g
10.	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	12 g
11.	Patra (Tejapatra API)	*Cinnamomum tamala*	Lf.	12 g
12.	Guggulu API - Śuddha	*Commiphora wightii*	O.R.	996 g

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.
Wash, dry and powder the ingredients number 1 to 11 of the formulation composition separately and pass through sieve number 85, weigh them separately in the required quantities and mix.
Crush weighed quantity of *Guggulu-Śuddha*, add fine powder of other mixed ingredients to it and pound well. Add *Gh¨ta* to an extent required to facilitate the pounding and continue pounding till a semi-solid uniformly mixed mass of suitable plasticity is obtained.
Expel the mass through *va˜ī* machine fitted with a suitable die and cut the *va˜īs* to a desired weight.
Roll the *va˜īs* on flat surface to round them by circular motion of palm covered with a glove and smeared with *Gh¨ta* or use suitable mechanical device.
Dry the rounded *va˜īs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
Pack it in tightly closed containers to protect from light and moisture.

Description:

Spherical pills, black or brownish-black in colour, agreeable distinct odour and bitter taste

Identification:

Thin layer chromatography:

Extract 5 g of formulation powder with 75 ml of n-*hexane* under reflux on a water-bath for 30 min. Filter and concentrate the extract to 25 ml and carry out the thin layer chromatography.

Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: acetone* (9 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light. It shows major spots at R_f 0.19, 0.37, 0.44 and 0.59 (all fluorescent blue) under 366 nm; and at R_f 0.35, 0.42 (both black) under 254 nm. Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.37, 0.44 and 0.59 (all pink changing to purple) in visible light.

Physico-chemical parameters:

Loss on drying:	Not more than 12 per cent,	Appendix 2.2.10
Total ash:	Not more than 9 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 3.5 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 22 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 23 per cent,	Appendix 2.2.8
*p*H (1% aqueous solution):	4.6 to 4.8,	Appendix 3.3

Other requirements:

Microbial Limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Gulma (abdominal lump); Ga´²amālā (cervical lymphadenitis); Apacī (chronic lymphadenopathy / scrofula); Granthi (cyst); Vra´a (ulcer); Ku¾°ha (diseases of skin); Bhagandara (fistula-in-ano); Ślīpada (filariasis).

Dose: 2-3 g daily in divided doses.

Anupāna: Mu´²ī kvātha, Khadirasāra kvātha, Harītakī kvātha, Hot water.

LĀK½Ā GUGGULU
(AFI, Part-I, 5:8)

Definition:

Lāk¾ā Guggulu va°ī is a preparation made with the ingredients in the Formulation composition given below with *Guggulu* as the basic ingredient.

Formulation composition:

1.	Lāk¾ā	*Laccifer lacca*	Res. Enc.	1 Part
2.	Asthisa¼h¨t API	*Cissus quadrangularis*	St.	1 Part
3.	Kakubha (Arjuna API)	*Terminalia arjuna*	St. Bk.	1 Part
4.	Aśvagandhā API	*Withania somnifera*	Rt.	1 Part
5.	Nāgabalā API	*Sida veronicaefolia*	Ar. Pt.	1 Part
6.	Guggulu API - Śuddha	*Commiphora wightii*	O.R.	5 Parts

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.
Wash, dry and powder the ingredients number 1 to 5 of the formulation composition separately and pass through sieve number 85, weigh them separately in the required quantities and mix.
Weigh and crush *Guggulu-Śuddha.* Add equal amount of water and gently boil in an iron vessel to a thick consistency. Add fine powder of mixed ingredients with continuous stirring.
Take out the mass and pound. Use castor oil to an extent required to facilitate the pounding and continue pounding till a semi-solid uniformly mixed mass of suitable plasticity is obtained.
Expel the mass through *va ī* machine fitted with a suitable die and cut the *va īs* to a desired weight.
Roll the *va īs* on flat surface to round them by circular motion of palm covered with a glove and smeared with castor oil or use suitable mechanical device.
Dry the rounded *va īs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
Pack it in tightly closed containers to protect from light and moisture.

Description:

Spherical pills, blackish in colour with agreeable odour and bitter taste.

Identification:

Microscopy:

Take about 5 g of the sample, powder and add n-*hexane* (20 ml) stir for 10 min over a water-bath; pour out *hexane*. Repeat the process thrice adding fresh quantities of *hexane*; discard *hexane*. Wash the sediment thoroughly in hot water. Take a few mg of washed material, stain with iodine solution and mount in 50 per cent *glycerine*. Clarify another few

mg with *chloral hydrate* and mount in 50 per cent *glycerine*. Observe the following characters in different mounts.

Fragment of tissues showing idioblast containing raphids, fragments of stem epidermis in surface view with polyhedral, uniformally thick walled cells (**Asthisa¼h¨t**); large rosettes and idioblasts upto 200 µ in size with rhomboidal crystals of calcium oxalate, groups of thick-walled fibres (**Arjuna**); round, simple or 2 to 3 compound starch grains with slit like hilum (**Aśvagandhā**); fragments of stem epidermis in surface view, showing cells with rosette crystals of calcium oxalate, multicellular, stellar trichomes and broken bits of trichomes (**Nāgabalā**) and reddish-coloured crystalline particles of different shapes (**Lāk¾ā**) .

Thin layer chromatography:

Extract 5 g of formulation powder in 75 ml of n-*hexane* under reflux on a water-bath for 30 min. Filter and concentrate the extract to 25 ml and carry out the thin layer chromatography.

Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: acetone* (9 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.19, 0.37, 0.44 and 0.59 (all fluorescent blue). Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.37, 0.44 and 0.59 (all pink changing to purple) under visible light.

Physico-chemical parameters:

Loss on drying:	Not more than 12 per cent,	Appendix 2.2.10
Total ash:	Not more than 11 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 2.5 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 22 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 17.5 per cent,	Appendix 2.2.8
*p*H (1% aqueous solution):	4.71 to 5.19,	Appendix 3.3

Other requirements:

*Microbial Limit**:***	Appendix 2.4
*Aflatoxins**:***	Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Asthibha¬ga (bone fracture); Asthicyuti (improper alignment of bone); Asthirujā (ostealgia).

Dose: 2 - 3 g daily in divided doses.

Anupāna: Warm water

PA¿CĀM§TA LAUHA GUGGULU
(AFI Part-II, 5:1)

Definition:

Pa®cām¨ta lauha Guggulu vati is a brown spherical pill preparation made with the ingredients in the Formulation composition given below with *Guggulu* as the basic ingredient.

Formulation composition:

1.	Rasa(Śuddha pārada) API	Mercury		48 g
2.	Gandhaka (Śuddha) API	Sulphur		48 g
3.	Tāra (Rajata bhasma) API	Calcined rajata		48 g
4.	Abhra (Abhraka bhasma) API	Calcined abhraka		48 g
5.	Māk¾ika (Bhasma) API	Calcined m¢k¾ika		48 g
6.	Lauha (Bhasma) API	Calcined lauha		96 g
7.	Guggulu (Śuddha) API	*Commiphora wightii*	O.R.	336 g
8.	Kaॱu taila API	*Brassica campestris*	Sd. oil	Q. S.

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.
Weigh separately the ingredients numbered 2 to 6 of the formulation composition separately and pass through sieve numbered 85 in the required quantities and mix.
Prepare *Kajjalī* from *Śuddha Pārada* and *Śuddha Gandhaka*.
Crush weighed quantity of *Śuddha-Guggulu*, add fine powder of other mixed ingredients to it and pound well. Add *Kaॱu taila* to an extent required to facilitate the pounding and continue pounding till a semi-solid uniformly mixed mass of suitable plasticity is obtained.
Expel the mass through *vaॱī* machine fitted with a suitable die and cut the *vaॱīs* to a desired weight.
Roll the *vaॱīs* on flat surface to round them by circular motion of palm covered with a glove and smeared with *Kaॱu taila* or use suitable mechanical device.
Dry the rounded *vaॱīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
Pack it in tightly closed containers to protect from light and moisture.

Description:

Dark brown spherical pills with pleasant odour, sandy sensation on tongue with no characteristic taste

Identification:

Thin layer chromatography:

Extract 5 g of formulation powder with 75 ml n-*hexane* under reflux on a water bath for 30 min, filter and concentrate to 10 ml and carry out the thin-layer chromatography.

Apply 10 µl on a TLC plate. Develop the plate to a distance of 8 cm using n-*hexane: ethyl acetate* (8.5: 1.5) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.10, 0.16, 0.21, 0.38 (all fluorescent blue). Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.14 (purple), 0.22 (greyish green), 0.34 (purplish grey), 0.45 and 0.54 (both purple) in visible light.

Reflux n-*hexane* extracted material with 75 ml of *chloroform* on a water bath for 30 min, filter and concentrate to 10 ml and carry out the thin-layer chromatography.

Apply 10 µl on TLC plate. Develop the plate to a distance of 8 cm using *toluene: ethyl acetate: methanol* (9 : 1 : 1) as mobile phase. After development allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.11, 0.19, 0.24 (all blue), 0.39, 0.40 (both fluorescent blue), 0.45, 0.45, 0.49 (all faded blue), 0.56, 0.61 (both fluorescent blue). Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.14 (grayish blue), 0.17 (pink), 0.32 (purple), 0.44 (green), 0.61 (purple), 0.71 (greyish green) and 0.81 (greyish green) in visible light.

Physicochemical parameters:

Loss on drying:	Not more than 24 per cent,	Appendix 2.2.10
Total ash:	Not more than 53 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 36 per cent,	Appendix 2.2.4
Alcoholic-soluble extractive :	Not less than 12 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 17 per cent,	Appendix 2.2.8
*p*H *(1% aqueous solution):*	5.0 to 5.5,	Appendix 3.3

Other requirements:

Microbial Limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic Indications: Masti¾karoga (Brain disease); Snāyurujā (Pain in ligament); Vātaroga (Disease due to vāta do¾a).

Dose: 125 – 250 mg twice a day

Anupāna: Water and milk

PAÑCATIKTA GUGGULU GHṚTA

(A.F.I. Part- I, 6:27)

Definition:

Pañcatikta Guggulu ghṛta is semisolid preparation made with the ingredients given in the Formulation Composition given below.

Formulation Composition:

1.	Nimba tvak (Nimba) API)	*Azadirachta indica*	St. Bk.	480 g
2.	Amṛtā (Gu²ūcī API)	*Tinospora cordifolia*	St.	480 g
3.	Vṛ¾a (Vāsā API)	*Adhatoda vasica*	Rt.	480 g
4.	Paṭola API	*Trichosanthes dioica*	Lf./Pl.*	480 g
5.	Nidigdhikā (Ka´°kārī API)	*Solanum xanthocarpum*	Pl.	480 g
6.	Jala decoction reduced to	Water		12.288 l 1.5361
7.	Ghṛta API (Goghṛta API)	Clarified butter from Cow's milk		768 g
8.	Pā°hā API	*Cissampelos pareira*	Rt.	12 g
9.	Vi²a¬ga API	*Embelia ribes*	Fr.	12 g
10.	Suradāru (Devadāru API)	*Cedrus deodara*	Ht. Wd.	12 g
11.	Gajopakulyā (Gajapippalī API)	*Scindapsus officinalis*	Fr.	12 g
12.	Yava k¾āra (Yava API)	*Hordeum vulgare*	Pl.	12 g
13.	Sarjikāk¾āra (Svarjikṣāra API)			12 g
14.	Nāgara (Śu´°hī) API	*Zingiber officinale*	Rz.	12 g
15.	Niśā (Haridrā API)	*Curcuma longa*	Rz.	12 g
16.	Miśi (Miśreyā API)	*Foeniculum vulgare*	Fr.	12 g
17.	Cavya API	*Piper retrofractum*	St.	12 g
18.	Ku¾°ha API	*Saussurea lappa*	Rt.	12 g
19.	Tejovatī API	*Zanthoxylum alatum*	Fr.	12 g
20.	Marica API	*Piper nigrum*	Fr.	12 g
21.	Vatsaka (Ku°aja API)	*Holarrhena antidysenterica*	St. Bk.	12 g
22.	Dīpyaka (Yavānī API)	*Trachyspermum ammi*	Fr.	12 g
23.	Agni (Citraka API)	*Plumbago zeylanica*	Rt.	12 g
24.	Rohi´ī (Ka°ukā API)	*Picrorrhiza kurrooa*	Rz./Rt.	12 g
25.	Aru¾kara (Bhallātaka-śuddha API	*Semecarpus anacardium*	Fr.	12 g
26.	Vacā API	*Acorus calamus*	Rz.	12 g
27.	Ka´āmūla (Pippalī API)	*Piper longum*	Rt.	12 g
28.	Yuktā (Rāsnā API)	*Pluchea lanceolata*	Rt./Lf.*	12 g
29.	Mañji¾°hā API	*Rubia cordifolia*	Rt.	12 g

* Actual part used in the formulation.

30.	Ativi¾ā API	*Aconitum heterophyllum*	Rt. Tr.	12 g
31.	Vi¾ānī (Ativiṣā bheda API)	*Aconitum palmatum*	Rt.	12 g
32.	Yavānī API	*Trachyspermum ammi*	Fr.	12 g
33.	Guggulu API (Śuddha)	*Commiphora wightii*	O.R.	240 g

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 to 3 of the formulation composition separately and pass through sieve number 40.
Soak the coarse powder of ingredients numbered in 4 times of potable water for 12 h. Gently heat the mixture to boil and continue the boiling to reduce the volume of the mixture to one fourth of its original volume.
Stop the boiling and filter while still warm through a muslin cloth.
Wash, dry and powder the ingredients number 8 to 32 of the formulation composition separately and pass through sieve number 85, weigh them separately in the required quantities and mix.
Add *goghṛta* to the filtrate (*Kvath*ā) and gently heat to concentrate. Add *Śuddha -Guggulu* with continuous stirring. Add powdered ingredients 8 to 32 with continuous stirring in the above mixture to form a semisolid paste, to obtain a semi-solid mass of suitable plasticity.
Pack it in tightly closed containers to protect from light and moisture.

Description:

Dark brown, semi-solid paste, unctuous touch with pleasant and characteristic odour and slightly bitter taste

Identification:

Thin layer chromatography:

Extract 5 g of formulation powder with 75 ml n-*hexane* under reflux on a water bath for 30 min, filter and concentrate the extract to 10 ml and carry out the thin-layer chromatography.
Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using n-*hexane: ethyl acetate* (8.5 : 1.5) as mobile phase. After development allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.10, 0.17, 0.38, 0.43, 0.84 (all blue). Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.25 (faded pink), 0.34 (pinkish brown), 0.41, 0.65 (both blue), 0.78 (greenish blue) and 0.92 (blue) in visible light.
Reflux n-*hexane* extracted material with 75 ml of *chloroform* on a water bath for 30 min, filter and concentrate the extract to 10 ml and carry out the thin-layer chromatography. Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: methanol* (9 : 1 : 1) as mobile phase. After development allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.13 (faded blue), 0.44 (fluorescent blue), 0.62, 0.67, 0.76 (all blue). Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots

at R_f 0.13 (purple), 0.20 (purplish brown), 0.26 (fluorescent purple), 0.30 (purple), 0.45 (blue) and 0.65, 0.76, 0.86 (all purple) in visible light.
Reflux the chloroform extracted material with 75 ml *methanol*, filter and concentrate the extract to 10 ml and carry out thin-layer chromatography.
Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate* (8 : 2) as mobile phase. After development allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.24 (dark blue), 0.48 (greenish blue), 0.55, 0.68, 0.76, 0.84, 0.96 (all fluorescent blue) under 366 nm. Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.24 (yellow), 0.38 (blue), 0.43 (purple), 0.47 (purplish blue), 0.54 (purple), 0.63 (grayish black), 0.70 (purplish blue), 0.78 (purple), 0.89 (bluish purple) and 0.97 (blue) in visible light.

Physico-chemical parameters:

Loss on drying:	Not more than 17 per cent,	Appendix 2.2.10
Total ash:	Not more than 6 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 1.5 per cent,	Appendix 2.2.4
Alcoholic-soluble extractive:	Not less than 54 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 8 per cent,	Appendix 2.2.8
*p*H *(1% aqueous solution):*	5.3 to 5.5,	Appendix 3.3

Other requirements:

*Microbial limit**:***	Appendix 2.4
*Aflatoxins**:***	Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic Indications: Sandhigata vāta (osteoarthropathy); Asthigata vāta (Vata confined to bones); Majjāgata vāta (bone marrow related disorders); Nāḍ vra´a (sinsus); Kustḥa(Disease of skin); Arbuda (tumour); Bhagandara (fistula in ano); Ga´ḍamāla (goiter/cervical lymphadentis); Guda roga (Anorectal disease); Meha (excessive flow of urine); Yakṣmā (tuberculosis); Aruci (tastelessness); Svāsa (asthma); Pnasa (chronic rhinitis/sinusitis); Kāsa (cough); śopha (oedema); Hṛdroga (heart disease); Pā´ḍu (anaemia); Mada (intoxication); Vidradhi (abscess); Vātarakta (gout); Ūrdhva jatrugata roga (disease of head and neck).

Dose: 6-12 g daily in divided doses.

Anupā na: Warm water and milk

PUNARNAVĀ GUGGULU

(AFI Part-II, 5:2)

Definition:

Punarnavā Guggulu vat¤ is a preparation made with the ingredients in Formulation composition given below with *Guggulu* as the basic ingredient.

Formulation composition:

1.	Punarnavā mūla (Raktapunarnavā API)	*Boerhaavia diffusa*	Rt.	4.800 kg
2.	Rubūkamūla (Era´²a API)	*Ricinus communis*	Rt.	4.800 kg
3.	Śu´°hī API	*Zingiber officinale*	Rz.	768 g
4.	Jala for decoction reduced to	Water		32 l 4 l
5.	Kauśika (Guggulu API - Śuddha)	*Commiphora wightii*	O.R.	864 g
6.	Era´²a Taila API	*Ricinus communis*	Sd. Oil	192 ml
7.	Triv¨t API	*Ipomoea turpethum*	Rt.	240 g
8.	Nikumbha (Dantī API)	*Baliospermum montanum*	Rt.	48 g
9.	Gu²ūcī API	*Tinospora cordifolia*	St.	96 g
10..	Harītakī API	*Terminalia chebula*	P.	96 g
11.	Bibhītaka API	*Terminalia belerica*	P.	96 g
12.	Āmalakī API	*Emblica officinalis*	P.	96 g
13.	Śu´°hī API	*Zingiber officinale*	Rz.	96 g
14.	Marica API	*Piper nigrum*	Fr.	96 g
15.	Pippalī API	*Piper longum*	Fr.	96 g
16.	Sindhūttha (Saindhava API)			96 g
17.	Citraka API	*Plumbago zeylanica*	Rt.	96 g
18.	Bhallāta (Bhallātaka API-Śuddha)	*Semicarpus anacardium*	Fr.	96 g
19.	Vi²a¬ga API	*Embelia ribes*	Fr.	96 g
20.	Māk¾ika dhātu cūr´a (Bhasma) API			12 g
21.	Punarnavā (Rakta-Punarnavā API)	*Boerhaavia diffusa*	Rt.	48 g

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.

Wash, dry and powder the ingredients number 7 to 19 of the formulation composition separately and pass through sieve number 85, weigh them separately in the required quantities and mix.

Crush weighed quantity of *Guggulu - Śuddha.*

Wash, dry and powder the ingredients number 1 to 3 of the formulation composition separately and pass through sieve number 40. Soak the coarse powder mixture in 8 times of potable water for 12 h. Gently heat the mixture to boil and continue the boiling to reduce the volume of the mixture to half of its original volume.

Stop the boiling and filter while still warm through a muslin cloth.

Boil the filtrate *(Kvātha)* in an iron vessel. Add *Śuddha - Guggulu* to *Kvātha* and concentrate to *Gu²apāka* (semi-solid) condition.
Add fine powders of mixed ingredients and *Mākṣika Bhasma* with continuous stirring. Pound the mixture to a semi-solid uniformly mixed mass of suitable plasticity. Use *Gh¨ta* for smooth pounding.
Expel the pounded mass through *va¢ī* machine fitted with a suitable die and cut the *va¢īs* to a desired weight.
Roll the *va¢īs* on flat surface to round them by circular motion of palm covered with a glove and smeared with *Gh¨ta* or use suitable mechanical device.
Dry the rounded *va¢īs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
Pack it in tightly closed containers to protect from light and moisture.

Description:

Blackish brown spherical pills with pleasant odour, salty and bitter in taste

Identification:

Thin layer chromatography :

Extract 5 g of formulation powder with 75 ml n-*hexane* under reflux on a water bath for 30 min, filter and concentrate the extract to 10 ml and carry out the thin-layer chromatography. Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using n-*hexane: ethyl acetate* (9 : 1) as mobile phase. After development allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.12, 0.19, 0.22, 0.33, 0.51 under 254 nm and 0.10, 0.16 (both fluorescent blue), 0.21 (blue), 0.30 (navy blue), 0.38 (fluorescent blue). Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.18 (faded green), 0.22 (purple), 0.28 (greenish grey), 0.45 (greenish blue) and 0.54 (purple) in visible light.
Reflux n-*hexane* extracted material with 75 ml of *chloroform* on a water bath for 30 min, filter and concentrate the extract to 10 ml and carry out the thin-layer chromatography. Apply 10 µl on TLC plate. Develop the plate to a distance of 8 cm using *toluene: ethyl acetate: methanol* (9 : 1 : 1) as mobile phase. After development allow the plate to dry in air and examine under ultraviolet light. It shows major spots at R_f 0.13, 0.21, 0.29, 0.42, 0.54, 0.61, 0.71 under 254 nm and 0.15, 0.19 (both blue), 0.23 (red), 0.28 (blue), 0.40 (fluorescent blue), 0.45, 0.49, 0.61, 0.66 (all faded blue) under 366 nm. Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.14, 0.20 (both grey), 0.28 (purple), 0.41 (green), 0.61 (faded green), 0.69, 0.74 (both green) and 0.85 (greyish green) in visible light.

Physico-chemical parameters:

Loss on drying:	Not more than 12 per cent,	Appendix 2.2.10
Total ash:	Not more than 15 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 4 per cent,	Appendix 2.2.4
Water-soluble extractive:	Not less than 45 per cent,	Appendix 2.2.7
Alcoholic-soluble extractive :	Not less than 10 per cent,	Appendix 2.2.8
*p*H *(1% aqueous solution):*	4.7 to 5.0,	Appendix 3.3

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic Indications: Vātarakta (Gout); V¨ddhiroga (hydrocele disease); G¨dhrasī (sciatica); Ja¬ghā-ūru-p¨¾ºha-trika-sthāna and vastigata śūla (pain in urinary bladder); Āmavāta (rheumatism).

Dose: 2-3 g daily in divided doses.

Anupāna: Water

SAPTAVI»ŚATIKA GUGGULU
(AFI Part-I, 5:11)

Definition:

Saptavi¼śatika Guggulu vat¤ is a preparation made with the ingredients in Formulation composition given below with *Guggulu* as the basic ingredient.

Formulation composition:

1.	Śu´°hī API	*Zingiber officinale*	Rz.	1 part
2.	Marica API	*Piper nigrum*	Fr.	1 part
3.	Pippalī API	*Piper longum*	Fr.	1 part
4.	Harītakī API	*Terminalia chebula*	P.	1 part
5.	Bibhītaka API	*Terminalia belerica*	P.	1 part
6.	Āmalakī API	*Emblica officinalis*	P.	1 part
7.	Ku¾tha API	*Saussurea lappa*	Rt.	1 part
8.	Vi²a¬ga API	*Embelia ribes*	Fr.	1 part
9.	Amṛtā (Guḍūcī API)	*Tinospora cordifolia*	St.	1 part
10.	Citraka API	*Plumbago zeylanica*	Rt.	1 part
11.	Śatī API	*Hedychium spicatum*	Rz.	1 part
12.	Elā (Sūk¾mailā) API	*Elettaria cardamomum*	Sd.	1 part
13.	Pippalīmūla API	*Piper longum*	Rt.	1 part
14.	Havu¾ā (Hapu¾ā API)	*Juniperus communis*	Fr.	1 part
15.	Suradāru (Devadaru API)	*Cedrus deodara*	Ht. Wd.	1 part
16.	Tumburu (Tejovatī API)	*Zanthoxylum aromaticum*	Fr.	1 part
17.	Pu¾kara API	*Saussurea lappa*	Rt.	1 part
18.	Cavya API	*Piper chaba*	St.	1 part
19.	Viśālā (Rakta indravāru´ī API)	*Citrullus colocynthis*	Rt.	1 part
20.	Haridrā API	*Curcuma longa*	Rz.	1 part
21.	Dāruharidrā API	*Berberis aristata*	St.	1 part
22.	Viḍa lava´a API			1 part
23.	Sauvarcala lava´a API			1 part
24.	Yava k¾āra API (Yava)	*Hordeum vulgare*	Water soluble ash of Pl.	1 part
25.	Sarji k¾āra (Svarji k¾āra API)			1 part
26.	Saindhava lava´a API			1 part
27.	Gajapippalī API	*Scindapsus officinalis*	Fr.	1 part
28.	Guggulu-Śuddha API	*Commiphora wightii*	O.R.	54 parts

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 to 21 and 27 of the formulation composition separately and pass through sieve numbered 85. Powder the ingredients numbered 22 to 26 of the formulation composition separately and pass through sieve number 85. Weigh them all separately in the required quantities and mix.

Crush weighed quantity of *Śuddha -Guggulu*, add fine powder of other mixed ingredients to it and pound well. Add *Gh¨ta* in small quantity at regular intervals for smooth pounding and continue pounding till a semi-solid uniformly mixed mass of suitable plasticity is obtained.
Expel the mass through *va˜i* machine fitted with a suitable die and cut the *va˜is* to a desired weight.
Roll the *va˜is* on flat surface to round them by circular motion of palm covered with a glove and smeared with *Gh¨ta* or use suitable mechanical device.
Dry the rounded *va˜is* in a tray-dryer at a temperature not exceeding 60^0 for 8 to 10 h.
Pack it in tightly closed containers to protect from light and moisture.

Description:

Dark brown spherical pills with spicy pleasant odour, salty, bitter and astringent taste

Identification:

Thin layer chromatography:

Extract 5 g of formulation powder with 75 ml n-*hexane* under reflux on a water bath for 30 min, filter and concentrate the extract to 10 ml and carry out the thin-layer chromatography.
Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using n-*hexane: ethyl acetate* (8.5 : 1.5) as mobile phase. After development allow the plate to dry in air and examine under ultraviolet light. It shows major spots at R_f 0.12, 0.19, 0.22, 0.51, 0.67 under 254 nm and at 0.10, 0.16 (both fluorescent blue), 0.21 blue,, 0.38 (fluorescent blue) under 366 nm. Spray the plate with anisaldehyde *sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.18 (faded green), 0.22 (purple), 0.28 (greenish grey), 0.34 (purple), 0.45 (greenish blue), 0.54 (purple), 0.68 (brown) in visible light.
Reflux n-*hexane* extracted material with 75 ml of *chloroform* on a water bath for 30 min, filter and concentrate the extract to 10 ml and carry out the thin-layer chromatography. Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: ethyl acetate: methanol* (9: 1: 1) as mobile phase. After development allow the plate to dry in air and examine under ultraviolet light. It shows major spots at R_f 0.13, 0.21, 0.29, 0.42, 0.52, 0.61 under 254 nm and at R_f 0.15, 0.19 (both blue), 0.23 (red), 0.28 (sea green), 0.34, 0.36 (both yellowish green), 0.40 (fluorescent blue), 0.45, 0.49, 0.56, 0.61 (all faded blue) under 366 nm. Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.18 (green), 0.28 (purple), 0.41 (green), 0.51 (faded green), 0.62 (green), 0.70 (greyish green) and 0.77 (green) in visible light.

Physico-chemical parameters:

Loss on drying:	Not more than 13 per cent,	Appendix 2.2.10
Total ash:	Not more than 17 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 4 per cent,	Appendix 2.2.4
Water-soluble extractive:	Not less than 35 per cent,	Appendix 2.2.7
Alcoholic-soluble extractive :	Not less than 25 per cent,	Appendix 2.2.8
*p*H *(1% aqueous soution):*	4.5 to 5.0,	Appendix 3.3

Other requirements:

Microbial limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed container. Protect from light and moisture.

Therapeutic Indications: H¨cchūla (angina pectoris); Kāsa (cough); Śvāsa(asthma); Pārśvasūla (intercostal neuralgia); Śotha (inflammation); Arśa (piles); Bhagandara (fistula-in-ano); Kuk¾i rujā (pelvic pain); Vaktra rujā (pain in mouth); Guda rujā (pain in anus); Aśmarī (calculus); Mūtrak¨cchra (dysuria); Āntrav¨ddhi (hernia); K¨mi (worm infestation); Jvara (fever); K¾aya (pthisis); Apasmāra (epilepsy); Ānāha (distension of abdomen); Unmāda (psychosis); Ku¾ºha (skin diseases); Udara (diseases of abdomen); Nādīvra´a (sinus); Du¾ºavra´a (non-healing ulcer); Prameha (increased frequency and turidity of urine); Ślīpada (filariasis)

Dose: 2-3 g daily in divided doses.

Anupāna: Warm water and honey

SI»HANĀDA GUGGULU

(AFI, Part-I, 5:12)

Definition:

Si¼hanāda Guggulu va¢ī is a preparation made with the ingredients in the Formulation composition given below with *Guggulu* as the basic ingredient.

Formulation composition:

1.	Harītakī API	*Terminalia chebula*	P.	48 g
2.	Bibhītaka API	*Terminalia belerica*	P.	48 g
3.	Āmalakī API	*Emblica officinalis*	P.	48 g
4.	Jala for decoction	Water		576 ml
	reduced to			144 ml
5.	Gandhaka API - Śuddha	Sulphur		48 g
6.	Guggulu API - Śuddha	*Commiphora wightii*	O.R.	48 g
7.	Citra (Era´²a API) taila	*Ricinus communis*	Sd. Oil	30 g

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 to 3 of the formulation composition separately and pass through sieve number 40.
Soak the coarse powder of ingredients numbered 1 to 3 in 4 times of potable water for 12 h.
Gently heat the mixture to boil and continue the boiling to reduce the volume of the mixture to one fourth of its original volume.
Stop the boiling and filter while still warm through a muslin cloth.
Powder the *Gandhaka Śuddha* and pass through sieve number 120.
Add *Era´²a taila* to the filtrate *(Kv¢tha)* and gently heat to concentrate. Add *Śuddha - Gandaka* and *Śuddha -Guggulu* with continuous stirring to obtain a semi-solid mass of suitable plasticity.
Expel the mass through *va¢ī* machine fitted with a suitable die and cut the *va¢īs* to a desired weight.
Roll the *va¢īs* on flat surface to round them by circular motion of palm covered with a glove and smeared with *Era´²a taila* or use suitable mechanical device.
Dry the rounded *va¢īs* in a tray-dryer at a temperature not exceeding 60^0 for 12 to 15 h.
Pack it in tightly closed containers to protect from light and moisture.

Description:

Spherical pills, brownish-black to black in colour with agreeable odour and bitter taste

Identification:

Thin layer chromatography:

Extract 5 g of formulation powder in 75 ml of n-*hexane* under reflux on a water-bath for 30 min. Filter and concentrate the extract to 25 ml and carry out the thin layer chromatography.
Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene : acetone* (9 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light. It shows major spots at R_f 0.19, 0.37, 0.44 and 0.59 (all fluorescent blue) under 366 nm and at R_f 0.35, 0.42 (both black) under 254 nm. Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.37, 0.44 and 0.59 (all pink changing to purple) in visible light.

Test for sulphur:
Burn 100 mg of tablet powder in a flame. The evolution of sulphur dioxide is recognized by its characteristic suffocating odour.
To about 500 mg of tablet powder, add 0.25 g of *zinc* and *sodium carbonate reagent*, mix and transfer into a small test tube. Carefully heat the test tube to a red heat, starting at the upper end and heating towards the bottom end. Drop the content quickly into about 20 ml of water. Filter and acidify the filtrate with hydrochloric acid. The fumes evolve, which turn the lead acetate paper brown or black.

Physico-chemical parameters:

Loss on drying:	Not more than 12 per cent,	Appendix 2.2.10
Total ash:	Not more than 7 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 3.5 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 31 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 23 per cent,	Appendix 2.2.8
*p*H (1% aqueous solution):	4.87 to 5.33,	Appendix 3.3

Other requirements:

Microbial Limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Kha®ja (limping); Pā´²u (anaemia); Āmavāta (rheumatism); Vātarakta (gout); Ku¾°ha (diseases of skin); Vāta roga (disease due to vāta do¾a /neurological diseaese); Kapha roga (disease due to kapha do¾a); Pitta roga (disease due to pitta do¾a); Pa¬gu (paraplegia); Śvāsa (dyspnoea/asthma); Kāsa (cough); Gulma (abdominal lump); Śūla (pain); Udara (diseases of abdomen); Jarā (senility/progeriasis); Palita (graying of hair); Agnimāndya (digestive impairment).

Dose: 2-3 g daily in divided doses.

Anupāna: Warm water.

TRAYODAŚĀ«GA GUGGULU

(AFI, Part-I, 5:4)

Definition:

Trayodaśā¬ga Guggulu va°ī is a preparation made with the ingredients in the Formulation composition given below with *Guggulu* as the basic ingredient.

Formulation composition:

1.	Babbūla API	*Acacia arabica*	St. Bk.	1 Part
2.	Aśvagandhā API	*Withania somnifera*	Rt.	1 Part
3.	Hapu¾ā API	*Juniperus communis*	Fr.	1 Part
4.	Gu²ūcī API	*Tinospora cordifolia*	St.	1 Part
5.	Śatāvarī API	*Asparagus racemosus*	Rt	1 Part
6.	Gok¾ura API	*Tribulus terrestris*	Fr.	1 Part
7.	V¨ddhadāru API	*Ipomoea petaloidea*	Rt.	1 Part
8.	Rāsnā API	*Pluchea lanceolata*	Lf.	1 Part
9.	Śatāhvā API	*Anethum sowa*	Fr.	1 Part
10.	Śa°ī API	*Hedychium spicatum*	Rz.	1 Part
11.	Yavānī API	*Trachyspermum ammi*	Fr.	1 Part
12.	Śu´°hī API	*Zingiber officinale*	Rz.	1 Part
13.	Guggulu API - Śuddha	*Commiphora wightii*	O.R.	12 Parts
14.	Gogh¨ta API	Clarified butter from Cow's milk.		1 Part

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.

Wash, dry and powder the ingredients number 1 to 12 of the formulation composition separately and pass through sieve number 85, weigh them separately in the required quantities and mix.

Crush weighed quantity of *Guggulū-Śuddha*, add fine powder of other mixed ingredients to it and pound well. Add *Gh¨ta* in small quantity at regular intervals for smooth pounding and continue pounding till a semi-solid uniformly mixed mass of suitable plasticity is obtained.

Expel the mass through *va°ī* machine fitted with a suitable die and cut the *va°ī*s to a desired weight.

Roll the *va°ī*s on flat surface to round them by circular motion of palm covered with a glove and smeared with *Gh¨ta* or use suitable mechanical device.

Dry the rounded *va°ī*s in a tray-dryer at a temperature not exceeding 60^0 for 8 to 10 h.

Pack it in tightly closed containers to protect from light and moisture.

Description:

Spherical pills, blackish in colour with agreeable odour and bitter taste

Identification:

Thin layer chromatography:

Extract 5 g of formulation powder in 75 ml of n-*hexane* under reflux on a water-bath for 30 min. Filter and concentrate the extract to 25 ml and carry out the thin layer chromatography.
Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: acetone* (9 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (366 nm.). It shows major spots at R_f 0.19, 0.37, 0.44 and 0.59 (all fluorescent blue). Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.40 and 0.61 (all pink changing to purple) in visible light.

Physico-chemical parameters:

Loss on drying:	Not more than 11 per cent,	Appendix 2.2.10
Total ash:	Not more than 15 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 4 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 17.5 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 21 per cent,	Appendix 2.2.8
*p*H (1% aqueous solution):	4.45 to 5.96,	Appendix 3.3

Other requirements:

Microbial Limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Ka°igraha (stiffness in lumbo-sacral region); G¨dhrasī (sciatica); Hanugraha (lockjaw); Bāhuśūla (pain in arm); Jānustabdhatā (stiffness of the knee); Asthivāta (bone disease due to vāta do¾a); Majjāvāta (bone marrow disorder); Snāyu vāta (inflammation of ligamnets); H¨tgraha (cardiac failure); Vātakapha roga (disease due to vāta do¾a and kapha do¾a); Yonido¾a (disorders of female genital tract); Asthibha¬ga (bone fracture); Vidradhi (abscess); Kha®ja vāta (limping due to vitiation of vāta).

Dose: 2-3 g daily in divided doses.

Anupā na: Triphalā kvātha, Madhu, Laśuna svarasa, Yū¾a, Mando¾´a jala, Milk.

TRIPHALĀ GUGGULU

(AFI, Part-I, 5:5)

Definition:

Triphalā Guggulu vaṭī is a preparation made with the ingredients in the Formulation composition given below with *Guggulu* as the basic ingredient.

Formulation composition:

1.	Harītakī API	*Terminalia chebula*	P.	48 g
2.	Bibhītaka API	*Terminalia belerica*	P.	48 g
3.	Āmalakī API	*Emblica officinalis*	P.	48 g
4.	Pippalī API	*Piper longum*	Fr.	48 g
5.	Guggulu API - Śuddha	*Commiphora wightii*	O.R.	240 g

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.
Wash, dry and powder the ingredients number 1 to 4 of the formulation composition separately and pass through sieve number 85, weigh them separately in the required quantities and mix.
Crush weighed quantity of *Guggulū-Śuddha*, add fine powder of other mixed ingredients to it and pound well. Add *Ghṭa* to an extent required to facilitate the pounding and continue pounding till a semi-solid uniformly mixed mass of suitable plasticity is obtained.
Expel the mass through *vaṭī* machine fitted with a suitable die and cut the *vaṭis* to a desired weight.
Roll the *vaṭis* on flat surface to round them by circular motion of palm covered with a glove and smeared with *Ghṭa* or use suitable mechanical device.
Dry the rounded *vaṭis* in a tray-dryer at a temperature not exceeding 60^0 for 8 to 10 h.
Pack it in tightly closed containers to protect from light and moisture.

Description*:*

Spherical pills, black in colour with agreeable odour and bitter taste.

Identification:

Microscopy:

Take about 5 g of the sample, powder and add c*hloroform* (20 ml); stir for 10 min over a water-bath; pour out c*hloroform*. Repeat the process thrice adding fresh quantities of c*hloroform*; discard *chloroform*. Wash the sediment thoroughly in hot water. Take a few mg of washed material, stain with iodine solution and mount in 50 per cent *glycerine*. Clarify a few mg with *chloral hydrate* and mount in 50 per cent *glycerine*. Observe the following characters in different mounts.

Fragment of thick-walled epicarp cells in surface view several with beaded walls, and thin cross walls, long fibres with blunt or pegged tips (**Harītakī**); simple, unicellular or

bicellular trichomes with a swollen basal cell (**Bibhītaka**); fragments of parenchyma cells with corner thickenings, containing minute rosette crystals of calcium oxalate; fragments of epidermal tissue with silica crystals **(Āmalakī**); perisperm cells (**Pippalī**); abundant sclereids of various sizes and shapes fibres with blunt tips and broad lumen and minute starch grains are common characteristics.

Thin layer chromatography:

Extract 5 g of formulation powder in 75 ml of n-*hexane* under reflux on a water-bath for 30 min. Filter and concentrate the extract to 25 ml and carry out the thin layer chromatography. Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using *toluene: acetone* (9 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.19, 0.37, 0.44 and 0.59 (all fluorescent blue). Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.40, 0.61 (both pink changing to purple) in visible light.

Physico-chemical parameters:

Loss on drying:	Not more than 13 per cent,	Appendix 2.2.10
Total ash:	Not more than 12 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 7 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 13.5 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 30 per cent,	Appendix 2.2.8
*p*H (1% aqueous solution)*:*	4.35 to 4.70,	Appendix 3.3

Other requirements:

Microbial Limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed container protect from light and moisture.

Therapeutic uses: Śotha (inflammation); Bhagandara (fistula-in-ano); Arśa (piles); Gulma (abdominal lump).

Dose: 2-3 g daily in divided doses.

Anupāna: Warm water

VĀTĀRI GUGGULU

(AFI, Part-I, 5:10)

Definition:

Vātāri Guggulu vaṭī is a preparation made with the ingredients in the Formulation composition given below with *Guggulu* as the basic ingredient.

Formulation composition:

1.	Vātāri taila (Eraṇḍa API)	*Ricinus communis*	Sd. Oil.	$^1/_8$ Part
2.	Gandhaka API - Śuddha	Sulphur		1 Part
3.	Guggulu API - Śuddha	*Commiphora wightii*	O.R.	1 Part
4.	Harītakī API	*Terminalia chebula*	P.	1 Part
5.	Bibhītaka API	*Terminalia belerica*	P.	1 Part
6.	Āmalakī API	*Emblica officianalis*	P.	1 Part

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.

Wash, dry and powder the ingredients numbered 4 to 6 of the formulation composition separately and pass through sieve number 85. Powder *Śuddha Gandhaka* to a fine powder and pass through sieve number 85. Weigh all of them separately in the required quantities and mix.

Crush weighed quantity of *Guggulu-Śuddha*, add fine powder of other mixed ingredients to it and pound well. Add *Eraṇḍa taila* in small quantity at regular intervals for smooth pounding and pound to a semi-solid uniformly mixed mass of suitable plasticity.

Expel the mass through *vaṭī* machine fitted with a suitable die and cut the *vaṭīs* to a desired weight.

Roll the *vaṭīs* on flat surface to round them by circular motion of palm covered with a glove and smeared with *Eraṇḍa taila* or use suitable mechanical device.

Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 8 to 10 h.

Pack it in tightly closed containers to protect from light and moisture.

Description:

Spherical pills, greyish-black in colour with agreeable odour and bitter taste

Identification:

Microscopy:

Take about 5 g of the sample, powder and add *chloroform* (20 ml); stir for 10 min over a water-bath; pour out *chloroform*. Repeat the process thrice adding fresh quantities of *chloroform*; discard *chloroform*. Wash the sediment thoroughly in hot water. Take a few mg of washed material, stain with iodine solution and mount in 50 per cent *glycerin*. Clarify a few mg with *chloral hydrate* and mount in 50 per cent *glycerin*. Observe the following characters in different mounts.

Fragment of thick-walled epicarp cells in surface view several with beaded walls, and thin cross walls, long fibres with blunt or pegged tips (**Harītakī**); simple, unicellular or bicellular trichomes with a swollen basal cell (**Bibhītaka**); fragments of parenchyma cells with corner thickenings, minute rosette crystals of calcium oxalate (**Āmalakī**); perisperm cells (**Pippalī**); abundant sclereids of various sizes and shapes fibres with blunt tips and broad lumen and minute starch grains are common characteristics.

Thin layer chromatography:

Extract 5 g of formulation powder in 75 ml of n-*hexane* under reflux on a water-bath for 30 min. Filter and concentrate the extract to 25 ml and carry out the thin layer chromatography. Apply 10 µl of n-*hexane* extract on TLC plate and develop the plate to a distance of 8 cm using *toluene: acetone* (9 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light. It shows major spots at R_f 0.19, 0.37, 0.44 and 0.59 (all fluorescent blue) under 366 nm and at R_f 0.35, 0.42 (both black) under 254 nm. Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.46, 0.66, 0.76 (both pink changing to purple) in visible light.

Physico-chemical parameters:

Loss on drying:	Not more than 17 per cent,	Appendix 2.2.10
Total ash:	Not more than 5.5 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 2 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 28 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 26 per cent,	Appendix 2.2.8
*p*H (1% aqueous solution)*:*	4.45 to 4.52,	Appendix 3.3

Other requirements:

Microbial Limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Āmavāta (rheumatism); Ka°īśūla (lower backache); Grdh¨asī (sciatica); Kha®ja (limping); Vātarakta (gout); Pa¬gu (paraplegia); Śotha (inflammation); Dāha (burning sensation); Kro¾°hu śīr¾aka (deformed knee due to chronic arthritis).

Dose: 2-3 g daily in divided doses.

Anupāna: Warm water

VYO½ĀDI GUGGULU

(AFI, Part-I, 5:9)

Definition:

Vyo¾ādi Guggulu va°ī is a preparation made with the ingredients in the Formulation composition given below with *Guggulu* as the basic ingredient.

Formulation composition:

1.	Śu´°hī API	*Zingiber officinale*	Rz.	1 Part
2.	Marica API	*Piper nigrum*	Fr.	1 Part
3.	Pippalī API	*Piper longum*	Fr.	1 Part
4.	Citraka API	*Plumbago zeylanica*	Rt.	1 Part
5.	Must¢ API	*Cyperus rotundus*	Rz.	1 Part
6.	Harītakī API	*Terminalia chebula*	P.	1 Part
7.	Bibhītaka API	*Terminalia belerica*	P.	1 Part
8.	Āmalakī API	*Emblica officinalis*	P.	1 Part
9.	Vi²a¬ga API	*Embelia ribes*	Fr.	1 Part
10.	Guggulu API - Śuddha	*Commiphora wightii*	O.R.	9 Parts

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 to 9 of the formulation composition separately and pass through sieve number 85, weigh them separately in the required quantities and mix.
Crush weighed quantity of *Guggulu-Śuddha*, add fine powder of other mixed ingredients to it and pound well. Add *Era´²a oil* to an extent required to facilitate the pounding and continue pounding till a semi-solid uniformly mixed mass of suitable plasticity is obtained.
Expel the mass through *va˜ī* machine fitted with a suitable die and cut the *va˜īs* to a desired weight.
Roll the *va˜īs* on flat surface to round them by circular motion of palm covered with a glove and smeared with *Era´²a oil* or use suitable mechanical device.
Dry the rounded *va˜īs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
Pack it in tightly closed containers to protect from light and moisture.

Description:
Spherical pills, black in colour with pleasant odour and bitter taste

Identification:

Microscopy:

Take about 5 g of the sample, powder it and add n-*hexane* (20 ml) stir for 10 min thoroughly over a water-bath; pour out *hexane*. Repeat the process thrice adding fresh quantities of *hexane*; discard *hexane*. Wash the sediment thoroughly in hot water. Take a

few mg of washed material, stain with *iodine* solution and mount in 50 per cent *glycerine*. Clarify another few mg with *chloral hydrate* and mount in 50 per cent *glycerine*. Observe the following characters in different mounts.

Groups of parenchymatous cells, densely packed starch grains, isolated starch grains, simple, oval to rod shaped, measuring 15 to 70 µ in length, hilum eccentric, lamellae distinct, yellow coloured oleo-resin cells, non-lignified, septate fibres some of them bearing marks of adjacent cells pressing against them, 30 to 50 µ broad **(Śu´ºhī**); groups of isodiameric or slightly elongated stone cells with moderately thickened walls, interspersed with thin walled polygonal parenchyma cells **(Maricā)**; groups of elongated, spindle shaped, wide lumened lignified stone cells **(Pippalī);** fibre sclereids from scale leaves in packed rows (**Mustā**); prismatic crystals of calcium oxalate, spiral vessels and stone cells in different shapes and sizes with prominent pits from testa and elongated sclereids with broad lumen and pitted walls (**Vi²a¬ga**); short, unicellular, thick walled trichomes with sharp tips and bulbous bases and fragments of polyhedral epidermis showing cicatrices (**Bibhītaka**); groups of parenchymatous epidermal cells having beaded walls, several showing a thin cross wall, crisscross layer of sclerenchymatous fibres **(Harītakī);** thin walled cells of epidermal tissue with paracytic stomata and containing silica crystals, sclereids with pitted wide lumen, parenchymatous tissue with large irregular thick walled cells showing corner thickenings **(Āmalakī)**; cork cells in surface view, uniseriate and multiseriate ray parenchyma cells, bifurcated short fibres and pitted vessels (**Citraka)**.

Thin layer chromatography:

Extract 5 g of formulation powder in 75 ml of n-*hexane* under reflux on a water-bath for 30 min. Filter and concentrate the extract to 25 ml and carry out the thin layer chromatography. Apply 10 µl of n-*hexane* extract on TLC plate and develop the plate to a distance of 8 cm using *toluene: acetone* (9 : 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.19, 0.37, 0.44 and 0.59 (all fluorescent blue). Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.45, 0.53, 0.72 and 0.77 (all pink changing to purple) in visible light.

Physico-chemical parameters:

Loss on drying:	Not more than 15 per cent,	Appendix 2.2.10
Total ash:	Not more than 11 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 3 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 21 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 24 per cent,	Appendix 2.2.8
*p*H (1% aqueous solution)*:*	4.57 to 4.69,	Appendix 3.3

Other requirements:

Microbial Limit:	Appendix 2.4
Aflatoxins:	Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture.

Therapeutic uses: Medoroga (obesity); Kapha roga (disease due to kapha do¾a); Āmavāta (rheumatism),

Dose: 2-3 g daily in divided doses.

Anupāna: Warm water.

YOGARĀJA GUGGULU

(A.F.I. Part-I, 5:7)

Definition:

Yogarāja Guggulu va°ī is preparation made with the ingredients in the Formulation Composition, given below, with *Guggulu* as the basic ingredient.

Formulation Composition:

1.	Citraka API	*Plumbago zeylanica*	Rt.	1 part
2.	Pippalīmūla API	*Piper longum*	Rt.	1 part
3.	Yamānī (Yavānī API)	*Trachyspermum ammi*	Sd.	1 part
4.	Kāravī (K¨¾´a jīraka API)	*Carum carvi*	Fr.	1 part
5.	Vi²a¬ga API	*Embelia ribes*	Fr.	1 part
6.	Ajamodā API	*Apium leptophyllum*	Fr.	1 part
7.	Jīraka (Śveta jīraka API)	*Cuminum cyminum*	Fr.	1 part
8.	Suradāru (Devadāru API)	*Cedrus deodara*	Ht. Wd.	1 part
9.	Cavya API	*Piper chaba*	St.	1 part
10.	Elā (Sūk¾mailā API)	*Elettaria cardamomum*	Sd.	1 part
11.	Saindhava lava´a API	Rock Salt		1 part
12.	Ku¾°ha API	*Saussurea lappa*	Rt.	1 part
13.	Rāsnā API	*Pluchea lanceolata*	Rt./ Lf.*	1 part
14.	Gok¾ura API	*Tribulus terrestris*	Fr.	1 part
15.	Dhānyaka API	*Coriandrum sativum*	Fr.	1 part
16.	Harītakī API	*Terminalia chebula*	P.	1 part
17.	Bibhītaka API	*Terminalia belerica*	P.	1 part
18.	Āmalakī API	*Emblica officinalis*	P.	1 part
19.	Mustaka (Mustā API)	*Cyperus rotundus*	Rz.	1 part
20.	Śu´°hī API	*Zingiber officinale*	Rz.	1 part
21.	Marica API	*Piper nigrum*	Fr.	1 part
22.	Pippalī API	*Piper longum*	Fr.	1 part
23.	Tvak API	*Cinnamomum zeylancium*	St. Bk.	1 part
24.	Uśīra API	*Vetiveria zizanoides*	Rt.	1 part
25.	Yavāgraja (Yava) k¾āra API	*Hordeum vulgare*	Water soluble ash of Pl.	1 part
26.	Tālisa patra API	*Taxus wallichii*	Lf.	1 part
27.	Patra (Tejapatra) API	*Cinnamomum tamala*	Lf.	1 part
28.	Guggulu API - Śuddha	*Commiphora wightii*	O.R.	27 parts
29.	Sarpi (Gogh¨ta API)	Clarified butter from Cow's milk		1 part

***** Actual part used in the formulation.

Method of preparation:

Take all the ingredients of the pharmacopoeial quality.
Wash, dry and powder the ingredients numbered 1 to 27 of the formulation composition separately and pass through sieve number 85, weigh them separately in the required quantities and mix.
Crush weighed quantity of *Guggulu-Śuddha*, add fine powder of other mixed ingredients to it and pound well. Add *Gh¨ta* in small quantity at regular intervals for smooth pounding and continue pounding till a semi-solid uniformly mixed mass of suitable plasticity is obtained.
Expel the mass through *va¢* machine fitted with a suitable die and cut the *va¢s* to a desired weight.
Roll the *va¢s* on flat surface to round them by circular motion of palm covered with a glove and smeared with *Era´²a taila* or use suitable mechanical device.
Dry the rounded *va¢s* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
Pack it in tightly closed containers to protect from light and moisture.

Description*:*

Dark brown spherical vati with spicy pleasant odour and astringent taste

Identification:

Thin layer chromatography :

Extract 5 g of formulation powder with 75 ml n-*hexane* under reflux on a water bath for 30 min, filter and concentrate to 10 ml and carry out the thin-layer chromatography.
Apply 10 µl on TLC plate and develop the plate to a distance of 8 cm using n-*hexane: ethyl acetate* (8.5 : 1.5) as mobile phase. After development allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.10, 0.17, 0.38, 0.43, 0.84 (all blue). Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.22 (pink), 0.31 (purple), 0.34 (brown), 0.41 blue, 0.52 (greyish blue), 0.59 (grayish brown), 0.65 (blue), and 0.78 (greenish blue) in visible light.

Physicochemical parameters:

Loss on drying:	Not more than 10 per cent,	Appendix 2.2.10
Total ash:	Not more than 6 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 1 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 16 per cent,	Appendix 2.2.7
Water-soluble extractive:	Not less than 19 per cent,	Appendix 2.2.8
*p*H *(1% aqueous soluion):*	4.7 to 5.0,	Appendix 3.3

Other requirements:

*Microbial Limit**:***	Appendix 2.4
*Aflatoxins**:***	Appendix 2.7

Storage: Store in a cool place in tightly closed containers, protect from light and moisture.

Therapeutic Indications: Udararoga (diseases of abdomen); Āmavāta (rheumatism); Ā²hyavāta (gout); K¨mi (worm infestation); Du¾°avra´a (non-healing ulcer); Plīhāv¨ddhi (splenomegally); Gulma (abdominal lump); Ānāha (distension of abdomen); Arśa (piles); Agnimāndya (digestive impairement); Daurbalya (weakness); Sandhigata vāta (osteoarthropathy); Majjāgata vāta (bone marrow disordes).

Dose: 2-3 g daily in divided doses.

Anupāna: Warm water and milk.

TAILA

General Description:

Tailas are preparations in which *Taila* is boiled with prescribed liquid media [*Svarasa* / *Kvātha* Etc.] and a fine paste [*Kalka*] of the drugs specified in the formulation composition. Unless specified otherwise *Taila* means *Tila Taila.*

General Method of Preparation:

1. The *Taila* preferably should be fresh.
2. There are usually three essential components in the manufacture of *Taila Kalpanā*.
    a. *Drava* [Any liquid medium as prescribed in the composition]
    b. *Kalka* [Fine paste of the specified drug]
    c. *Sneha dravya* [*Taila*]
    d. And, occasionally,
    e. *Gandha dravya* [Perfuming agents]
3. Unless otherwise specified in the verse, if *Kalka* is one part by weight, *Taila* should be four parts and the *Drava dravya* should be sixteen parts.
4. There are a few exceptions for the above general rule:
    a. Where *Drava dravya* is either *Kvātha* or *Svarasa*, the ratio of *Kalka* should be one-sixth and one-eighth respectively to that of *Taila.*
    If the *Drava dravya* is either *Kÿīra* or *Dadhi* or *Mā¼sa rasa* or *Takra,* the ratio of *Kalka* should be one-eighth to that of *Taila.*
    When flowers are advised for use as *Kalka,* it should be one-eighth to that of *Taila.*
    b. Where the numbers of *Drava dravyas* are four or less than four, the total quantity should be four times to that of *Taila.*
    c. Where the number of *Drava dravyas* is more than four, each *drava* should be equal to that of *Taila.*
    d. If, *Kalka dravya* is not prescribed in a formulation, the drugs specified for the *Drava dravya* [*Kvātha* or *Svarasa*] should be used for the preparation of *Kalka*.
    e. Where no *Drava dravya* is prescribed in a formulation, four parts of water should be added to one part of *Taila*.

5. In general, the *Taila* should be subjected to *Mūrcchana* process, followed by addition of increments of *Kalka* and *Drava dravya* in specified ratio. The contents are to be stirred continuously thoroughout the process in order to avoid charring.
6. The process of boiling is to be continued till the whole amount of moisture gets evaporated and characteristic features of *Taila* appears.
7. The whole process of *Paka* should be carried out on a mild to moderate flame.
8. Three stages of *Paka* are specified for therapeutic purposes.
    a. *M¨du Pāka*: In this stage, the *Kalka* looks waxy and when rolled between fingers, it rolls like lac without sticking. The *Taila* obtained at this stage is used for *Nasya* [Nasal instillation].

b. *Madhyama Pāka*: In this stage, the *Kalka* becomes harder and rolls in to *Varti*. It burns without crackling sounds when exposed to fire and *phena* [Froth] will appear over the *Taila. Taila* obtained at this stage is used for *Pana* [Internal administration] and *Vasti* [Enema].
c. *Khara Pāka:* Further heating of the *Taila*, leads to *Khara paka*. *Kalka* becomes brittle when rolled in between fingers. The *Taila* obtained at this stage is used only for *Abhyanga* [External application].

9. The period of *Pāka* depends upon the nature of liquid media used in the process.
   a. *Takra* or *Āranala* 5 Nights
   b. *Svarasa* 3 Nights
   c. *K¾ra* 2 Nights

10. *Pātra pāka:* It is the process by which the *Taila* is augmented or flavored by certain prescribed substances. The powdered drugs are suspended in a vessel containing warm, filtered *Taila*.

The medicated *Taila* will have the odour, colour and taste of the drugs used in the process. If a considerable amount of milk is used in the preparation, the *Taila* will become thick and may solidify in cold seasons.

Tailas are preserved in good quality of glass, steel or polythene containers. These medicated preparations retain the therapeutic efficacy for sixteen months.

ŚAMBŪKĀDYA TAILA

(AFI, Part II, 8:17)

Definition:

Śambūkādya Taila is a medicated preparation made with the ingredients in the Formulation composition given below with Sarṣapa Taila as the basic ingredient.

Formulation composition:

1.	Kaṭu Taila API	*Brassica campestris*	Sd. Oil	768 g
Kalka dravya :				
2.	Śambūka	*Pila globosa*	Entire	250 g
3.	Jala	Water		3 l

Method of Preparation:

Take the raw materials of Pharmacopoeial quality.
Clean live Apple Snail (*Pila globosa)* thoroughly with tap water, and remove the foreign matter.
Boil *Pila globosa* with shell for 20 – 25 min.
Wash and drain the excess water.
Grind entire *Śambūka* to prepare *Kalka.*
Treat *Sarṣapa taila* to prepare *Mūrcchita Sarṣapa Taila* (Appendix 6.2.8.).
Take *Mūrcchita Sarṣapa Taila* in a stainless steel vessel and heat it mildly.
Add increments of *Śambūka Kalka* and mix. Stir thoroughly while adding the water in specified ratio.
Heat with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Continue heating with constant stirring.
Observe the boiling mixture for appearance of froth.
Expose the oil to flame and confirm the absence of crackling sound indicating absence of moisture.
Stop heating when froth appears and filter while hot (about 80^0) through *muslin cloth* and allow to cool.
Pack it in tightly closed glass containers to protect from light and moisture.

Description:

A medicated oil, yellow in colour, with strong, unpleasant odour

Identification:

Thin layer chromatography :

Extract 5 g of formulation with 50 ml of *methanol* by keeping the mixture for 12 h at 37^0 with occasional shaking. Filter and concentrate the extract to 10 ml and carry out thin layer chromatography.
Apply 10 µl of the extract on TLC plate and develop the plate to a distance of 8 cm using *chloroform: methanol: glacial acetic acid* (9:1:0.2) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *ethanolic sulphuric acid reagent* followed

by heating at 105^0 for about 10 min and examine the plate under ultraviolet light (366 nm). It shows major spots at R_f 0.50 (greenish blue), 0.60 (light blue), 0.70 (fluoroscent blue) and 0.80 (fluoroscent blue).

Physico-chemical parameters:

Refractive index at 40^0:	1.4710 to 1.4880,	Appendix 3.1
Specefic gravity at 40^0:	0.907 to 0.910,	Appendix 3.2
Saponification Value:	180.0 to 186.0,	Appendix 3.10
Iodine Value:	Not more than 104,	Appendix3.11
Acid Value:	Not more than 2,	Appendix3.12
*Peroxide Value***:**	Not more than 6,	Appendix3.13

Other requirements:

Mineral oil:	Absent,	Appendix 3.15
Microbial Limits:		Appendix 2.4
Aflatoxins:		Appendix 2.7

Storage: Store in a cool place in tightly closed container, protect from light and moisture

Therapeutic Uses: Karṇagata nāḍīvraṇa (abscess in ear).

Dose: 5-10 drops, for external use, once or twice a day.

K½ĀRA SŪTRA (Medicated Thread)

(Suºruta Samhitā, Cikitsā-Sthāna-17 / 26-30)
and
(Cakradatta, Arśa Cikitsā -148)

Definition:

K¾āra Sūtra is a medicated device prepared with a linen thread of specified physical characteristics, to meet the quality of the finished product described below, by coating it with layers of materials obtained from plants as mentioned.

1. Linen Thread of 20 gauge, of suitable length			
2. Snuhī K¾īra API	*Euphorbia neriifolia*	Fresh Stem Latex	Q.S.
3. Apāmārga K¾āra API	*Achyranthes aspera*	Water soluble ash of Pl.	Q.S.
4. Haridrā API	*Curcuma longa*	Rz.	Q.S.

Method of Preparation:

Spread the surgical linen thread of size 20 throughout the length and breadth of the hanger of the specially designed cabinet known as *K¾āra Sūtra* (K.S.) Cabinet.
Smear the thread with latex, uniformly and carefully, all around the thread, with the help of clean gauze piece soaked in the *Snuhī K¾īra*. After smearing all the threads on the hanger, place the hanger in the K¾āra Sūtra cabinet for drying.
Close the cabinet properly and dry at 50^0 leaving it overnight. Close all the outlets of the K¾āra Sūtra cabinet properly in order to prevent the entry of moisture in to the cabinet.
After eleven such coatings with *Snuhī K¾īra*, process next day for the 12^{th} coat of *Snuhī K¾īra* and then pass the wet thread through a heap of finely powdered *Apāmārga k¾āra* immediately.
After smearing all the threads with *k¾āra*, shake the hanger gently allowing the excess particles of *k¾āra* to fall down. Place the hanger in the K¾āra Sūtra Cabinet and dry. Repeat this process till seven coatings of *Snuhī K¾īra* and *Apāmārga K¾āra* are achieved, thus completing 18 coatings on the thread.
Perform the remaining 3 coatings with *Snuhī K¾īra* and fine powder of *Haridr*ā as per the above said procedure making a total 21 coatings on the thread.
Put on the ultraviolet lamp of the K¾āra Sūtra cabinet daily for 20-30 minutes to maintain sterile atmosphere right from the 1^{st} day of coating.
Cut the threads of a uniform length i.e. 30-32 cm for packing as directed.
Put the sealed Glass Tube in a cabinet and expose it to ultraviolet radiation.

Description:

A dark brown coloured thread, with a dry coat of medicament that remains intact on handling and smooth to touch. The thread used is of linen consisting of processed pericyclic fibres from stems of *Linum usitatissimum*, complying with microscopy given below.

Microscopy:

1. Take a thread, wash thoroughly with *chloroform* 2 or 3 times followed by hot water also 3 times to remove the coated materials. Cut the washed thread into small pieces and digest it by boiling with a 10% aqueous solution of *sodium carbonate*. Wash to remove *sodium carbonate* and take small amount of the material on a micro slide and crush it with a glass rod. Mount and observe the characteristics.

a. Fibers with cell walls very thick with uniformly narrow lumen and tapering to a very fine point.
b. Fine, oblique or transverse markings present on the walls, sometimes crossing one another.

2. Take another small portion of the washed material, mount in *Cuoxam* (0.5 g of *copper carbonate* triturated with 10 ml of distilled water, gradually adding strong solution of *ammonia*, specific gravity 0.88, with continued stirring) and observe. No bulbous swelling is present (distinction from cotton).

Physico-chemical Characters:

Length of thread:	29 to 31 cm,	Appendix 7.1.1
Weight:	0.9 to 1 g,	Appendix 7.1.2
Diameter/Thickness:	1.75 to 2.0 mm	Appendix 7.1.3
Tensile Strength:	Breaking load not less than 5 kg,	Appendix 7.1.4
Loss on drying at 105^0:	Not more than 5 per cent,	Appendix 7.2.1
Water-soluble extractive:	Not less than 85 per cent,	Appendix 7.2.2
Hexane-soluble extractive:	Not less than 6 per cent,	Appendix 7.2.3
**Sulphated ash:*	80 to 82 per cent,	Appendix 7.6.9
**pH (1% aqueous solution):*	9.3 to 10.5,	Appendix 7.2.4
**Total alkalies (calculated as carbonates):*	Not less than 20% w/w,	Appendix 7.2.6

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* For these tests and assays, collect sufficient quantity of the coated material from a set of K¾āra Sūtra, by scraping gently with a spatula.

Assay:

Sodium:	Not less than 1 per cent,	Appendix 7.2.5
Potassium:	Not less than 35 per cent,	Appendix 7.2.5
Curcumin:	Not less than 0.05 per cent,	Appendix 7.2.8
Turmeric:	Not less than 4 per cent,	Appendix 7.2.7
Euphol:	Not less than 3 per cent,	Appendix 7.2.10

Microbial limits: Appendix 2.4

Therapeutic uses: Bhagandara (Fistula-in-ano and other fistulae of perianal region), Nā²īvra´a (sinuses), Arśa (haermorrhoids), Du¾°a nā²īvra´a (chronic-infected, non-healing ulcers), Vra´a (ulcers), Vidhradhi (abscesses of different location, Pilonidal sinus, Injection sinus), Arbuda (tumor), Adhimā¼sa (external growth of muscle and skin), Yoni arśa (vaginal polyps).

Contraindications:

The sinuses which are connected with the following lesions away from the ano-rectal canal viz. Osteomyelitis of pelvic bones, Osteomyelitis of femur, Tuberculosis of hip joint, Tuberculosis of spine, Intra abdominal cold abscesses, Chronic/acute ulcerative colitis, Regional ileitis, Appendicitis, Intestinal & pelvic malignancies, Venereal diseases, Strictures of urethra causing urethral sinuses, Cases of RVF and VVF and Cron's disease etc.

Note: competent surgeon should make judicious decision on such conditions if *K¾ārasūtra* application is needed along with systemic treatment (Medical/Surgical).

Packing, Labeling and Storage: Giving a single fold, keep the thread inside a polythene sachet, pack in a glass tube, and seal it along with a silica bag (as dessicant). Label each pack as per requirement.

Storage: Keep in moisture free condition, away from direct sunlight & heat.

APPENDICES

APPENDICES

APPENDIX-1

APPARATUS FOR TESTS AND ASSAYS

1.1. - Nessler Cylinders

Nessler cylinders which are used for comparative tests are matched tubes of clear colourless glass with a uniform internal diameter and flat, transparent base. They comply with Indian Standard 4161-1967. They are of transparent glass with a nominal capacity of 50 ml. The overall height is about 150 mm, the external height to the 50 ml mark 110 to 124 mm, the thickness of the wall 1.0 to 1.5 mm and the thickness of the base 1.5 to 3.0 mm. The external height to the 50 ml mark of the cylinder used for a test must not vary by more than 1 mm.

1.2. - Sieves

Sieves for pharmacopoeial testing are constructed from wire cloth with square meshes, woven from wire of brass, bronze, stainless steel or any other suitable material. The wires should be of uniform circular cross-section and should not be coated or plated. There must be no reaction between the material of the sieve and the substance being sifted.

Sieves conform to the following specifications –

Table 1

Approximate sieve number*	Nominal mesh aperture size mm	Tolerance average aperture size ± mm
4	4.0	0.13
6	2.8	0.09
8	2.0	0.07
10	1.7	0.06
12	1.4	0.05
16	1.0	0.03
--	µm	±µm
22	710	25
25	600	21
30	500	18
36	425	15
44	355	13
60	250	3(9.9) **

85	180	11(7.6)
100	150	9.4(6.6)
120	125	8.1(5.8)
150	106	7.4(5.2)
170	90	6.6(4.6)
200	75	6.1(4.1)
240	63	5.3(3.7)
300	53	4.8(3.4)
350	45	4.8(3.1)

* Sieve number is the number of meshes in a length of 2.54 cm. in each transverse direction parallel to the wires.

** Figures in brackets refer to close tolerances, those without brackets relate to full tolerances.

1.3. - Thermometers

Unless otherwise specified, thermometers suitable for pharmacopoeial tests conform to Indian Standard 4825-1968 and are standardised in accordance with the 'Indian Standard Method of Calibrating Liquid-in-Glass Thermometers', 6274-1971.

The thermometers are of the mercury-in-glass type and are filled with a dried inert gas, preferably nitrogen. They may be standardised for total immersion or for partial immersion. Each thermometer should be employed according to the condition of immersion under which it was standardised. In the selection of the thermometer it is essential to consider the conditions under which it is to be used.

1.4. - Ultraviolet Lamp (For general purposes and for chromatography work)

An instrument consisting of mercury vapour lamp and a filter which gives an emission band with maximum intensity at about 254 nm (near UV rays) and 366 nm (far UV rays) is used. To ensure that the required emission is being given by the lamp, carry out the following test periodically.

Apply to a plate coated with *silica gel* G, 5 µl of a 0.04 per cent w/v solution of *sodium salicylate* in *ethanol* (95%) for lamps of maximum output at 254 nm and 5 µl of a 0.2 per cent w/v solution in *ethanol* (95%) for lamps of maximum output at 365 nm. Examine the spot in a position normal to the radiation. The distance between the lamp and the plate under examination used in a pharmacopoeial test should not exceed the distance used to carry out the above test.

1.5. - Volumetric Glassware

Volumetric apparatus is normally calibrated at 27^0. However, the temperature generally specified for measurements of volume in the analytical operations of the pharmacopoeia, unless otherwise stated, is 25^0. The discrepancy is inconsequential as long as the room temperature in the laboratory is reasonably constant and is around 27^0.

Pharmacopoeial assays involving volumetric measurements require the use of accurately calibrated glassware. Volumetric apparatus must be suitably designed to assure accuracy. The design, construction and capacity of volumetric glassware should be in accordance with those laid down by the Bureau of Indian Standards. The tolerances on capacity for volumetric flasks, pipettes and burettes, as laid down in the relevant Indian Standards, are permisibile.

1.6. - Weights and Balances

Pharmacopoeial tests and assays require the use of analytical balances that vary in capacity, sensitivity and reproducibility. The accuracy needed for a weighing should dictate the type of balance. Where substances are to be "accurately weighed", the weighing is to be performed so as to limit the error to not more than 0.1 per cent. For example, a quantity of 50 mg is to be weighed to the nearest 0.05 mg; a quantity of 0.1 g is to be weighed to the nearest 0.1 mg; and quantity of 10 g is to be weighed to the nearest 10 mg. A balance should be chosen such that the value of three times the standard deviation of the reproducibility of the balance, divided by the amount to be weighed, does not exceed 0.001.

1.7. - Muslin Cloth

Muslin cloth is a cotton fabric where warp is 22 per cm±1 and weft is 18 ±1 per centimeter.

Method: Take a cardboard or an aluminium plate with a centimeter square opening. Keep the plate on the cloth to be used, so that the edges on the X or Y axis coincides with a warp or weft yarn in the fabric.Count the number of the threads of both warp and weft within the opening.

APPENDIX - 2

TESTS AND DETERMINATIONS

2.1. - Microscopic identification:

Microscopic identification of the botanical ingredients is a standard for statutory purposes in several solid and semi-solid compound formulations. Microscopic identification tests are confined to those formulations where the botanical ingredients are **not more than ten**, and where they are added *'in situ'* in powder form as *'Praksepa Dravyās'*. Such comminuted ingredients lend themselves for microscopic identification, as they are not drastically changed in cell structure or contents while processing, and appear intact in microscopic slide preparations, after proper treatment.

Appropriate processing for separation and isolation of botanical debris from a formulation without loss of debris, by hand picking, shifting, washing, sedimentation, density separation or by floatation etc., are the preliminary steps. This is followed by clearing the debris in chemical reagents, reacting it with suitable reagents and stains and finally mounting a little part on a slide in a medium of suitable refractive index (see later part) that helps to show the unit structures in good relief. Identification of the discrete, but disoriented units from the botanical ingredients in a formulation will not be possible without proper isolation, and should not be attempted.

Monographs where the test is prescribed give both a relevant method of isolation and diagnostic features specific to the expected ingredients in that formulation. Only a brief method and a few of the characteristics for each ingredient are given, but an analyst may use other methods of isolation and choose more characteristics to draw a correct conclusion.

Although monographs prescribe standards only for the *'Praksepa Dravyās'*, characteristics from other ingredients that are processed into extracts or decoctions prior to their addition to a formulation may also be seen in a slide preparation, giving rise to recognisable unique characteristics. In addition, cell or tissue structures common to several ingredients added to a formulation, and therefore not specific to any one of them, would also be present. Caution should therefore be exercised so that such features are not construed as parts from adulterants or substitutes or foreign parts. Proper study of the individual ingredients using authentic material and reference to their monographs in the Ayurvedic Pharmacopoeia for Single Drugs would help avoid errors of this nature. Skill in the recognition of discrete and disoriented tissue components and the knowledge required to ascribe them to their correct source should be acquired by the analyst.

A. Stains and Reagents for Microchemical Reactions:

The Ayurvedic Pharmacopoeia volumes on single drugs already include microchemical reactions for ergastic substances and may be consulted in addition to the following for use on isolated debris:

Acetic acid: Dilute 6 ml of glacial acetic acid with 100 ml of distilled water; *used for identification of cystoliths, which dissolve with effervescence.*

Aniline Chloride Solution: Dissolve 2 g in a mixture of 65 ml of 30 per cent ethyl alcohol and 15 ml distilled water and add 2 ml of conc. Hydrochloric acid. *Lignified tissues are stained bright yellow.*

Bismarck Brown: Dissolve 1 g in 100 ml of 95 per cent of ethyl alcohol; *used as a general stain for macerated material (with Schultze's).*

Chlorinated Soda Solution (Bleaching Solution): Dissolve 75 g of sodium carbonate in 125 ml of distilled water; triturate 50 g of chlorinated lime (bleaching powder) in a mortar with 75 ml of distilled water, adding it little by little. Mix the two liquids and shake occasionally for three or four hours. Filter and store, protected from light. *Used for lighting highly coloured material, by warming in it and washing the tissues thoroughly.*

Breamer's reagent: Dissolve 1 g of sodium tungstate and 2 g of sodium acetate in sufficient quantity of water to make 10 ml yellowish to brown precipitates; *indicate the presence of tannin.*

Canada Balsam (as a Mountant): Heat Canada balsam on a water bath until volatile matter is removed and the residue sets to a hard mass on cooling. Dissolve residue in xylene to form a thin syrupy liquid. *Used for making permanent mounts of reference slides of selected debris.*

Chloral Hydrate Solution: Dissolve 50 g of chloral hydrate in 20 ml of distilled water. *A valuable clarifying agent for rendering tissues transparent and clear, by freeing them from most of the ergastic substances, but leaving calcium oxalate crystals unaffected.*

Chloral Iodine: Saturate chloral hydrate solution with iodine, leaving a few crystals undissolved; useful *for detecting minute grains of starch otherwise undetectable.*

Chlorziniciodine (Iodinated Zinc Chloride solution): Dissolve 20 g of zinc chloride and 6.5 g of potassium iodide in 10 ml of distilled water. Add 0.5 g of iodine and shake for about fifteen minutes before filtering. Dilute if needed prior to use. *Renders cellulosic walls bluish violet and lignified walls yellowish brown to brown.*

Chromic acid Solution: 10 g of dissolved in 90 ml of dilute sulphuric acid: *macerating agent similar to Schultze's.*

Corallin Soda: Dissolve 5 g of corallin in 100 ml of 90 per cent ethyl alcohol. Dissolve 25 g of sodium carbonate in 100 ml distilled water; keep the solutions separate and mix when required, by adding 1 ml of the corallin solution to 20 ml of the aqueous sodium carbonate solution. Prepare fresh each time, as the mixture will not keep for long. *Used for staining sieve plates and callus bright pink and imparts a reddish tinge to starch grains and lignified tissues.*

Ammoniacal solution of Copper oxide (Cuoxam): Triturate 0.5 g of copper carbonate in a mortar with 10 ml of distilled water and gradually add 10 ml of strong solution of ammonia (sp. gr. 0.880) with continued stirring; *used for dissolving cellulosic materials.*

Eosin: 1 per cent solution in 90 per cent ethyl alcohol; *stains cellulose and aleurone grains red.*

Ferric Chloride solution: A per cent solution ferric chloride in distilled water. *Taninn containing tissues coloured bluish or greenish black.*

Glycerin: Pure or diluted as required with one or two volumes of distilled water. *Used as a general mountant.*

Haematoxylin, Delafield's: Prepare a saturated solution of ammonia alum. To 100 ml of this add a solution of 1 g of Haematoxylin in 6 ml of ethyl alcohol (97 per cent). Leave the mixed solution exposed to air and light in an unstopped bottle for three or four days. Filter and add to the filtrate 25 ml of glycerin and 25 ml of methyl alcohol. Allow the solution to stand exposed to light, till it acquires a dark colour (about two months). Refilter and store as a stock solution. Dilute it 3 or 4 times volumes with distilled water. *Stains cellulosic fibers blue; used only on water washed material.*

Iodine Water: Mix 1 volume of decinormal iodine with 4 volumes of distilled water. *Stains starch blue, and reveals crystalloids and globoids when present in aleurone grains.*

Iodine and Potassium iodide solution: Dissolve 1 g of *potassium iodide* in 200 ml of distilled water and 2 g of iodine; *stains lignified walls yellow and cellulosic walls blue.*

Lactophenol (Amman's Fluid): *Phenol* 20 g, *lactic acid* 20 g, *glycerin* 40 g, *distilled water* 20 ml dissolve; *reveals starch grains in polarised light with a well marked cross at hilum, and also minute crystals of calcium oxalate as brightly polarising points of light.*

Methylene blue: A solution in 25 ml of *ethyl alcohol* (95 per cent). *A general stain for nucleus and bacteria.*

Millon''s Reagent: Dissolve 1 volume of mercury in 9 volumes of fuming nitric acid (sp. Gr. 1.52), keeping the mixture well cooled during reaction. Add equal volume distilled water when cool. *Stains proteins red.*

Naphthol Solution: Dissolve 10 g of Naphthol in 100 ml of *ethyl alcohol*; *a specific stain for detection of inulin; cells containing inulin turn deep reddish violet.*

Pholorglucinol: 1 g of *phloroglucinol* dissolved in 100 ml of 90 per cent *ethyl alcohol*; mount debris in a few drops, allow to react for a minute, draw off excess of reagent with a filter paper strip, and add a drop of conc. hydrochloric acid to the slide; *lignified tissues acquire a deep purplish red colour; very effective on water washed material but not in chloral hydrate washed debris.*

Picric acid Solution (Trinitrophenol Solution): A saturated aqueous solution made by dissolving 1 g of picric acid in 95 ml of distilled water; *stains animal and insect tissues, a light to deep yellow; in a solution with ethyl alcohol, aleurone grains and fungal hyphae are stained yellow.*

Potash, Caustic: A 5 per cent aqueous solution*; used to separate tenacious tissues of epidermis and also laticiferous elements and vittae, both of which are stained brown.*

Ruthenium Red: Dissolve 0.008 g of ruthenium red in 10 ml of a 10 per cent solution of lead acetate; (to be freshly prepared) *used for identification of most kinds of mucilage containing tissues, which turn pink. A 0.0008 g ruthenium red dissolved in 10 ml of distilled water and used immediately stains cuticular tissues in debris to a light pink.*

Safranin: A 1 per cent solution in ethyl alcohol 50 per cent; *used to stain lignified cell walls deep red, even after clearing with choral hydrate.*

Schultze's Maceration Fluid: Add isolated debris to 50 per cent conc. *nitric acid* in a test tube and warm over water bath: add a few crystals of *potassium chlorate* while warming, till tissues soften; cool, wash with water thoroughly and tease out for mounting hard tissues; *isolated cell structures are clearly revealed, but the structures are not useful for measurement of dimensions*.

Sudan Red III: Dissolve 0.01 g of sudan red III in 5 ml of *ethyl alcohol* (90 per cent) and 5 ml of pure *glycerin*; *suberised walls of cork cells, and fatty material in cells are stained bright red.*

Sulphovanadic Acid (Mandelin's Reagent)**:** Triturate 1 g of ammonium vandate with 100 ml conc. s*ulphuric acid*. Allow the deposit to subside and use the clear liquid. *This is to be prepared fresh; useful for identification of alkaloids, particularly strychnine which turns violet in the cells containing it.*

Table 3 - Refractive Indices of Certain Mountants

Water	1.333
Lactophenol	1.444
Chloral Hydrate solution	1.44 to 1.48
Olive oil	1.46 to 1.47
Glycerol	1.473
Castor oil	1.48
Clove oil	1.53
Cresol	1.53
Cassia oil	1.6
Xylol	1.49
Alcohol	1.36
Chloroform	1.44

2.2. - Determination of Quantitative Data:

2.2.1. - Net Content: The content of the final or retail pack shall not be less than 98 percent of the declared net content.

2.2.2. - Foreign Matter: The sample shall be free from visible signs of mold growth, sliminess, stones, rodent excreta, insects or any other noxious foreign matter when examined as given below.

Take a representative portion from a large container, or remove the entire contents of the packing if 100 g or less, and spread in a thin layer in a suitable dish or tray. Examine

in daylight with unaided eye.Transfer suspected particles, if any, to a petri dish, and examine with 10x lens in daylight.

2.2.3. - Determination of Total Ash:

Incinerate about 2 to 3 g accurately weighed, of the ground drug in a tared platinum or silica dish at a temperature not exceeding 450^0 until free from carbon, cool and weigh. If a carbon free ash cannot be obtained in this way, exhaust the charred mass with hot water, collect the residue on an ashless filter paper, incinerate the residue and filter paper, add the filtrate, evaporate to dryness, and ignite at a temperature not exceeding 450^0. Calculate the percentage of ash with reference to the air-dried drug.

2.2.4. - Determination of Acid-Insoluble Ash:

To the crucible containing total ash, add 25 ml of *dilute hydrochloric acid*. Collect the insoluble matter on an ashless filter paper (Whatman 41) and wash with hot water until the filtrate is neutral. Transfer the filter paper containing the insoluble matter to the original crucible, dry on a hot-plate and ignite to constant weight. Allow the residue to cool in a suitable desiccator for 30 minutes and weigh without delay. Calculate the content of acid-insoluble ash with reference to the air-dried drug.

2.2.5. - Determination of Water Soluble Ash:

Boil the ash for 5 minutes with 25 ml of water; collect insoluble matter in a Gooch crucible or on an ashless filter paper, wash with hot water, and ignite for 15 minutes at a temperature not exceeding 450^0. Subtract the weight of the insoluble matter from the weight of the ash; the difference in weight represents the water-soluble ash. Calculate the percentage of water-soluble ash with reference to the air-dried drug.

2.2.6. - Determination of Sulphated Ash:

Heat a silica or platinum crucible to redness for 10 minutes, allow to cool in a desiccator and weigh. Put 1 to 2 g of the substance, accurately weighed, into the crucible, ignite gently at first, until the substance is thoroughly charred. Cool, moisten the residue with 1 ml of *sulphuric acid*, heat gently until white fumes are no longer evolved and ignite at $800^0 \pm 25^0$ until all black particles have disappeared. Conduct the ignition in a place protected from air currents. Allow the crucible to cool, add a few drops of *sulphuric acid* and heat. Ignite as before, allow to cool and weigh. Repeat the operation until two successive weighing do not differ by more than 0.5 mg.

2.2.7. - Determination of Alcohol Soluble Extractive:

Macerate 5 g of the air dried drug, coarsely powdered, with 100 ml of alcohol the specified strength in a closed flask for twenty-four hours, shaking frequently during six hours and allowing to stand for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105^0, to constant weight and weigh. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried drug.

2.2.8. - Determination of Water Soluble Extractive:

Proceed as directed for the determination of alcohol-soluble extractive, using *chloroform-water* instead of ethanol.

2.2.9. - Determination of Ether Soluble Extractive (Fixed Oil Content):

Transfer a suitably weighed quantity (depending on the fixed oil content) of the air-dried, crushed drug to an extraction thimble, extract with *solvent ether* (or *petroleum ether*, b.p. 40^0 to 60^0) in a continuous extraction apparatus (Soxhlet extractor) for 6 hours. Filter the extract quantitatively into a tared evaporating dish and evaporate off the solvent on a water bath. Dry the residue at 105^0 to constant weight. Calculate the percentage of ether-soluble extractive with reference to the air-dried drug.

2.2.10. - Determination of Moisture Content (Loss on Drying):

Procedure set forth here determines the amount of volatile matter (i.e., water drying off from the drug). For substances appearing to contain water as the only volatile constituent, the procedure given below, is appropriately used.

Place about 10 g of drug (without preliminary drying) after accurately weighing (accurately weighed to within 0.01 g) it in a tared evaporating dish. For example, for unground or unpowderd drug, prepare about 10 g of the sample by cutting shredding so that the parts are about 3 mm in thickness.

Seeds and fruits, smaller than 3 mm should be cracked. Avoid the use of high speed mills in preparing the samples, and exercise care that no appreciable amount of moisture is lost during preparation and that the portion taken is representative of the official sample. After placing the above said amount of the drug in the tared evaporating dish, dry at 105^0 for 5 hours, and weigh. Continue the drying and weighing at one hour interval until difference between two successive weighing corresponds to not more than 0.25 per cent. Constant weight is reached when two consecutive weighing after drying for 30 minutes and cooling for 30 minutes in a desiccator, show not more than 0.01 g difference.

2.2.11. - Determination of Volatile Oil in Drugs

The determination of volatile oil in a drug is made by distilling the drug with a mixture of *water* and *glycerin*, collecting the distillate in a graduated tube in which the aqueous portion of the distillate is automatically separated and returned to the distilling flask, and measuring the volume of the oil. The content of the volatile oil is expressed as a percentage v/w.

The apparatus consists of the following parts (see Fig. 1). The clevenger's apparatus described below is recommended but any similar apparatus may be used provided that it permits complete distillation of the volatile oil. All glass parts of the apparatus should be made of good quality resistance glass.

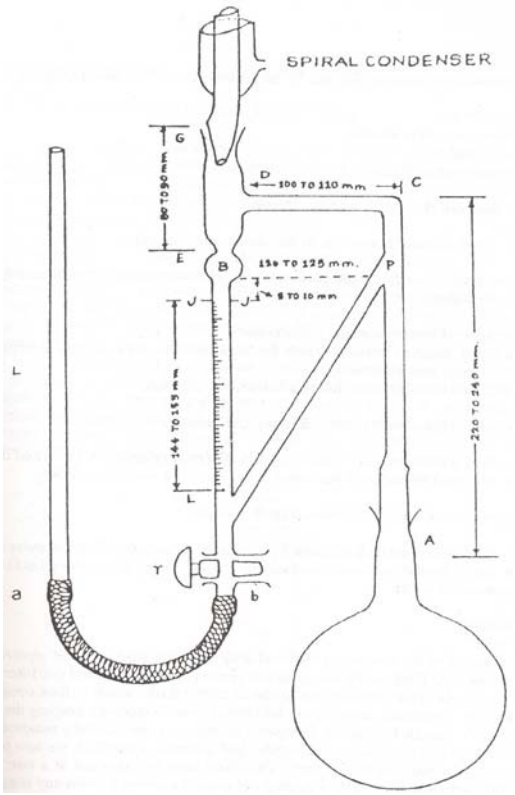

Fig. 1 Apparatus for volatile oil determination

The apparatus is cleaned before each distillation by washing successively with *acetone* and *water*, then inverting it, filling it with *chromic sulphuric acid* mixture, after closing the open end at G, and allowing to stand, and finally rinsing with water.

Method of determination:

A suitable quantity of the coarsely powdered drug together with 75 ml of *glycerin* and 175 ml of *water* in the one litre distilling flask, and a few pieces of porous earthen ware and one filter paper 15 cm cut into small strips, 7 to 12 mm wide, are also put in the distilling flask, which is then connected to the still head. Before attaching the condenser, water is run into the graduated receiver, keeping the tap T open until the water overflows, at P. Any air bubbles in the rubber tubing a—b are carefully removed by pressing the tube. The tap is then closed and the condenser attached. The contents of the flask are now heated and stirred by frequent agitation until ebullition commences. The distillation is continued at a rate, which keeps the lower end of the condenser cool. The flask is rotated occasionally to wash down any material that adheres to its sides.

At the end of the specified time (3 to 4 hours) heating is discontinued, the apparatus is allowed to cool for 10 minutes and the tap T is opened and the tube L_1 lowered slowly; as soon as the layer of the oil completely enters into the graduated part of the receiver the tap is closed and the volume is read.

The tube L_1 is then raised till the level of water in it is above the level of B, when the tap T is slowly opened to return the oil to the bulb. The distillation is again continued for another hour and the volume of oil is again read, after cooling the apparatus as before. If necessary, the distillation is again continued until successive readings of the volatile oil do not differ.

The measured yield of volatile oil is taken to be the content of volatile oil in the drug. The dimensions of the apparatus may be suitably modified in case of necessity.

2.2.12. - Special Processes Used in Alkaloidal Assays:

A-Continuous extraction of drug:

Where continuous extraction of a drug of any other substance is recommended in the monograph, the process consists of percolating it with suitable solvent at a temperature approximately that of the boiling point of the solvent. Any apparatus that permits the uniform percolation of the drug and the continuous flow of the vapour of the solvent around the percolator may be used. The type commonly known as the Soxhlet apparatus is suitable for this purpose.

B -Tests for complete extraction of alkaloids: Complete extraction is indicated by the following tests:

When extracting with an aqueous or alcoholic liquid: After extracting at least three times with the liquid, add to a few drops of the next portion, after acidifying with 2 *N hydrochloric acid* if necessary, 0.05 ml of *potassium mercuri-iodide solution* or for solanaceous alkaloids 0.05 ml of *potassium iodobismuthate solution;* no precipitate or turbidity, is produced.

When extracting with an immiscible solvent: After extracting at least three times with the solvent, add to 1 to 2 ml of the next portion 1 to 2 ml of 0.1 *N hydrochloric acid*, remove the organic solvent by evaporation, transfer the aqueous residue to a test tube, and add 0.05 ml of *potassium mercuri-iodide solution* for solanaceous alkaloids 0.05 ml of *potassium iodobismuthate solution* or for emetine, 0.05 ml of *iodine solution;* not more than a very faint opalescenece is produced.

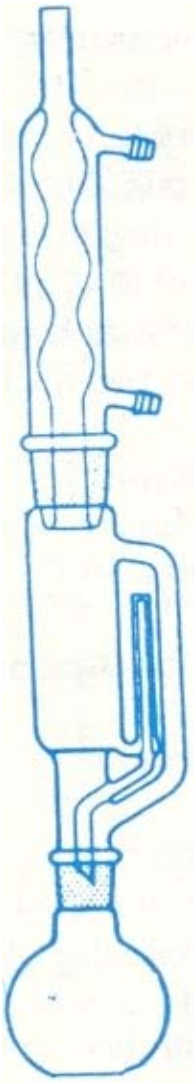

Fig. 2 - Apparatus for the continuous extraction of Drugs (Soxhlet apparatus)

2.2.13. - Thin-Layer Chromatography (TLC):

Thin-layer chromatography is a technique in which a solute undergoes distribution between two phases, stationary phase acting through adsorption and a mobile phase in the form of a liquid. The adsorbent is a relatively thin, uniform layer of dry finely powdered material applied to a glass, plastic or metal sheet or plate. Precoated plates are most commonly used. Separation may also be achieved on the basis of partition or a combination of partition and adsorption, depending on the particular type of support, its preparation and its use with different solvent.

Identification can be effected by observation of spots of identical R_f value and about equal magnitude obtained, respectively, with an unknown and a reference sample chromatographed on the same plate. A visual comparison of the size and intensity of the spots usually serves for semi-quantitative estimation.

Apparatus:

(a) Flat glass plates of appropriate dimensions which allow the application at specified points of the necessary quantities of the solution being examined and appropriate reference solutions and which allow accommodation of the specified migration path-length. The plates are prepared as described below; alternatively, commercially prepared plates may be used.

(b) An aligning tray or a flat surface on which the plates can be aligned and rested when the coating substance is applied.

(c) The adsorbent or coating substance consisting of finely divided adsorbent materials, normally 5 µm to 40 µm in diameter is suitable for chromatography. It can be applied directly to the plate or can be bonded to the plate by means of plaster of paris (Hydrated Calcium Sulphate) or with any other suitable binders. The adsorbent may contain fluorescing material to help in visualising spots that absorb ultra-violet light.

(d) A spreader which, when moved over the glass plate, will apply a uniform layer of adsorbent of desired thickness over the entire surface of the plate.

(e) A storage rack to support the plates during drying and transportation.

(f) A developing chamber that can accommodate one or more plates and can be properly closed and sealed. The chamber is fitted with a plate support rack that supports the plates, back to back, with lid of the chamber in place.

(g) Graduated micro-pipettes capable of delivering microlitre quantities say 10 µl and less.

(h) A reagent sprayer that will emit a fine spray and will not itself be attacked by the reagent.

(i) An ultra-violet light, suitable for observation at short (254 nm) and long (366 nm) ultra-violet wavelengths.

Preparation of plates: Unless otherwise specified in the monograph, the plates are prepared in the following manner. Prepare a suspension of the coating substance in accordance with the instructions of the supplier and, using the spreading device designed for the purpose, spread a uniform layer of the suspension, 0.20 to 0.30 mm thick, on a flat glass plate 20 cm long. Allow the coated plates to dry in air, heat at 100^0 to 105^0 for at least 1 hour (except in the case of plates prepared with cellulose when heating for 10 minutes is normally sufficient) and allow to cool, protected from moisture. Store the plates protected from moisture and use within 3 days of preparation. At the time of use, dry the plates again, if necessary, as prescribed in the monographs. Now a days pre coated plates of silica gel on glass/aluminium/ plastic sheets are also available.

Method:

Unless unsaturated conditions are prescribed, prepare the tank by lining the walls with sheets of filter paper; pour into the tank, saturating the filter paper in the process, sufficient of the mobile phase to form a layer of solvent 5 to 10 mm deep, close the tank and allow to stand for 1 hour at room temperature. Remove a narrow strip of the coating substance, about 5 mm wide, from the vertical sides of the plate. Apply the solutions being examined in the form of circular spots about 2 to 6 mm in diameter, or in the form of bands (10 to 20 mm x 2 to 6 mm unless otherwise specified) on a line parallel with, and 20 mm from, one end of the plate, and not nearer than 20 mm to the sides; the spots should be 15 mm apart. If necessary, the solutions may be applied in portions, drying between applications. Mark the sides of the plate 15 cm, or the distance specified in the monograph, from the starting line. Allow the solvent to evaporate and place the plate in the tank, ensuring that it is as nearly vertical as possible and that the spots or bands are above the level of the mobile phase. Close the tank and allow to stand at room temperature, until the mobile phase has ascended to the marked line. Remove the plate and dry and visualise as directed in the monograph; where a spraying technique is prescribed it is essential that the reagent be evenly applied as a fine spray.

For two-dimensional chromatography dry the plate after the first development and carry out the second development in a direction perpendicular to the first.

When the method prescribed in the monograph specifies ‘protected from light’ or ‘in subdued light’ it is intended that the entire procedure is carried out under these conditions.

Visualisation:

The phrases *ultra-violet light (254 nm)* and *ultra-violet light (366 nm)* indicate that the plate should be examined under an ultra-violet light having a maximum output at about 254 or at about 365 nm, as the case may be.

The term *secondary spot* means any spot other than the principal spot. Similarly, a *secondary band* is any band other than the principal band.

R_f Value :

Measure and record the distance of each spot from the point of its application and calculate the R_f value by dividing the distance travelled by the spots by the distance travelled by the front of the mobile phase.

2.2.14. - Starch estimation (Mont Gomery, 1957) [Spectrophotometric method]:

Prepare 10 per cent homogenate of the plant tissue in 80 per cent *ethanol*. Centrifuge at 2000 rpm for 15 minutes. To the residue thus obtained, add 4 ml of *distilled water*, heat on a water bath for 15 minutes and macerate with the help of glass rod. To each

of the samples, add 3 ml of *52* per cent *perchloric acid* and centrifuge at 2000 rpm for 15 minutes. The supernatant thus obtained is made upto known volume (generally upto 10 ml or depending on the expected concentration of starch). Take 0.1 ml aliquot, add 0.1 ml of 80 per cent *phenol* and 5 ml conc. sulphuric acid, cool and then read the absorbance at 490 nm.

2.2.15. - Sugar estimation (Mont Gomery, 1957) [Spectrophotometric method]:

Prepare 10 per cent homogenate of the plant tissue in 80 per cent *ethanol*. Centrifuge at 2000 rpm for 15 minutes. The supernatant obtained is made upto known volume (generally upto 10 ml or depending on the expected concentration of sugar). Take 0.1 ml aliquot, add 0.1 ml of 80 per cent phenol and 5 ml conc. sulphuric acid, cool and then read the absorbance at 490 nm.

2.2.16. - Fatty oil estimation:

To estimate fatty oils, extract accurately weighed air-dried powdered plant material with *petroleum ether* ($40\text{-}60^0$) in a Soxhlet apparatus. Dry the extract over *anhydrous sodium sulphate* and remove the solvent under vacuum at 40^0. Weigh the residue and calculate the percentage with reference to the weight of plant material used.

2.2.17. - Protein estimation (Lowry et. al 1951):

Homogenise 100 mg plant metarial with 3 ml of 10% *trichloroacetic acid*. Centrifuge the homogenate at 10,000 rpm. Discard the supernatant. Treat the pallets obtained after centrifugation with 3 ml *1N sodium hydroxide*, heat on water bath for 7 minutes and cool. Centrifuge the solution again for five to ten minutes at 5000 rpm. To 0.5 ml of supernatant thus obtained after centrifugation, add 5 ml reagent containing 100 parts of 2% solution of sodium carbonate and one part of 2% solution of *sodium potassium* tartrate. Allow it so stand for ten to fifteen minutes. Then add 5 ml *Folin and Ciocalteu's Phenol reagent* (diluted with distilled water in ratio of 1:1) and allow to stand for half-hour for development of colour and then finally measure the absorbance at 700 nm.

2.2.18. - Method for Alkaloid estimation:

Macerate the plant material with 2 per cent acetic acid in water, filter and concentrate the filtrate under reduced pressure at 45^0 to one third of the original volume. Adjust the pH to 2 by *4 M hydrochloric acid*. The yellow precipitate will be separated from the solution (A). Dissolve in it 0.1 M *hydrochloric acid* to give solution (B). Add *Mayer's reagent* to the solution A and B to give precipitate of alkaloid-Mayers reagent complex. Dissolve it again in *acetone - methanol - water* (6 : 2 : 10) to give solution. Pass this complex finally through Amberlite IRA 400 anion exchange resin (500 g) to give an aqueous solution of alkaloid chlorides.

2.3. - Limit Tests:

Table 4- Permissible Limits of Heavy Metals

S.No.	Heavy Metal contents	Permissible limits
1.	Lead	10 ppm
2	Arsenic	3 ppm
3.	Cadmium	0.3 ppm
4.	Mercury	1 ppm

2.3.1. - Limit Test for Arsenic

In the limit test for arsenic, the amount of arsenic is expressed as arsenic, As ppm

Apparatus –

A wide-mouthed bottle capable of holding about 120 ml is fitted with a rubber bung through which passes a glass tube. The latter, made from ordinary glass tubing, has a total length of 200 mm and an internal diameter of exactly 6.5 mm (external diameter about 8 mm). It is drawn out at one end to a diameter of about 1 mm and a hole not less than 2 mm in diameter is blown in the side of the tube, near the constricted part. When the bung is inserted in the bottle containing 70 ml of liquid, the constricted end of the tube is above the surface of the liquid, and the hole in the side is below the bottom of the bung. The upper end of the tube is cut off square, and is either slightly rounded or ground smooth.

Two rubber bungs (about 25 mm x 25 mm), each with a hole bored centrally and true, exactly 6.5 mm in diameter, are fitted with a rubber band or spring clip for holding them tightly together. Alternatively the two bungs may be replaced by any suitable contrivance satisfying the conditions described under *the General Test.*

Reagents:

Ammonium oxalate AsT: *Ammonium oxalate* which complies with the following additional test:

Heat 5 g with 15 ml of *water,* 5 ml of *nitric acid AsT,* and 10 ml of *sulphuric acid AsT* in narrow necked, round-bottomed flask until frothing ceases, cool, and apply the General Test; no visible stain is produced.

Arsenic solution, dilute, AsT:

Strong Arsenic solution AsT	1 ml
Water sufficient to produce	100 ml

Dilute arsenic solution, AsT must be freshly prepared.
1 ml contains 0.01 mg of arsenic, as.

Arsenic solution, strong, AsT:

Arsenic trioxide	0.132 g
Hydrochloric acid	50 ml
Water sufficient to produce	100 ml

Brominated hydrochloric acid AsT:

Bromine solution AsT	1 ml
Hydrochloric acid AsT	100 ml

Bromine solution AsT:

Bromine	30 g
Potassium bromide	30 g
Water sufficient to produce	100 ml

It complies with the following test:

Evaporate 10 ml on a water-bath nearly to dryness, add 50 ml of purified water, 10 ml of *hydrochloric acid AsT* and sufficient *stannous chloride solution AsT* to reduce the remaining bromine and apply the General Test; the stain produced is not deeper than 1 ml *standard stain,* showing that the proportion of arsenic present does not exceed 1 part per million.

Citric acid AsT: *Citric acid* which complies with the following additional tests: Dissolve 10 g in 50 ml of water add 10 ml of *stannated hydrochloric acid AsT* and apply the General Test; no visible stain is produced.

Hydrochloric acid AsT: *Hydrochloric acid* diluted with *water* to contain about 32 per cent w/w of *hydrochloride acid* and complying with the following additional tests:

(i) Dilute 10 ml with sufficient water to produce 50 ml, add 5 ml of *ammonium thiocyanate solution* and stir immediately; no colour is produced.

(ii) To 50 ml add 0.2 ml of *bromine solution AsT,* evaporate on a water-bath until reduced to 16 ml adding more *bromine solution AsT,* if necessary, in order that an excess, as indicated by the colour, may be present throughout the evaporation; add 50 ml of *water* and 5 drops of *stannous chloride solution AsT,* and apply the General Test; the stain produced is not deeper than a 0.2 ml *standard stain* prepared with the same acid, showing that the proportion of arsenic present does not exceed 0.05 part per million.

Hydrochloric acid (constant-boiling composition) As T : Boil *hydrochloric acid* AsT to constant boiling Composition in the presence of *hydrazine hydrate,* using 1 ml of 10 per cent w/v solution in *water* per litre of the acid.

***Mercuric Chloride Paper:** Smooth white filter paper, not less than 25 mm in width, soaked in a saturated solution of *mercuric chloride*, pressed to remove superfluous solution, and dried at about 60^0, in the dark. The grade of the filter paper is such that the weight is between 65 and 120 g per sq. mm; the thickness in mm of 400 papers is approximately equal numerically, to the weight in g per sq. mm.

Nitric acid AsT: *Nitric acid* which complies with the following additional test:

Heat 20 ml in a porcelain dish with 2 ml of *sulphuric acid AsT,* until white fumes are given off. Cool, add 2 ml of water, and again heat until white fumes are given off; cool, add 50 ml of water and 10 ml of *stannated hydrochloric acid AsT,* and apply the General Test; no visible stain is produced.

Potassium chlorate AsT: *Potassium chlorate* which complies with the following additional test:

Mix 5 g in the cold with 20 ml of *water* and 22 ml of *hydrochloric acid AsT;* when the first reaction has subsided, heat gently to expel chlorine, remove the last traces with a few drops of *stannous chloride solution AsT,* add 20 ml of water, and apply the General Test; no visible stain is produced.

Potassium iodide AsT: *Potassium iodide* which complies with the following additional test:

Dissolve 10 g in 25 ml of *hydrochloric acid AsT* and 35 ml of *water,* add 2 drops of *stannous chloride solution AsT* and apply the General Test; no visible stain is produced.

Potassium iodide AsT: *Potassium iodide* which complies with the following additional test:

Dissolve 10 g in 25 ml of *hydrochloric acid AsT* and 35 ml of *water,* add 2 drops of *stannous chloride solution AsT* and apply the General Test; no visible stain is produced.

Sodium carbonate, anhydrous AsT: *Anhydrous sodium carbonate* which complies with the following additional test:

Dissolve 5 g in 50 ml of *water,* add 20 ml of *brominated hydrochloric acid AsT,* remove the excess of bromine with a few drops of *stannous chloride solution AsT,* and apply the General Test; no visible stain is produced.

Sodium Salicylate: Of the Indian Pharmacopoeia.

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*NOTE –*Mercuric chloride paper should be stored in a stoppered bottle in the dark. Paper which has been exposed to sunlight or to the vapour of ammonia affords a lighter stain or no stain at all when employed in the limit test for arsenic.*

Stannated hydrochloric acid AsT:

Stannous chloride solution AsT	1 ml
Hydrochloric Acid AsT	100 ml

Stannous Chloride solution AsT: Prepared from *stannous chloride solution* by adding an equal volume of *hydrochloric acid*, boiling down to the original volume, and filtering through a fine-grain filter paper.

It complies with the following test:

To 10 ml add 6 ml of water and 10 ml of *hydrochloric acid AsT*, distil and collect 16 ml. To the distillate and 50 ml of *water* and 2 drops of *stannuous chloride solution AsT* and apply the General Test; the stain produced is not deeper than a 1-ml *standard stain,* showing that the proportion of arsenic present does not exceed 1 part per million.

Sulphuric acid AsT: *Sulphuric acid* which complies with the following additional test:

Dilute 10 g with 50 ml of water, add 0.2 ml of *stannous chloride solution AsT,* and apply the General Test; no visible stain is produced.

Zinc AsT: *Granulated Zinc* which complies with following additional test:

Add 10 ml of *stannated hydrochloric acid AsT* to 50 ml of *water*, and apply the General Test, using 10 of the zinc and allowing the action to continue for one hour; no visible stain is produced (limit of arsenic). Repeat the test with the addition of 0.1 ml of *dilute arsenic solution AsT;* a faint but distinct yellow stain is produced (test for sensitivity).

General Method of Testing: By a variable method of procedure suitable to the particular needs of each substance, a solution is prepared from the substance being examined which may or may not contain that substance, but contains the whole of the arsenic (if any) originally present in that substance. This solution, referred to as the `test solution', is used in the actual test.

General Test: The glass tube is lightly packed with cotton wool, previously moistened with *lead acetate solution* and dried, so that the upper surface of the cotton wool is not less than 25 mm below the top of the tube. The upper end of the tube is then inserted into the narrow end of one of the pair of rubber bungs, either to a depth of about 10 mm when the tube has a rounded-off end, or so that the ground end of the tube is flush with the larger end of the bung. A piece of *mercuric chloride paper* is placed flat on the top of the bung and the other bung placed over it and secured by means of the rubber band or spring clip in such a manner that the borings of the two bungs (or the upper bung and the glass tube) meet to form a true tube 6.5 mm in diameter interrupted by a diaphragm of *mercuric chloride paper*.

Instead of this method of attaching the *mercuric chloride paper,* any other method may be used provided (1) that the whole of the evolved gas passes through the paper; (2) that the portion of the paper in contact with the gas is a circle 6.5 mm in diameter; and (3) that the paper is protected from sunlight during the test. The test solution prepared as

specified, is placed in the wide-mouthed bottle, 1 g of *potassium iodide AsT* and 10 g of *zinc AsT* added, and the prepared glass tube is placed quickly in position. The action is allowed to proceed for 40 minutes. The yellow stain which is produced on the *mercuric chloride paper* if arsenic is present is compared by day light with the *standard stains* produced by operating in a similar manner with known quantities of *dilute arsenic solution AsT*. The comparison of the stains is made immediately at the completion of the test. The standard stains used for comparison are freshly prepared; they fade on keeping.

By matching the depth of colour with *standard stains*, the proportion of arsenic in the substance may be determined. A stain equivalent to the 1-ml standard stain, produced by operating on 10 g of substance indicates that the proportion of arsenic is 1 part per million.

NOTE: (1) The action may be accelerated by placing the apparatus on a warm surface, care being taken that the *mercuric chloride paper* remains dry throughout the test.

(2) The most suitable temperature for carrying out the test is generally about 40^0 but because the rate of the evolution of the gas varies somewhat with different batches zinc AsT, the temperature may be adjusted to obtain a regular, but not violent, evolution of gas.

(3) The tube must be washed with *hydrochloric acid AsT*, rinsed with water and dried between successive tests.

Standard Stains: Solutions are prepared by adding to 50 ml of water, 10 ml of *stannated hydrochloric acid AsT* and quantities of *dilute arsenic solutions AsT* varying from 0.2 ml to 1 ml. The resulting solutions, when treated as described in the General Test, yield stains on the *mercuric chloride paper* referred to as the standard stains.

Preparation of the Test Solution: In the various methods of preparing the test solution given below, the quantities are so arranged unless otherwise stated, that when the stain produced from the solution to be examined is not deeper than the 1-ml standard stain, the proportion of arsenic present does not exceed the permitted limit.

Ammonium Chloride: Dissolve 2.5 g in 50 ml of *water*, and 10 ml of *stannated hydrochloric acid AsT*.

Boric acid: Dissolve 10 g with 2 g of *citric acid AsT* in 50 ml water, and add 12 ml of *stannated hydrochloric acid AsT*.

Ferrous Sulphate: Dissolve 5 g in 10 ml of *water and 15 ml of stannated hydrochloric* acid *AsT and* disitil 20 ml; to the distillate add a few drops of *bromine solution AsT*. Add 2 ml of *stannated hydrochloric acid AsT*, heat under a reflux condenser for one hour, cool, and add 10 ml of *water* and 10 ml of *hydrochloric acid AsT*.

Glycerin: Dissolve 5 g in 50 ml of water, and add 10 ml of *stannated hydrochloric acid AsT*.

Hydrochloric acid: Mix 10 g with 40 ml of water and 1 ml of *stannous chloride solution AsT.*

Magnesium Sulphate: Dissolve 5 g in 50 ml of *water* and add 10 ml of stannated *hydrochloric acid AsT.*

Phosphoric acid: Dissolve 5 g in 50 ml of *water* and add 10 ml of *stannated hydrochloric acid AsT*

Potassium iodide: Dissolve 5 g in 50 ml of *water* and add 2 ml of *stannated hydrochloric acid AsT.*

Sodium bicarbonate: Dissolve 5 g in 50 ml of *water* and add 15 ml of *brominated hydrochloric acid AsT,* and remove the excess of bromine with a few drops of *stannous chloride solution AsT.*

Sodium hydroxide: Dissolve 2.5 g in 50 ml of *water,* add 16 ml of *brominated hydrochloric acid AsT,* and remove the excess of *bromine* with a few drops of *stannous chloride solution AsT.*

2.3.2. - Limit Test for Chlorides:

Dissolve the specified quantity of the substance in *water* or prepare a solution as directed in the text and transfer to a *Nessler cylinder.* Add 10 ml of *dilute nitric acid,* except when nitric acid is used in the preparation of the solution, dilute to 50 ml with water, and add 1 ml of *silver nitrate solution.* Stir immediately with a glass rod and allow to stand for 5 minutes. The opalescence produced is not greater than the *standard opalescence,* when viewed transversely.

Standard Opalescence:

Place 1.0 ml of a 0.05845 per cent w/v solution of *sodium chloride* and 10 ml of *dilute nitric acid* in a *Nessler cylinder*. Dilute to 50 ml with water and add 1 ml of *silver nitrate solution*. Stir immediately with a glass rod and allow to stand for five minutes.

2.3.3. - Limit Test for Heavy metals:

The test for heavy metals is designed to determine the content of metallic impurities that are coloured by sulphide ion, under specified conditions. The limit for heavy metals is indicated in the individual monographs in terms of the parts of lead per million parts of the substance (by weight), as determined by visual comparison of the colour produced by the substance with that of a control prepared from a standard lead solution.

Determine the amount of heavy metals by one of the following methods and as directed in the individual monographs. Method A is used for substances that yield clear colourless solutions under the specified test conditions. Method B is used for substances that do not yield clear, colourless solutions under the test conditions specified for method A, or for substances which, by virtue of their complex nature, interfere with the

precipitation of metals by sulphide ion. Method C is used for substances that yield clear, colourless solutions with *sodium hydroxide solution.*

Special Reagents:

Acetic acid Sp.: *Acetic acid* which complies with the following additional test : Make 25 ml alkaline with *dilute ammonia solution Sp.,* add 1 ml of *potassium cyanide solution Sp.,* dilute to 50 ml with *water* and add two drops of *sodium sulphide* solution; no darkening is produced.

Dilute acetic acid Sp.: *Dilute acetic acid,* which complies with the following additional test – Evaporate 20 ml in a porcelain dish, nearly to dryness on a water-bath. Add to the residue 2 ml of the acid and dilute with water to 25 ml, add 10 ml of *hydrogen sulphide solution.* Any dark colour produced is not more than that of a control solution consisting of 2 ml of the acid and 4.0 ml of *standard lead solution* diluted to 25 ml with *water.*

Ammonia solution Sp.: *Strong ammonia solution* which complies with the following additional test : Evaporate 10 ml to dryness on a water-bath; to the residue add 1 ml of *dilute hydrochloric acid Sp. a*nd evaporate to dryness. Dissolve the residue in 2 ml of dilute acetic acid Sp. Add sufficient water to produce 25 ml.

Add 10 ml of *hydrogen sulphide solution.* Any darkening produced is not greater than in a blank solution containing 2 ml of dilute acetic acid Sp. 1.0 ml of *standard lead solution* and sufficient *water* to produce 25 ml.

Dilute ammonia solution Sp.: *Dilute ammonia solution* which complies with the following additional test: To 20 ml add 1 ml of *potassium cyanide solution Sp.,* dilute to 50 ml with *water,* and add two drops of *sodium sulphide solution;* no darkening is produced.

Hydrochloric acid: *Hydrochloric acid* which complies with the following additional test: Evaporate off the acid in a beaker to dryness on a water-bath. Dissolve the residue in 2 ml of *dilute acid Sp.,* dilute to 17 ml with water and add 10 ml of *hydrogen sulphide solution;* any darkening produced is not greater than in a blank solution containing 2.0 ml of *standard lead solution,* 2 ml of *dilute acetic acid Sp.* and dilute to 40 ml with water.

Dilute hydrochloric acid Sp.: *Dilute hydrochloric acid,* which complies with the following additional test: Treat 10 ml of the acid in the manner described under *Hydrochloric acid Sp.*

Lead nitrate stock solution: Dissolve 0.1598 g of *lead nitrate* in 100 ml of *water* to which has been added 1 ml of *nitric acid,* then dilute with *water* to 1000 ml. This solution must be prepared and stored in polyethylene or glass containers free from soluble lead salts.

Standard lead solution: On the day of use, dilute 10.0 ml of *lead nitrate* stock solution with *water* to 100.0 ml. Each ml of *standard lead solution* contains the equivalent of 10 µg of lead. A control comparison solution prepared with 2.0 ml of standard lead solution contains, when compared to a solution representing 1.0 g of the substance being tested, the equivalent of 20 parts per million of lead.

Nitric acid Sp.: *Nitric acid* which complies with the following additional test: Dilute 10 ml with 10 ml of *water,* make alkaline with *ammonia solution Sp.,* add 1 ml of *potassium cyanide solution Sp.,* dilute to 50 ml with water, and add two drops of *sodium sulphide solution;* no darkening is produced.

Potassium cyanide solution Sp.: See Appendix 2.3.5.

Sulphuric acid Sp.: Sulphuric acid which complies with following additional test: Add 5 g to 20 ml of *water* make alkaline with *ammonia solution Sp.,* add 1 ml of *potassium cyanide solution Sp.,* dilute to 50 ml with *water* and add two drops of *sodium sulphide solution;* no darkening is produced.

Method A

Standard solution: Into a 50 ml *Nessler cylinder,* pipette 2 ml of *standard lead solution* and dilute with *water* to 25 ml. Adjust with *dilute acetic acid Sp.* or *dilute ammonia solution Sp* to a pH between 3.0 and 4.0, dilute with *water* to about 35 ml, and mix.

Test solution: In to a 50 ml *Nessler cylinder,* place 25 ml of the solution prepared for the test as directed in the individual monograph, or using the stated volume of acid when specified in the individual monograph, dissolve and dilute with *water* to 25 ml the specified quantity of the substance being tested. Adjust with *dilute acetic acid Sp.* or *dilute ammonia solution Sp.* to a pH between 3.0 and 4.0, dilute with *water* to about 35 ml and mix.

Procedure: To each of the cylinders containing the *standard solution* and test solution, respectively, add 10 ml of freshly prepared *hydrogen sulphide solution,* mix, dilute with *water* to 50 ml, allow to stand for five minutes, and view downwards over a white surface; the colour produced in the *test solution* is not darker than that produced in the *standard solution.*

Method B

Standard solution: Proceed as directed under Method A.

Test solution: Weigh in a suitable crucible the quantity of the substance specified in individual monograph, add sufficient *sulphuric acid Sp.* to wet the sample, and ignite carefully at a low temperature until thoroughly charred. Add to the charred mass 2 ml of *nitric acid Sp.* and five drops of *sulphuric acid Sp.* and heat cautiously until white fumes are no longer evolved. Ignite, preferably in a muffle furnace, at 500^0 to 600^0 until the carbon is completely burnt off. Cool, add 4 ml of *hydrochloric acid Sp.,* cover, digest on a water bath for 15 minutes, uncover and slowly evaporate to dryness on a water-bath. Moisten the residue with one drop of *hydrochloric acid Sp.,* add 10 ml of hot water and digest for two minutes. Add *ammonia solution* sp.*,* dropwise, until the solution is just alkaline to *litmus paper,* dilute with *water* to 25 ml and adjust with dilute acetic acid Sp. to a pH between 3.0 and 4.0. Filter if necessary, rinse the crucible and the filter with 10 ml of water, combine the filtrate and washings in a 50 ml *Nessler cylinder,* dilute with *water,* to about 35 ml, and mix. Procedure: Proceed as directed under Method A.

Method C

Standard solution: Into a 50 ml *Nessler cylinder,* pipette 2 ml of *standard lead solution,* add 5 ml of *dilute sodium hydroxide solution.,* dilute with *water* to 50 ml and mix.

Test solution: Into a 50 ml *Nessler cylinder,* place 25 ml of the solution prepared for the test as directed in the individual monograph; or, if not specified otherwise in the individual monograph, dissolve the specified quantity in a mixture of 20 ml of *water* and 5 ml of *dilute sodium hydroxide solution.* Dilute 50 ml with water and mix.

Procedure: To each of the cylinders containing the *standard solution* and the *test solution,* respectively add 5 drops of *sodium sulphide solution,* mix, allow to stand for five minutes and view downwards over a white surface; the colour produced in the *test solution* is not darker than that produced in the *standard solution.*

2.3.4. - Limit Test for Iron

Standard Iron solution: Weigh accurately 0.1726 g of *ferric ammonium sulphate* and dissolve in 10 ml of 0.1 *N sulphuric acid* and sufficient *water* to produce 1000.0 ml. Each ml of this solution contains 0.02 mg of Fe.

Method:

Dissolve the specified quantity of the substance being examined in 40 ml of *water,* or use 10 ml of the solution prescribed in the monograph, and transfer to a *Nessler cylinder.* Add 2 ml of a 20 per cent w/v solution of *iron-free citric acid* and 0.1 ml of *thioglycollic acid,* mix, make alkaline with *iron-free ammonia solution,* dilute to 50 ml with *water* and allow to stand for five minutes. Any colour produced is not more intense than the standard colour.

Standard colour: Dilute 2.0 ml of *standard iron solution* with 40 ml of *water* in a *Nessler cylinder.* Add 2 ml of a 20 per cent w/v solution of *iron-free citric acid* and 0.1 ml of *thioglycollic acid,* mix, make alkaline with *iron-free ammonia solution,* dilute to 50 ml with *water* and allow to stand for five minutes.

2.3.5. - Limit Test for Lead

The following method is based on the extraction of lead by solutions of *dithizone*. All reagents used for the test should have as low a content of lead as practicable. All reagent solutions should be stored in containers of borosilicate glass. Glassware should be rinsed thoroughly with warm *dilute nitric acid,* followed by *water.*

Special Reagents:

(1) Ammonia-cyanide solution Sp.: Dissolve 2 g of *potassium cyanide* in 15 ml of *strong ammonia solution* and dilute with *water* to 100 ml.

(2) Ammonium citrate solution Sp.: Dissolve 40 g of *citric acid* in 90 ml *water.* Add two drops of phenol *red solution* then add slowly *strong ammonia solution* until the solution

acquires a reddish colour. Remove any lead present by extracting the solution with 20 ml quantities of *dithizone* extraction solution until the *dithizone* solution retains its orange-green colour.

(3) Dilute standard lead solution: Dilute 10.0 ml of *standard lead solution* with sufficient 1 per cent v/v solution of nitric acid to produce 100 ml. Each ml of this solution contains 1 µg of lead per ml.

(4) Dithizone extraction solution: Dissolve 30 mg of *diphenylthiocarbazone* in 1000 ml of *chloroform* and add 5 ml of *alcohol.* Store the solution in a refrigerator. Before use, shake a suitable volume of the solution with about half its volume of 1 per cent v/v solution of *nitric acid* and discard the acid.

(5) Hydroxylamine hydrochloride solution Sp.: Dissolve 20 g of *hydroxylamine hydrochloride* in sufficient *water* to produce about 65 ml. Transfer to separator, add five drops of *thymol blue solution*, add *strong ammonia solution* until the solution becomes yellow. Add 10 ml of a 4 per cent w/v solution of *sodium diethyldithiocarbamate* and allow to stand for five minutes. Extract with successive quantities, each of 10 ml, of *chloroform* until a 5 ml portion of the extract does not assume a yellow colour when shaken with dilute copper sulphate solution. Add *dilute hydrochloric acid* until the solution is pink and then dilute with sufficient water to produce 100 ml.

(6) Potassium cyanide solution Sp.: Dissolve 50 g of *potassium cyanide* in sufficient *water* to produce 100 ml. Remove the lead from this solution by extraction with successive quantities, each of 20 ml of *dithizone extraction solution* until the dithizone solution retains its orange-green colour. Extract any dithizone remaining in the cyanide solution by shaking with *chloroform.* Dilute this cyanide solution with sufficient *water* to produce a solution containing 10 g of *potassium cyanide* in each 100 ml.

(7) Standard dithizone solution: Dissolve 10 ml of *diphenylthiocarbazone* in 1000 ml of *chloroform.* Store the solution in a glass-stoppered, lead-free bottle, protected from light and in a refrigerator.

(8) Citrate-cyanide wash solution: To 50 ml of *water* add 50 ml of *ammonium citrate solution Sp.* and 4 ml of *potassium cyanide solution Sp.*, mix, and adjust the pH, if necessary, with strong *ammonia solution* to 9.0.

(9) Buffer solution *p*H 2.5: To 25.0 ml of 0.2 *M potassium hydrogen phthalate add* 37.0 ml of 0.1 N *hydrochloric acid,* and dilute with sufficient *water* to produce 100.0 ml.

(10) Dithizone-carbon tetrachloride solution:– Dissolve 10 mg of *diphenylthiocarbazone* in 1000 ml of carbon tetrachloride. Prepare this solution fresh for each determination.

(11) *p*H 2.5 wash solution: To 500 ml of a 1 per cent v/v *nitric acid* add *strong ammonia solution* until the pH of the mixture is 2.5, then add 10 ml of *buffer solution* pH 2.5 and mix.

(12) Ammonia-cyanide wash solution: To 35 ml of pH 2.5 *wash solution* add 4 ml of *ammonia-cyanide solution Sp.,* and mix.

Method

Transfer the volume of the prepared sample directed in the monograph to a separator and unless otherwise directed in monograph, add 6 ml of *ammonium citrate solution Sp.,* and 2 ml *hydroxylamine hydrochloride solution Sp.,* (For the determination of lead in iron salts use 10 ml of *ammonium citrate solution Sp.).* Add two drops of *phenol red solution* and make the solution just alkaline (red in colour) by the addition *of strong ammonnia solution.* Cool the solution if necessary, and add 2 ml of *potassium cyanide solution* Sp. Immediately extract the solution with several quantities each of 5 ml, of *dithizone extraction solution,* draining off each extract into another separating funnel, until the dithizone extraction solution retains its green colour. Shake the combine dithizone solutions for 30 seconds with 30 ml of a 1 per cent w/v solution of *nitric acid* and discard the chloroform layer. Add to the solution exactly 5 ml of *standard dithizone solution* and 4 ml of *ammonia-cyanide solution* Sp. and shake for 30 seconds; the colour of the chloroform layer is of no deeper shade of violet than that of a control made with a volume of *dilute standard lead solution* equivalent to the amount of lead permitted in the sample under examination.

2.3.6. - Limit Test for Sulphates:

Reagents

Barium Sulphate reagent: Mix 15 ml of 0.5 *M barium chloride,* 55 ml of *water,* and 20 ml of *sulphate free alcohol,* add 5 ml of a 0.0181 per cent w/v solution of potassium sulphate, dilute to 100 ml with *water,* and mix. Barium sulphate reagent must be freshly prepared.

0.5 M Barium Chloride: *Barium chloride* dissolved in *water* to contain in 1000 ml 122.1 g of $BaCl_2$, $2H_2O$.

Method

Dissolve the specified quantity of the substance in *water,* or prepare a solution as directed in the text, transfer to a *Nessler cylinder,* and add 2 ml of *dilute hydrochloric acid,* except where *hydrochloric acid* is used in the preparation of the solution. Dilute to 45 ml with *water*, add 5 ml of barium sulphate reagent. Stir immediately with a glass rod, and allow to stand for five minutes. The turbidity produced is not greater than the *standard turbidity,* when viewed transversely. Standard turbidity : Place 1.0 ml of 0.1089 per cent w/v solution of potassium sulphate and 2 ml of *dilute hydrochloric acid* in a *Nessler cylinder*,dilute to 45 ml with *water,* add 5 ml of barium sulphate reagent, stir immediately with a glass rod and allow to stand for five minutes.

2.3.7. - Heavy Metals by Atomic absorption spectrophotometry:

Atomic absorption spectrophotometry is used in the determination of heavy metal elements and some nonmetal elements in the atomic state.

The light of characteristic wave length emitted from a cathodic discharge lamp is absorbed when it passes through the atomic vapor generated from sample containing the element being examined atomized to the ground state. The assay of the element being examined is tested by determining the decreased degree of light intensity of radiation. Atomic absorption obeys the general rule for absorption spectrophotometry. The assay is carried out by comparing the abosorbance of the test preparation with that of the reference preparation.

Apparatus

An atomic absorption spectrophotometer consists of a light source, an atomic generator, a monochromator and a detector system. Some are equipped with a background compensation system and automatic sampling system, etc.

1.Light Source: A hollow-cathode discharge lamp is usually used. The cathode is made of the element being examined.
2.Atomic Generator: There are four main types : flame atomizer, graphite furnace atomizer, hydride-generated atomizer, cold vapor atomizer.

(1) **Flame atomizer:** It mainly consists of a nebulizer and a burner. Its function is to nebulize the test solution into aerosol, which is mixed with combustion gas. And the mixture is introduced into the flame generated by the burner. So that the substance being examined is to be dried, evaporated to form the ground state atoms of the element being examined. The burning flame is generated by different mixtures of gases, acetylene-air is mostly used. By modifying the proportion of combustion gas, the temperature of the flame can be controlled and a better stability and a better sensitivity can be obtained.

(2) **Furnace atomizer:** It consists of electric furnace and a power supply. Its function is to dry and incinerate the substance being examined. During the stage of high temperature atomization, the ground state atoms of the element being examined are to be formed. Graphite is commonly used as the heater. Protection gas is introduced into the furnace to avoid oxidation and used to transfer the sample vapor.

(3) **Hydride-generated atomizer:** It consists of hydride generator and atomic absorption cell. It is used for the determination of the elements such as arsenic, selenium and antimony etc. Its function is to reduce the element to be examined in acidic medium to the low-boiling and easily pyrolyzed hydride. The hydride is then swept by a stream of carrier gas into the atomic absorption cell which consists of quartz tube and heater etc., in which the hydride is pyrolyzed by heating to form the ground-state atom.

(4) **Cold vapor atomizer:** It consists of a mercury vapor atomizer and an absorption cell. It is suitable for the determination of mercury. Its function is to reduce the mercuric ion into mercury vapor which is swept into the quartz absorption cell by carrier gas.

3. Monochromator: Its function is to separate the specified wavelength radiation from the electromagnetic radiations erradiated from the light source. The optical path of the

apparatus should assure the good spectra resolution and has the ability to work well at the condition of narrow spectral band (0.2 nm). The commonly used wavelength region is 190.0 - 900.0 nm.

4. Detector system: It consists of a detector, a signal processor and a recording system. It should have relatively higher sensitivity and better stability and can follow the rapid change of the signal absorption.

5. Background compensation system: System employed for the correction of atmospheric effects on the measuring system. Four principles can be utilized for background compensation: continuous spectrum sources (a deuterium lamp is often used in the UV region), the Zeeman effect, the self inversion phenomenon and the non resonance spectrum. In the analysis using atomic absorption spectrophotometry, the interference to the determination caused by background and other reasons should be noticed. Changes of some experimental conditions, such as the wavelength, the slit width, the atomizing condition, etc., may affect the sensitivity, the stability and the interference. If it is flame, the suitable wavelength, slit width and flame temperature, the addition of complexing agents and releasing agents and the use of Standard addition method may eliminate interference. If it is furnace, system, the selection of suitable background compensation system and the addition of suitable matrix modifying agents, etc may remove the interference. Background compensation method shall be selected as specified in the individual monograph.

Procedure

Method (direct calibration method)

Prepare not less than 3 reference solutions of the element being examined of different concentrations, covering the range recommended by the instrument manufacturer and add separately the corresponding reagents as that for the test solution and prepare the blank reference solution with the corresponding reagents. Measure the absorbances of the blank reference solution and each reference solution of different concentrations separately, record the readings and prepare a calibration curve with the average value of 3 readings of each concentration on the ordinate and the corresponding concentration on the abscissa.

Prepare a test solution of the substance being examined as specified in the monograph, adjust the concentration to fall within the concentration range of the reference solution. Measure the absorbance 3 times, record the readings and calculate the average value. Interpolate the mean value of the readings on the calibration curve to determine the concentration of the element.

When used in the test for impurities, prepare two test preparations of the same concentration as specified in the monograph. To one of the test preparation add an amount of the reference substance equivalent to the limit of the element specified in the monograph. Proceed as directed above and measure this solution to give an appropriate reading a; then measure the test preparation without the addition of the reference substance under the same condition and record the reading b; b is not greater than (a-b).

Determination of Lead, Cadmium, Arsenic, Mercury and Copper:

(1) Determination of lead (graphite oven method):

Determination conditions Reference condition: dry temperature: 100-120^0 , maintain 20 seconds; ash temperature: 400-750^0, maintain 20-25 seconds; atomic temperature: 1700-2100^0 , maintain 4-5 seconds; measurement wavelength: 283.3 nm; background calibration: deuterium lamp (D lamp) or Zeeman effect.

Preparation of lead standard stock solution: Measure accurately a quantity of lead single-element standard solution to prepare standard stock solution with 2 per cent nitric acid solution, which containing 1 μg per ml, stored at 0-5^0.

Preparation of calibration curve: Measure accurately a quantity of lead standard stock solutions respectively, diluted with 2 per cent nitric acid solution to the concentration of 0, 5, 20, 40, 60, 80 ng per ml, respectively. Measure respectively accurately 1 ml the above solution, add respectively 1 ml of 1 per cent ammonium dihydrogen phosphate and 0.2 per cent *magnesium nitrate* mix well, pipette accurately 20 μl to inject into the atomic generator of graphite oven and determine their absorbance, then draw the calibration curve with absorbance as vertical axis and concentration as horizontal ordinate.

Preparation of test solution:

Method: Weigh accurately 0.5 g of the coarse powder of the substance being examined, transfer into a casparian flask, add 5-10 ml of the mixture of *nitric acid* and *perchloric acid* (4 : 1), add a small hopper on the flask-top, macerate overnight, heat to slake on the electric hot plate, keep somewhat-boiling, if brownish-black, add again a quantity of the above mixture, continuously heat till the solution becomes clean and transparent, then raise temperature, heat continuously to thick smoke, till white smoke disperse, the slaked solution becomes colourless and transparent or a little yellow, cool, transfer it into a 50 ml volumetric flask, wash the container with 2 per cent *nitric acid solution* add the washing solution into the same volumetric flask and dilute with the same solvent to the volume, shake well. Prepare synchronously the reagent blank solution according to the above procedure.

Determination: Measure accurately 1 ml of the test solution and its corresponding reagent blank solution respectively, add 1 ml of solution containing 1per cent *ammonium dihydrogen phosphate* and 0.2 per cent *magnesium nitrate*, shake well, pipette accurately 10-20 μl to determine their absorbance according to the above method of "Preparation of calibration curve". Calculate the content of lead (Pd) in the test solution from the calibration curve.

(**2) Determination of cadmium (Cd) (graphite oven method):**

Determination conditions Reference condition: dry temperature: 100-120^0 , maintain 20 seconds; ash temperature: 300-500^0 , maintain 20-25 seconds; atomic temperature: 1500-1900^0, maintain 4-5 seconds; measurement wavelength: 228.8 nm; background calibration: deuterium lamp (D lamp) or Zeeman effect.

Preparation of Cd standard stock solution: Measure accurately a quantity of Cd single-element standard solution to prepare standard stock solution Cd with 2 per cent nitric acid, which containing 0.4 μg per ml Cd, stored at 0-5^0.

Preparation of calibration curve: Measure accurately a quantity of cadmium standard stock solutions, diluted to the concentration of 1.6, 3.2, 4.8, 6.4 and 8.0 ng per ml with 2 per cent nitric acid, respectively. Pipette accurately 10 μl the above solutions respectively, inject them into the graphite oven, determine their absorbance, and then draw the calibration curve with absorbance as vertical axis and concentration as horizontal ordinate.

Preparation of test solution: Reference to "Preparation of test solution" of Pb in the above.

Determination: Pipette accurately 10-20 μl of the test solution and its corresponding reagent blank solution respectively, determine their absorbance according to the above method of "Preparation of calibration curve. If interference occurs, weigh accurately respectively 1 ml of the standard solution, blank solution and test solution, add 1 ml of a solution containing 1per cent *ammonium dihydrogen phosphate* and 0.2 per cent *magnesium nitrate*, shake well, determine their absorbance according to the method above, calculate the content of Cd in the test solution from the calibration curve.

(3) Determination of Arsenic (As) (hydride method):

Determination conditions Apparatus: suitable hydride generator device, reducing agent: a solution containing 1 per cent *sodium borohydride* and 0.3 per cent *sodium hydroxide*; carrier liquid: 1 per cent *hydrochloric acid*; carrier gas: nitrogen; measurement wavelength: 193.7 nm; background calibration: deuterium lamp (D lamp) or Zeeman effect.

Preparation of As standard stock solution: Measure accurately a quantity of As single-element standard solution to prepare standard stock solution with 2 per cent *nitric acid* solution, which containis 1.0 μg per ml As, stored at $0\text{-}5^0$.

Preparation of calibration curve: Measure accurately proper quantity of arsenic standard stock solutions, diluted with 2 per cent *nitric acid* to the concentration of 2, 4, 8, 12 and 16 ng per ml respectively. Accurately transfer 10 ml of each into 25 ml volumetric flask respectively, add 1 ml of 25 per cent *potassium iodide solution* (prepared prior to use), shake well, add 1 ml of *ascorbic acid solution* (prepared prior to use), shake well, dilute with hydrochloric acid solution (20-100) to the volume, shake well, close the stopper and immerse the flask in a water bath at 80^0 for 3 minutes. Cool, transfer proper quantities of each solution respectively into the hydride generator device, determine the absorbance, then plot the calibration curve with peak area (absorbance) as vertical axis and concentration as horizontal ordinate.

Preparation of test solution: Reference to A or B method of "Preparation of test solution" of Pb in the above.

Determination: Pipette accurately 10 ml of the test solution and its corresponding reagent blank solution respectively, proceed as described under "Preparation of calibration curve" beginning at the words "add 1 ml of 25 per cent *potassium iodide solution*". Calculate the content of As in the test solution from the calibration curve.

(4) Determination of Mercury (Hg) (cold absorption method):

Determination conditions: Apparatus: suitable hydride generator device; reducing agent: a solution containing 0.5 per cent *sodium borohydride* and 0.1 per cent *sodium hydroxide*; carrier liquid: 1 per cent *hydrochloric acid*; carrier gas: nitrogen; measurement wavelength: 253.6 nm; background calibration: deuterium lamp (D lamp) or Zeeman effect.

Preparation of mercury standard stock solution: Measure accurately a proper quantity of mercury single-element standard solution to prepare standard stock solution with 2 per cent nitric acid solution, which containing 1.0 µg per ml Hg, stored at $0\text{-}5^0$.

Preparation of calibration curve: Measure accurately 0, 0.1, 0.3, 0.5, 0.7 and 0.9 ml of mercury standard stock solution, transfer into a 50 ml volumetric flask respectively, add 40 ml 4 per cent *sulphuric acid solution* and 0.5 ml of 5 per cent *potassium permanganate solution*, shake well, drop 5 per cent *hydroxylamine hydrochloride solution* until the violet red just disappears, dilute with 4 per cent *sulfuric acid solution* to the volume, shake well. A quantity of each solution is injected to the hydride generator device, determine the absorbance, then plot the calibration curve with peak area (absorbance) as vertical axis and concentration as horizontal ordinate.

Preparation of test solution:

Method : Transfer 1 g of the coarse powder of the substance being examined, accurately weighed, into a casparian flask, add 5-10 ml of the mixture solution of *nitric acid* and *perchloric acid* (4 : 1), mix well, fix a small hopper on the flask-top, immerse overnight, heat to slake on the electric hot plate at $120\text{-}140^0$ for 4-8 hours until *slaking* completely, cool, add a quantity of 4 per cent *sulfuric acid solution* and 0.5 ml of 5 per cent *potassium permanganate solution*, shake well, drop 5 per cent *hydroxylamine hydrochloride solution* until the violet red colour just disappears, dilute with 4 per cent *sulphuric acid solution*s to 25 ml, shake well, centrifugate if necessary, the supernatant is used as the test solution. Prepare synchronally the reagent blank solute based on the same procedure.

Determination: Pipette accurately a quantity of the test solution and its corresponding reagent blank solution, respectively, proceed as described under "Preparation of calibration curve" beginning at the words "add 1 ml of 25 per cent *potassium iodide solution*". Calculate the content of mercury (Hg) in the test solution from the calibration curve.

(5) Determination of Copper (flame method):

Determination conditions: Measurement wavelength: 324.7 nm; flame: air -acetylene flame; background calibration: deuterium lamp or Zeeman effect.

Preparation of copper standard stock solution: Measure accurately a proper quantity of copper single-element standard solution, to prepare the standard stock solution with 2 per cent *nitric acid solution*, which containing 10 µg per ml Cu, stored at $0\text{-}5^0$.

Preparation of calibration curve: Measure accurately a quantity of copper standard stock solutions, dilute with 2 per cent *nitric acid* to the concentrations of 0.05, 0.2, 0.4, 0.6 and 0.8 µg per ml, respectively. Inject each standard solution into the flame and determine the absorbance, respective, then plot the calibration curve with absorbance as vertical axis and concentration as horizontal ordinate.

Preparation of test solution: Reference to "Preparation of test solution" of Pb in the above.

Determination: Pipette accurately quantities of the test solution and its corresponding reagent blank solution respectively, proceed as described under "Preparation of calibration curve". Calculate the content of Cu in the test solution from the calibration curve.

2.4. - Microbial Limit Tests:

The following tests are designed for the estimation of the number of viable aerobic micro-organisms present and for detecting the presence of designated microbial species in pharmaceutical substances. The term 'growth' is used to designate the presence and presumed proliferation of viable micro-organisms.

Preliminary Testing

The methods given herein are invalid unless it is demonstrated that the test specimens to which they are applied do not, of themselves, inhibit the multiplication under the test conditions of micro-organisms that can be present. Therefore, prior to doing the tests, inoculate diluted specimens of the substance being examined with separate viable cultures of *Escherichia coli*, *Salmonella* species, *Pseudomonas aeruginosa* and *Staphylococcus aureus*. This is done by adding 1 ml of not less than 10^{-3} dilutions of a 24 h broth culture of the micro-organisms to the first dilution (in buffer solution pH 7.2, fluid soyabean-casein digest medium or fluid lactose medium) of the test material and following the test procedure. If the organisms fail to grow in the relevant medium the procedure should be modified by (a) increasing the volume of diluent with the quantity of test material remaining the same, or (b) incorporating a sufficient quantity of a suitable inactivating agent in the diluents, or (c) combining the aforementioned modifications so as to permit growth of the organisms in the media. If inhibitory substances are present in the sample, 0.5 per cent of soya lecithin and 4 per cent of polysorbate 20 may be added to the culture medium. Alternatively, repeat the test as described in the previous paragraph, using fluid casein digest-soya lecithin-polysorbate 20 medium to demonstrate neutralization of preservatives or other antimicrobial agents in the test material. Where inhibitory substances are contained in the product and the latter is soluble, the Membrane filtration method described under Total Aerobic Microbial Count may be used.

If in spite of incorporation of suitable inactivating agents and a substantial increase in the volume of diluent it is still not possible to recover the viable cultures described above and where the article is not suitable for applying the membrane filtration method it can be assumed that the failure to isolate the inoculated organism may be due to the bactericidal activity of the product. This may indicate that the article is not likely to be contaminated with the given species of micro-organisms. However, monitoring should be continued to establish the spectrum of inhibition and bactericidal activity of the article.

Media

Culture media may be prepared as given below or dehydrated culture media may be used provided that, when reconstituted as directed by the manufacturer, they have similar

ingredients and / or yield media comparable to those obtained from the formulae given below.

Where agar is specified in a formula, use agar that has a moisture content of not more than 15 per cent. Where water is called for in a formula, use purified water. Unless otherwise indicated, the media should be sterilized by heating in an autoclave at 115^0 for 30 minutes.

In preparing media by the formulas given below, dissolve the soluble solids in the water, using heat if necessary, to effect complete solution and add solutions of hydrochloric acid or sodium hydroxide in quantities sufficient to yield the required *p*H in the medium when it is ready for use. Determine the *p*H at $25^0 \pm 2^0$.

Baird-Parker Agar Medium

Pancreatic digest of casein	10.0	g
Beef extract	5.0	g
Yeast extract	1.0	g
Lithium chloride	5.0	g
Agar	20.0	g
Glycine	12.0	g
Sodium pyruvate	10.0	g
Water to	1000	ml

Heat with frequent agitation and boil for 1 minute. Sterilise, cool to between 45^0 and 50^0, and add 10 ml of a one per cent w/v solution of sterile *potassium tellurite* and 50 ml of egg-yolk emulsion. Mix intimately but gently and pour into plates. (Prepare the egg-yolk emulsion by disinfecting the surface of whole shell eggs, aseptically cracking the eggs, and separating out intact yolks into a sterile graduated cylinder. Add sterile saline solution, get a 3 to 7 ratio of egg-yolk to saline. Add to a sterile blender cup, and mix at high speed for 5 seconds). Adjust the *p*H after sterilization to 6.8 ± 0.2.

Bismuth Sulphite Agar Medium

Solution (1)

Beef extract	6	g
Peptone	10	g
Agar	24	g
Ferric citrate	0.4	g
Brilliant green	10	mg
Water to	1000	ml

Dissolve with the aid of heat and sterilise by maintaining at 115º for 30 minutes.

Solution (2)

Ammonium bismuth citrate	3	g
Sodium sulphite	10	g

Anhydrous disodium hydrogen Phosphate	5	g
Dextrose monohydrate	5	g
Water to	100	ml

Mix, heat to boiling, cool to room temperature, add 1 volume of solution (2) to 10 volumes of solution (1) previously melted and cooled to a temperature of 55^0 and pour.

Bismuth Sulphite Agar Medium should be stored at 2^0 to 8^0 for 5 days before use.

Brilliant Green Agar Medium

Peptone	10.0	g
Yeast extract	3.0	g
Lactose	10.0	g
Sucrose	10.0	g
Sodium chloride	5.0	g
Phenol red	80.0	g
Brilliant green	12.5	mg
Agar	12.0	g
Water to	1000	ml

Mix, allow to stand for 15 minutes, sterilise by maintaining at 115^0 for 30 minutes and mix before pouring.

Buffered Sodium Chloride-Peptone Solution pH 7.0

Potassium dihydrogen phosphate	3.56	g
Disodium hydrogen phosphate	7.23	g
Sodium chloride	4.30	g
Peptone (meat or casein)	1.0	g
Water to	1000	ml

0.1 to 1.0 per cent w/v polysorbate 20 or polysorbate 80 may be added. Sterilise by heating in an autoclave at 121^0 for 15 minutes.

Casein Soyabean Digest Agar Medium

Pancreatic digest of casein	15.0	g
Papaic digest of soyabean meal	5.0	g
Sodium chloride	5.0	g
Agar	15.0	g
Water to	1000	ml

Adjust the pH after sterilization to 7.3±0.2.

Cetrimide Agar Medium

Pancreatic digest of gelatin	20.0	g
Magnesium chloride	1.4	g

Potassium sulphate	10.0	g
Cetrimide	0.3	g
Agar	13.6	g
Glycerin	10.0	g
Water to	1000	ml

Heat to boiling for 1 minute with shaking. Adjust the *p*H so that after sterilization it is 7.0 to 7.4. Sterilise at 121^0 for 15 minutes.

Desoxycholate-Citrate Agar Medium

Beef extract	5.0	g
Peptone	5.0	g
Lactose	10.0	g
Trisodium citrate	8.5	g
Sodium thiosulphate	5.4	g
Ferric citrate	1.0	g
Sodium desoxycholate	5.0	g
Neutral red	0.02	g
Agar	12.0	g
Water to	1000	ml

Mix and allow to stand for 15 minutes. With continuous stirring, bring gently to the boil and maintain at boiling point until solution is complete. Cool to 80^0, mix, pour and cool rapidly.

Care should be taken not to overheat Desoxycholate Citrate Agar during preparation. It should not be remelted and the surface of the plates should be dried before use.

Fluid Casein Digest-Soya Lecithin-Polysorbate 20 Medium

Pancreatic digest of casein	20	g
Soya lecithin	5	g
Polysorbate 20	40	ml
Water to	1000	ml

Dissolve the pancreatic digest of casein and soya lecithin in water, heating in a water-bath at 48^0 to 50^0 for about 30 minutes to effect solution. Add polysorbate 20, mix and dispense as desired.

Fluid Lactose Medium

Beef extract	3.0	g
Pancreatic digest of gelatin	5.0	g
Lactose	5.0	g
Water to	1000	ml

Cool as quickly as possible after sterilization. Adjust the pH after sterilization to 6.9 ± 0.2.

Lactose Broth Medium

Beef extract	3.0	g
Pancreatic digest of gelatin	5.0	g
Lactose	5.0	g
Water to	1000	ml

Adjust the pH after sterilisation to 6.9±0.2.

Levine Eosin-Methylene Blue Agar Medium

Pancreatic digest of gelatin	10.0	g
Dibasic potassium phosphate	2.0	g
Agar	15.0	g
Lactose	10.0	g
Eosin Y	400	mg
Methylene blue	65	mg
Water to	1000	ml

Dissolve the pancreatic digest of gelatin, dibasic potassium phosphate and agar in water with warming and allow to cool. Just prior to use, liquefy the gelled agar solution and the remaining ingredients, as solutions, in the following amounts and mix. For each 100 ml of the liquefied agar solution use 5 ml of a 20 per cent w/v solution of lactose, and 2 ml of a 2 per cent w/v solution of eosin Y, and 2 ml of a 0.33 per cent w/v solution of methylene blue. The finished medium may not be clear. Adjust the *p*H after sterilisation to 7.1±0.2.

MacConkey Agar Medium

Pancreatic digest of gelatin	17.0	g
Peptone (meat and casein, equal parts)	3.0	g
Lactose	10.0	g
Sodium chloride	5.0	g
Bile salts	1.5	g
Agar	13.5	g
Neutral red	30	mg
Crystal violet	1	mg
Water to	1000	ml

Boil the mixture of solids and water for 1 minute to effect solution. Adjust the *p*H after sterilisation to 7.1 ± 0.2.

MacConkey Broth Medium

Pancreatic digest of gelatin	20.0	g
Lactose	10.0	g
Dehydrated ox bile	5.0	g
Bromocresol purple	10	mg
Water to	1000	ml

Adjust the *p*H after sterilisation to 7.3±0.2.

Mannitol-Salt Agar Medium

Pancreatic digest of gelatin	5.0	g
Peptic digest of animal tissue	5.0	g
Beef extract	1.0	g
D-Mannitol	10.0	g
Sodium chloride	75.0	g
Agar	15.0	g
Phenol red	25	mg
Water to	1000	ml

Mix, heat with frequent agitation and boil for 1 minute to effect solution. Adjust the *p*H after sterilisation to 7.4 ± 0.2.

Nutrient Agar Medium : Nutrient broth gelled by the addition of 1 to 2 per cent w/v of agar.

Nutrient Broth Medium

Beef extract	10.0	g
Peptone	10.0	g
Sodium chloride	5	mg
Water to	1000	ml

Dissolve with the aid of heat. Adjust the pH to 8.0 to 8.4 with *5M sodium hydroxide* and boil for 10 minutes. Filter, and sterilise by maintaining at 115^0 for 30 minutes and adjust the *p*H to 7.3±0.1.

Pseudomonas Agar Medium for Detection of Flourescein

Pancreatic digest of casein	10.0	g
Peptic digest of animal tissue	10.0	g
Anhydrous dibasic potassium phosphate	1.5	g
Magnesium sulphate hepta hydrate	1.5	g
Glycerin	10.0	ml
Agar	15.0	g
Water to	1000	ml

Dissolve the solid components in water before adding glycerin. Heat with frequent agitation and boil for 1 minute to effect solution. Adjust the *p*H after sterilisation to 7.2±0.2.

Pseudomonas Agar Medium for Detection of Pyocyanin

Pancreatic digest of gelatin	20.0	g
Anhydrous magnesium chloride	1.4	g
Anhydrous potassium sulphate	10.0	g
Agar	15.0	g
Glycerin	10.0	ml
Water to	1000	ml

Dissolve the solid components in water before adding glycerin. Heat with frequent agitation and boil for 1 minute to effect solution. Adjust the *p*H after sterilisation to 7.2±0.2.

Sabouraud Dextrose Agar Medium

Dextrose	40	g
Mixture of equal parts of peptic digest of animal tissue and Pancreatic digest of casein	10	g
Agar	15	g
Water to	1000	ml

Mix, and boil to effect solution. Adjust the *p*H after sterilisation to 5.6 ± 0.2.

Sabouraud Dextrose Agar Medium with Antibiotics

To 1 liter of Sabouraud Dextrose Agar Medium add 0.1 g of benzylpenicillin sodium and 0.1 g of tetracycline or alternatively add 50 mg of chloramphenicol immediately before use.

Selenite F Broth

Peptone	5	g
Lactose	4	g
Disodium hydrogen phosphate	10	g
Sodium hydrogen selenite	4	g
Water to	1000	ml

Dissolve, distribute in sterile containers and sterilise by maintaining at 100º for 30 minutes.

Fluid Selenite-Cystine Medium

Pancreatic digest of casein	5.0	g
Lactose	4.0	g
Sodium phosphate	10.0	g
Sodium hydrogen selenite	4.0	g
L-Cystine	10.0	mg
Water to	1000	ml

Mix and heat to effect solution. Heat in flowing steam for 15 minutes. Adjust the final *p*H to 7.0±0.2. Do not sterilise.

Tetrathionate Broth Medium

Beef extract	0.9	g
Peptone	4.5	g
Yeast extract	1.8	g
Sodium chloride	4.5	g
Calcium carbonate	25.0	g
Sodium thiosulphate	40.7	g
Water to	1000	ml

Dissolve the solids in water and heat the solution to boil. On the day of use, add a solution prepared by dissolving 5 g of potassium iodide and 6 g of iodine in 20 ml of water.

Tetrathionate-Bile-Brilliant Green Broth Medium

Peptone	8.6	g
Dehydrated ox bile	8.0	g
Sodium chloride	6.4	g
Calcium carbonate	20.0	g
Potassium tetrathionate	20.0	g
Brilliant green	70	mg
Water to	1000	ml

Heat just to boiling; do not reheat. Adjust the *p*H so that after heating it is 7.0±0.2.

Triple Sugar-Iron Agar Medium

Beef extract	3.0	g
Yeast extract	3.0	g
Peptone	20.0	g
Lactose	10.0	g
Sucrose	10.0	g
Dextrose monohydrate	1.0	g
Ferrous sulphate	0.2	g
Sodium chloride	5.0	g
Sodium thiosulphate	0.3	g
Phenol red	24	mg

Agar	12.0	g
Water to	1000	ml

Mix, allow standing for 15 minutes, bringing to boil and maintain at boiling point until solution is complete, mix, distributing in tubes and sterilising by maintaining at 115^0 for 30 minutes. Allow to stand in a sloped form with a butt about 2.5 cm long.

Urea Broth Medium

Potassium dihydrogen orthophosphate	9.1	g
Anhydrous disodium hydrogen phosphate	9.5	g
Urea	20.0	g
Yeast extract	0.1	g
Phenol red	10	mg
Water to	1000	ml

Mix, sterilise by filtration and distribute aseptically in sterile containers.

Vogel-Johnson Agar Medium

Pancreatic digest of casein	10.0	g
Yeast extract	5.0	g
Mannitol	10.0	g
Dibasic potassium phosphate	5.0	g
Lithium chloride	5.0	g
Glycerin	10.0	g
Agar	16.0	g
Phenol red	25.0	mg
Water to	1000	ml

Boil the solution of solids for 1 minute. Sterilise, cool to between 45^0 to 50^0 and add 20 ml of a 1 per cent w/v sterile solution of potassium tellurite. Adjust the *p*H after sterilisation to 7.0±0.2.

Xylose-Lysine-Desoxycholate Agar Medium

Xylose	3.5	g
L-Lysine	5.0	g
Lactose	7.5	g
Sucrose	7.5	g
Sodium chloride	5.0	g
Yeast extract	3.0	g
Phenol red	80	mg
Agar	13.5	g
Sodium desoxycholate	2.5	g
Sodium thiosulphate	6.8	g
Ferric ammonium citrate	800	mg
Water to	1000	ml

Heat the mixture of solids and water, with swirling, just to the boiling point. Do not overheat or sterilise. Transfer at once to a water-bath maintained at about 50^0 and pour into plates as soon as the medium has cooled. Adjust the final *p*H to 7.4 ± 0.2.

Sampling : Use 10 ml or 10 g specimens for each of the tests specified in the individual monograph.

Precautions : The microbial limit tests should be carried out under conditions designed to avoid accidental contamination during the test. The precautions taken to avoid contamination must be such that they do not adversely affect any micro-organisms that should be revealed in the test.

2.4.1. - Total Aerobic Microbial Count:

Pretreat the sample of the product being examined as described below.

Water-soluble products : Dissolve 10 g or dilute 10 ml of the preparation being examined, unless otherwise specified, in buffered sodium chloride-peptone solution *p*H 7.0 or any other suitable medium shown to have no antimicrobial activity under the conditions of test and adjust the volume to 100 ml with the same medium. If necessary, adjust the *p*H to about 7.

Products insoluble in Water (non-fatty): Suspend 10 g or 10 ml of the preparation being examined, unless otherwise specified, in buffered sodium chloride-peptone solution *p*H 7.0 or any other suitable medium shown not to have antimicrobial activity under the conditions of the test and dilute to 100 ml with the same medium. If necessary, divide the preparation being examined and homogenize the suspension mechanically.

A suitable surface-active agent such as 0.1 per cent w/v of polysorbate 80 may be added to assist the suspension of poorly wettable substances. If necessary, adjust the *p*H of the suspension to about 7.

Fatty products: Homogenise 10 g or 10 ml of the preparation being examined, unless otherwise specified, with 5 g of polysorbate 20 or polysorbate 80. If necessary, heat to not more than 40^0. Mix carefully while maintaining the temperature in the water-bath or in an oven. Add 85 ml of buffered sodium chloride-peptone solution *p*H 7.0 or any other suitable medium shown to have no antimicrobial activity under the conditions of the test, heated to not more than 40^0 if necessary. Maintain this temperature for the shortest time necessary for formation of an emulsion and in any case for not more than 30 minutes. If necessary, adjust the *p*H to about 7.

Examination of the sample: Determine the total aerobic microbial count in the substance being examined by any of the following methods.

Membrane filtration : Use membrane filters 50 mm in diameter and having a nominal pore size not greater than 0.45 µm the effectiveness of which in retaining bacteria has been established for the type of preparation being examined.

Transfer 10 ml or a quantity of each dilution containing 1 g of the preparation being examined to each of two membrane filters and filter immediately. If necessary, dilute the pretreated preparation so that a colony count of 10 to 100 may be expected. Wash each membrane by filtering through it three or more successive quantities, each of about 100 ml, of a suitable liquid such as *buffered sodium chloride-peptone solution pH 7.0.* For fatty substances add to the liquid *polysorbate 20* or *polysorbate 80.* Transfer one of the membrane filters, intended for the enumeration of bacteria, to the surface of a plate of *casein soyabean digest agar* and the other, intended for the enumeration of fungi, to the surface of a plate of *Sabouraud dextrose agar* with antibiotics.

Incubate the plates for 5 days, unless a more reliable count is obtained in shorter time, at 30^0 to 35^0 in the test for bacteria and 20^0 to 25^0 in the test for fungi. Count the number of colonies that are formed. Calculate the number of micro-organisms per g or per ml of the preparation being examined, if necessary counting bacteria and fungi separately.

Plate count for bacteria: Using Petri dishes 9 to 10 cm in diameter, add to each dish a mixture of 1 ml of the pretreated preparation and about 15 ml of liquefied *casein soyabean digest agar* at not more than 45^0. Alternatively, spread the pretreated preparation on the surface of the solidified medium in a Petri dish of the same diameter. If necessary, dilute the pretreated preparation as described above so that a colony count of not more than 300 may be expected. Prepare at least two such Petri dishes using the same dilution and incubate at 30^0 to 35^0 for 5 days, unless a more reliable count is obtained in a shorter time. Count the number of colonies that are formed. Calculate the results using plates with the greatest number of colonies but taking 300 colonies per plate as the maximum consistent with good evaluation.

Plate count for fungi: Proceed as described in the test for bacteria but use *Sabouraud dextrose agar with antibiotics* in place of *casein soyabean digest agar* and incubate the plates at 20^0 to 25^0 for 5 days, unless a more reliable count is obtained in a shorter time. Calculate the results using plates with not more than 100 colonies.

Multiple-tube or serial dilution method : In each of fourteen test-tubes of similar size place 9.0 ml of sterile *fluid soyabean casein digest medium.* Arrange twelve of the tubes in four sets of three tubes each. Put aside one set of three tubes to serve as controls. Into each of three tubes of one set (“100”) and into fourth tube (A) pipette 1 ml of the solution of suspension of the test specimen and mix. From tube A pipette 1 ml of its contents into the one remaining tube (B) not included in the set and mix. These two tubes contain 100 mg (or 100 µl) and 10 mg (or 10 µl) of the specimen respectively. Into each of the second set (“10”) of three tubes pipette 1 ml from tube

Table 5 – Most Probable Total Count by Multiple-Tube Or Serial Dilution Method

Observed combination of numbers of tubes showing growth in each set			Most probable number of micro-organisms per g or per ml
No.of mg (or ml) of specimen per tube			
100 (100 µl)	10 (10 µl)	1 (1 µl)	
3	3	3	>1100
3	3	2	1100
3	3	1	500
3	3	0	200
3	2	3	290
3	2	2	210
3	2	1	150
3	2	0	90
3	1	3	160
3	1	2	120
3	1	1	70
3	1	0	40
3	0	3	95
3	0	2	60
3	0	1	40
3	0	0	23

A, and into each tube of the third set ("1") pipette 1 ml from tube B. Discard the unused contents of tube A and B. Close well and incubate all of the tubes. Following the incubation period, examine the tubes for growth. The three control tubes remain clear. Observations in the tubes containing the test specimen, when interpreted by reference to Table 1, indicate the most probable number of micro-organisms per g or per ml of the test specimen.

2.4.2. - Tests for Specified Micro-organisms:

Pretreatment of the sample being examined: Proceed as described under the test for total aerobic microbial count but using lactose broth or any other suitable medium shown to have no antimicrobial activity under the conditions of test in place of buffered sodium chloride-peptone solution *p*H 7.0.

Escherichia coli : Place the prescribed quantity in a sterile screw-capped container, add 50 ml of nutrient broth, shake, allow to stand for 1 hour (4 hours for gelatin) and shake again. Loosen the cap and incubate at 37^0 for 18 to 24 hours.

Primary test: Add 1.0 ml of the enrichment culture to a tube containing 5 ml of MacConkey broth. Incubate in a water-bath at 36^0 to 38^0 for 48 hours. If the contents of the tube show acid and gas carry out the secondary test.

Secondary test: Add 0.1 ml of the contents of the tubes containing (a) 5 ml of MacConkey broth, and (b) 5 ml of peptone water. Incubate in a water-bath at 43.5^0 to 44.5^0 for 24 hours and examine tube (a) for acid and gas and tube (b) for indole. To test for indole, add 0.5 ml of Kovac's reagent, shake well and allow to stand for 1 minute; if a red colour is produced in the reagent layer indole is present. The presence of acid and gas and of indole in the secondary test indicates the presence of *Escherichia coli*.

Carry out a control test by repeating the primary and secondary tests adding 1.0 ml of the enrichment culture and a volume of broth containing 10 to 50 *Escherichia coli* (NCTC 9002) organisms, prepared from a 24-hour culture in nutrient broth, to 5 ml of MacConkey broth. The test is not valid unless the results indicate that the control contains *Escherichia coli.*

Alternative test: By means of an inoculating loop, streak a portion from the enrichment culture (obtained in the previous test) on the surface of MacConkey agar medium. Cover and invert the dishes and incubate. Upon examination, if none of the colonies are brick-red in colour and have a surrounding zone of precipitated bile the sample meets the requirements of the test for the absence of *Escherichia coli*.

If the colonies described above are found, transfer the suspect colonies individually to the surface of Levine eosin-methylene blue agar medium, plated on Petri dishes. Cover and invert the plates and incubate. Upon examination, if none of the colonies exhibits both a characteristic metallic sheen under reflected light and a blue-black appearance under transmitted light, the sample meets the requirements of the test for the absence of *Escherichia coli*. The presence of *Escherichia coli* may be confirmed by further suitable cultural and biochemical tests.

Salmonella : Transfer a quantity of the pretreated preparation being examined containing 1 g or 1 ml of the product to 100 ml of nutrient broth in a sterile screw-capped jar, shake, allow to stand for 4 hours and shake again. Loosen the cap and incubate at 35^0 to 37^0 for 24 hours.

Primary test: Add 1.0 ml of the enrichment culture to each of the two tubes containing (a) 10 ml of selenite F broth and (b) tetrathionate-bile-brilliant green broth and incubate at 36^0 to 38^0 for 48 hours. From each of these two cultures subculture on at least two of the following four agar media: bismuth sulphate agar, brilliant green agar, deoxycholatecitrate agar and xylose-lysine-deoxycholate agar. Incubate the plates at 36^0 to 38^0 for 18 to 24 hours. Upon examination, if none of the colonies conforms to the description given in Table 2, the sample meets the requirements of the test for the absence of the genus *Salmonella*.

If any colonies conforming to the description in Table 2 are produced, carry out the secondary test.

Secondary test: Subculture any colonies showing the characteristics given in Table 2 in triple sugar-iron agar by first inoculating the surface of the slope and then making a stab culture with the same inoculating needle, and at the same time inoculate a tube of urea broth. Incubate at 36^0 to 38^0 for 18 to 24 hours. The formation of acid and gas in the stab culture (with or without concomitant blackening) and the absence of acidity from the surface growth in the triple sugar iron agar, together with the absence of a red colour in the urea broth, indicate the presence of *Salmonella*. If acid but no gas is produced in the stab culture, the identity of the organisms should be confirmed by agglutination tests.

Carry out the control test by repeating the primary and secondary tests using 1.0 ml of the enrichment culture and a volume of broth containing 10 to 50 *Salmonella abony* (NCTC 6017) organisms, prepared from a 24-hour culture in nutrient broth, for the inoculation of the tubes (a) and (b). The test is not valid unless the results indicate that the control contains *Salmonella*.

Table 6 – Test for *Salmonella*

Medium	***Description*** **of colony**
Bismuth sulphite agar	Black or green
Brilliant green agar	Small, transparent and colourless, or opaque, pinkish or white (frequently surrounded by a pink or red zone)
Deoxycholate-citrate agar	Colourless and opaque, with or without black centers
Xylose-lysine-desoxy-cholate agar	Red with or without black centres

Pseudomonas aeruginosa : Pretreat the preparation being examined as described above and inoculate 100 ml of fluid soyabean-casein digest medium with a quantity of the solution, suspension or emulsion thus obtained containing 1 g or 1 ml of the preparation being examined. Mix and incubate at 35^0 to 37^0 for 24 to 48 hours. Examine the medium for growth and if growth is present, streak a portion of the medium on the surface of cetrimide agar medium, each plated on Petri dishes. Cover and incubate at 35^0 to 37^0 for 18 to 24 hours.

If, upon examination, none of the plates contains colonies having the characteristics listed in Table 3 for the media used, the sample meets the requirement for freedom from *Pseudomonas aeruginosa*. If any colonies conforming to the description in Table 3 are produced, carry out the oxidase and pigent tests.

Streak representative suspect colonies from the agar surface of cetrimide agar on the surfaces of *Pseudomonas* agar medium for detection of fluorescein and *Pseudomonas*

agar medium for detection of pyocyanin contained in Petri dishes. Cover and invert the inoculated media and incubate at 33^0 to 37^0 for not less than 3 days. Examine the streaked surfaces under ultra-violet light. Examine the plates to determine whether colonies conforming to the description in Table 3 are present.

If growth of suspect colonies occurs, place 2 or 3 drops of a freshly prepared 1per cent w/v solution of *N,N,N*^{1},*N*^{1}-tetramethyl-4-phenylenediamine dihydrochloride on filter paper and smear with the colony; if there is no development of a pink colour, changing to purple, the sample meets the requirements of the test for the absence of *Pseudomonas aeruginosa.*

Staphylococcus aureus : Proceed as described under *Pseudomonas aeruginosa* if, upon examination of the incubated plates, none of them contains colonies having the characteristics listed in Table 8 for the media used, the sample meets the requirements for the absence of *Staphylococcus aureus*.

If growth occurs, carry out the coagulase test. Transfer representative suspect colonies from the agar surface of any of the media listed in Table 4 to individual tubes, each containing 0.5 ml of mammalian, preferably rabbit or horse, plasma with or without additives. Incubate in water-bath at 37^0 examining the tubes at 3 hours and subsequently at suitable intervals up to 24 hours. If no coagulation in any degree is observed, the sample meets the requirements of the test for the absence of *Staphylococcus aureus*.

Validity of the tests for total aerobic microbial count:

Grow the following test strains separately in tubes containing fluid soyabean-casein digest medium at 30^0 to 35^0 for 18 to 24 hours or, for *Candida albicans*, at 20^0 for 48 hours.

Table 7 – Tests for *Pseudomonas aeruginosa*

Medium	**Characteristic colonial morphology**	**Fluorescence in UV light**	**Oxidase test**	**Gram stain**
Cetrimide agar	Generally greenish	Greenish	Positive	Negative rods
Pseudomonas agar medium for detection of fluorescein	Generally colourless to yellowish	Yellowish	Positive	Negative rods
Pseudomonas agar medium for detection of pyocyanin	Generally greenish	Blue	Positive	Negative rods

Table 8 – Tests for *Staphylococcus aureus*

Selective medium	**Characteristic colonial morphology**	**Gram stain**
Vogel-Johnson agar	Black surrounded by yellow zones	Positive cocci (in clusters)

Mannitol-salt agar	Yellow colonies with yellow zones	Positive cocci (in clusters)
Baird-Parker agar	Black, shiny, surrounded by clear zones of 2 to 5 mm	Positive cocci (in clusters)

Staphylococcus aureus (ATCC 6538; NCTC 10788)
Bacillus subtilis (ATCC 6633; NCIB 8054)
Escherichia coli (ATCC 8739; NCIB 8545)
Candida albicans (ATCC 2091; ATCC 10231)

Dilute portions of each of the cultures using buffered sodium chloride-peptone solution pH 7.0 to make test suspensions containing about 100 viable micro-organisms per ml. Use the suspension of each of the micro-organisms separately as a control of the counting methods, in the presence and absence of the preparation being examined, if necessary.

A count for any of the test organisms differing by not more than a factor of 10 from the calculated value for the inoculum should be obtained. To test the sterility of the medium and of the diluent and the aseptic performance of the test, carry out the total aerobic microbial count method using sterile buffered sodium chloride-peptone solution *p*H 7.0 as the test preparation. There should be no growth of micro-organisms.

Validity of the tests for specified micro-organisms: Grow separately the test strains of *Staphylococcus aureus* and *Pseudomonas aeruginosa* in fluid soyabean-casein digest medium and *Escherichia coli* and *Salmonella typhimurium* at 30^0 to 35^0 for 18 to 24 hours. Dilute portions of each of the cultures using buffered sodium chloride-peptone solution *p*H 7.0 to make test suspensions containing about 10^3 viable micro-organisms per ml. Mix equal volume of each suspension and use 0.4 ml (approximately 10^2 micro-organisms of each strain) as an inoculum in the test for *E. coli*, *Salmonella*, *P. aeruginosa* and *S. aureus*, in the presence and absence of the preparation being examined, if necessary. A positive result for the respective strain of micro-organism should be obtained.

Table 9- Microbial Contamination Limits

S.No.	Parameters	Permissible limits
1.	*Staphylococcus aureus*/g.	Absent
2.	*Salmonella* sp./g .	Absent
3.	*Pseudomonas aeruginosa*/g	Absent
4.	*Escherichia coli*	Absent
5.	Total microbial plate count (TPC)	10^5/g*
6.	Total Yeast & Mould	10^3/g

*For topical use, the limit shall be 10^7/g.

2.5 - Pesticide Residue:

Definition: For the purposes of the Pharmacopoeia, a pesticide is any substance or mixture of substances intended for preventing, destroying or controlling any pest, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of vegetable drugs. The item includes substances intended for use as growth-regulators, defoliants or desiccants and any substance applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport.

Limits: Unless otherwise indicated in the monograph, the drug to be examined at least complies with the limits indicated in Table -1, The limits applying to pesticides that are not listed in the table and whose presence is suspected for any reason comply with the limits set by European Community directives 76/895 and 90/642, including their annexes and successive updates. Limits for pesticides that are not listed in Table.-1 nor in EC directives are calculated using the following expression:

$$\frac{ADI \times M}{MDD \times 100}$$

ADI = Acceptable Daily Intake, as published by FAO-WHO, in milligrams per kilogram of body mass,

M = body mass in kilograms (60 kg),

MDD = daily dose of the drug, in kilograms.

If the drug is intended for the preparation of extracts, tinctures or other pharmaceutical forms whose preparation method modifies the content of pesticides in the finished product, the limits are calculated using the following expression:

$$\frac{ADI \times M \times E}{\text{MDD} \times 100}$$

E = Extraction factor of the method of preparation, determined experimentally.

Higher limits can also be authorised, in exceptional cases, especially when a plant requires a particular cultivation method or has a metabolism or a structure that gives rise to a higher than normal content of pesticides.

The competent authority may grant total or partial exemption from the test when the complete history (nature and quantity of the pesticides used, date of each treatment during cultivation and after the harvest) of the treatment of the batch is known and can be checked precisely.

Sampling

Method: For containers up to 1 kg, take one sample from the total content, thoroughly mixed, sufficient for the tests. For containers between 1 kg and 5 kg, take three samples, equal in volume, from the upper, middle and lower parts of the container, each being sufficient to carry out the tests. Thoroughly mix the samples and take from the mixture an amount sufficient to carry out the tests. For containers of more than 5 kg, take three samples, each of at least 250 g from the upper, middle and lower parts of the container. Thoroughly mix the samples and take from the mixture an amount sufficient to carry out the tests.

Size of sampling: If the number (n) of containers is three or fewer, take samples from each container as indicated above under Method. If the number of containers is more than three, take n+1 samples for containers as indicated under Method, rounding up to the nearest unit if necessary.

The samples are to be analysed immediately to avoid possible degradation of the residues. If this is not possible, the samples are stored in air-tight containers suitable for food contact, at a temperature below 0^0, protected from light.

Reagents: All reagents and solvents are free from any contaminants, especially pesticides, that might interfere with the analysis. It is often necessary to use special quality solvents or, if this is not possible, solvents that have recently been re-distilled in an apparatus made entirely of glass. In any case, suitable blank tests must be carried out.

Apparatus: Clean the apparatus and especially glassware to ensure that they are free from pesticides, for example, soak for at least 16 h in a solution of phosphate-free detergent, rinse with large quantities of *distilled water* and wash with *acetone* and *hexane* or *heptane*.

2.5.1 - Qualitative and Quantitative Analysis of Pesticide Residues:

The analytical procedures used are validated according to the regulations in force. In particular, they satisfy the following criteria :

- the chosen method, especially the purification steps, are suitable for the combination pesticide residue/substance to be analysed and not susceptible to interference from co-extractives; the limits of detection and quantification are measured for each pesticide-matrix combination to be analysed.

- between 70 per cent to 110 per cent of each pesticide is recovered.

- the repeatability of the method is not less than the values indicated in Table 10

- the reproducibility of the method is not less than the values indicated in Table 11

- the concentration of test and reference solutions and the setting of the apparatus are such that a linear response is obtained from the analytical detector.

Table -10

Substance	**Limit (mg/kg)**
Alachlor	0.02
Aldrin and Dieldrin (sum of)	0.05
Azinphos-methyl	1.0
Bromopropylate	3.0
Chlordane (sum of cis-, trans – and Oxythlordane)	0.05
Chlorfenvinphos	0.5
Chlorpyrifos	0.2
Chlorpyrifos-methyl	0.1
Cypermethrin (and isomers)	1.0
DDT (sum of p,p-‘DDT, o,p-‘DDT, p,p-‘DDE and p,p-‘TDE	1.0
Deltamethrin	0.5
Diazinon	0.5
Dichlorvos	1.0
Dithiocarbamates (as CS2)	2.0
Endosulfan (sum of isomers and Endosulfan sulphate)	3.0
Endrin	0.05
Ethion	2.0
Fenitrothion	0.5
Fenvalerate	1.5
Fonofos	0.05
Heptachlor (sum of Heptachlor and Heptachlorepoxide)	0.05
Hexachlorobenzene	0.1
Hexachlorocyclohexane isomers (other than γ)	0.3
Lindane (γ-Hexachlorocyclohexane)	0.6
Malathion	1.0
Methidathion	0.2
Parathion	0.5

Parathion-methyl	0.2
Permethrin	1.0
Phosalone	0.1
Piperonyl butoxide	3.0
Pirimiphos-methyl	4.0
Pyrethrins (sum of)	3.0
Quintozene (sum of quintozene, pentachloroaniline and methyl pentachlorophenyl sulphide)	1.0

Table -11

Concentration of the pesticide (mg/kg)	Repeatability (difference, ± mg/kg)	Reproducibility (difference, ± mg/kg)
0.010	0.005	0.01
0.100	0.025	0.05
1.000	0.125	0.25

2.5.2. Test for Pesticides:

Organochlorine, Organophosphorus and Pyrethroid Insecticides.

The following methods may be used, in connection with the general method above, depending on the substance being examined, it may be necessary to modify, sometimes extensively, the procedure described hereafter. In any case, it may be necessary to use, in addition, another column with a different polarity or another detection method (mass spectrometry) or a different method (immunochemical methods) to confirm the results obtained.

This procedure is valid only for the analysis of samples of vegetable drugs containing less than 15 per cent of water. Samples with a higher content of water may be dried, provided it has been shown that the drying procedure does not affect significantly the pesticide content.

Extraction

To 10 g of the substance being examined, coarsely powdered, add 100 ml of *acetone* and allow to stand for 20 min. Add 1 ml of a solution containing 1.8 µg/ml of *carbophenothion* in *toluene.* Homogenise using a high-speed blender for 3 min. Filter and wash the filter cake with two quantities, each of 25 ml, of *acetone.* Combine the filtrate and the washings and heat using a rotary evaporator at a temperature not exceeding 40^0 C until the solvent has almost completely evaporated. To the residue add a few milliliters of *toluene* and heat again until the acetone is completely removed. Dissolve the residue in 8 ml of *toluene.*

Filter through a membrane filter (45 µm), rinse the flask and the filter with *toluene* and dilute to 10.0 ml with the same solvent (solution A).

Purification

Organochlorine, organophosphorus and pyrethroid insecticides:

Examine by size-exclusion chromatography.
The chromatographic procedure may be carried out using:

- a stainless steel column 0.30 m long and 7.8 mm in internal diameter packed with styre:e-divinylbenzene copolymer (5 µm).
- as mobile phase *toluene* at a flow rate of 1 ml/min.

Performance of the column: Inject 100 µl of a solution containing 0.5 g/l of *methyl red* and 0.5 g/l of *oracet blue* in *toluene* and proceed with the chromatography. The column is not suitable unless the colour of the eluate changes from orange to blue at an elution volume of about 10.3 ml. If necessary calibrate the column, using a solution containing, in *toluene*, at a suitable concentration, the insecticide to be analysed with the lowest molecular mass (for example, dichlorvos) and that with the highest molecular mass (for example, deltamethrin). Determine which fraction of the eluate contains both insecticides.

Purification of the test solution: Inject a suitable volume of solution A (100 µl to 500 µl) and proceed with the chromatography. Collect the fraction as determined above (solution B). Organophosphorus insecticides are usually eluted between 8.8 ml and 10.9 ml. Organochlorine and pyrethroid insecticides are usually eluted between 8.5 ml and 10.3 ml.

Organochlorine and pyrethroid insecticides: In a chromatography column, 0.10 m long and 5 mm in internal diameter, introduce a piece of defatted cotton and 0.5 g of silica gel treated as follows: heat silica gel for chromatography in an oven at 150^0 for at least 4 h. Allow to cool and add dropwise a quantity of *water* corresponding to 1.5 per cent of the mass of silica gel used; shake vigorously until agglomerates have disappeared and continue shaking for 2 h using a mechanical shaker. Condition the column using 1.5 ml of *hexane.* Prepacked columns containing about 0.50 g of a suitable silica gel may also be used provided they are previously validated.

Concentrate solution B in a current of helium for chromatography or oxygen-free nitrogen almost to dryness and dilute to a suitable volume with *toluene* (200 µl to 1 ml according to the volume injected in the preparation of solution B). Transfer quantitatively onto the column and proceed with the chromatography using 1.8 ml of *toluene* as the mobile phase. Collect the eluate (solution C).

2.5.3. - Quantitative Analysis:

A. Organophosphorus insecticides: Examine by gas chromatography, using *carbophenothion* as internal standard. It may be necessary to use a second internal standard to identify possible interference with the peak corresponding to carbophenothion.

Test solution: Concentrate solution B in a current of helium for chromatography almost to dryness and dilute to 100 µl with *toluene.*

Reference solution: Prepare at least three solutions in *toluene* containing the insecticides to be determined and *carbophenothion* at concentrations suitable for plotting a calibration curve.

The chromatographic procedure may be carried out using:

- a fused-silica column 30 m long and 0.32 mm in internal diameter the internal wall of which is covered with a layer 0.25 µm thick of poly (dimethyl) siloxane.
- hydrogen for chromatography as the carrier gas. Other gases such as helium for chromatography or nitrogen for chromatography may also be used provided the chromatography is suitably validated.
- a phosphorus-nitrogen flame-ionisation detector or a atomic emission spectrometry detector.

Maintaining the temperature of the column at 80^0 for 1 min, then raising it at a rate of 30^0 /min to 150^0, maintaining at 150^0 for 3 min, then raising the temperature at a rate of 4^0/min to 280^0 and maintaining at this temperature for 1 min and maintaining the temperature of the injector port at 250^0 and that of the detector at 275^0. Inject the chosen volume of each solution. When the chromatograms are recorded in the prescribed conditions, the relative retention times are approximately those listed in Table 12 Calculate the content of each insecticide from the peak areas and the concentrations of the solutions.

B. Organochlorine and Pyrethroid Insecticides:

Examine by gas chromatography, using *carbophenothion* as the internal standard. It may be necessary to use a second internal standard to identify possible interference with the peak corresponding to *carbophenothion*.

Test solution: Concentrate solution C in a current of helium for chromatography or oxygen-free nitrogen almost to dryness and dilute to 500 µl with *toluene.*

Reference solution: Prepare at least three solutions in *toluene* containing the insecticides to be determined and *carbophenothion* at concentrations suitable for plotting a calibration curve.

Table 12- Relative Retention Times of Pesticides

Substance	**Relative retention times**
Dichlorvos	0.20
Fonofos	0.50
Diazinon	0.52
Parathion-methyl	0.59
Chlorpyrifos-methyl	0.60
Pirimiphos-methyl	0.66
Malathion	0.67

Parathion	0.69
Chlorpyrifos	0.70
Methidathion	0.78
Ethion	0.96
Carbophenothion	1.00
Azinphos-methyl	1.17
Phosalon	1.18

The chromatographic procedure may be carried out using:

- a fused silica column 30 m long and 0.32 mm in internal diameter the internal wall of which is covered with a layer 0.25 µm thick of *poly (dimethyl diphenyl) siloxane.*
- hydrogen for chromatography as the carrier gas. Other gases such as helium for chromatography or nitrogen for chromatography may also be used, provided the chromatography is suitably validated.
- an electron-capture detector.
- a device allowing direct cold on-column injection.

maintaining the temperature of the column at 80^0 for 1 min, then raising it at a rate of 30^0/min to 150^0, maintaining at 150^0 for 3 min, then raising the temperature at a rate of 4^0/min to 280^0 and maintaining at this temperature for 1 min and maintaining the temperature of the injector port at 250^0 and that of the detector at 275^0. Inject the chosen volume of each solution. When the chromatograms are recorded in the prescribed conditions, the relative retention times are approximately those listed in Table 13. Calculate the content of each insecticide from the peak areas and the concentrations of the solutions.

Table 13- Relative Retention Times of Insecticides

Substance	**Relative retention times**
α-Hexachlorocyclohexane	0.44
Hexachlorobenzene	0.45
β-Hexachlorocyclohexane	0.49
Lindane	0.49
δ-Hexachlorocyclohexane	0.54
ε-Hexachlorocyclohexane	0.56
Heptachlor	0.61
Aldrin	0.68
cis-Heptachlor-epoxide	0.76
o,p'- DDE	0.81

α-Endosulfan	0.82
Dieldrin	0.87
p,p'- DDE	0.87
o,p'- DDD	0.89
Endrin	0.91
β-Endosulfan	0.92
o,p'- DDT	0.95
Carbophenothion	1.00
p,p'- DDT	1.02
cis-Permethrin	1.29
trans-Permethrin	1.31
Cypermethrin*	1.40
Fenvalerate*	1.47 and 1.49
Deltamethrin	1.54

*The substance shows several peaks.

2.6. - Gas Chromatography:

Gas chromatography (GC) is a chromatographic separation technique based on the difference in the distribution of species between two non-miscible phases in which the mobile phase is a carrier gas moving through or passing the stationary phase contained in a column. It is applicable to substances or their derivatives, which are volatilized under the temperatures employed.

GC is based on mechanisms of adsorption, mass distribution or size exclusion.

Apparatus

The apparatus consists of an injector, a chromatographic column contained in an oven, a detector and a data acquisition system (or an integrator or a chart recorder). The carrier gas flows through the column at a controlled rate or pressure and then through the detector.

The chromatography is carried out either at a constant temperature or according to a given temperature programme.

Injectors

Direct injections of solutions are the usual mode of injection, unless otherwise prescribed in the monograph. Injection may be carried out either directly at the head of the

column using a syringe or an injection valve, or into a vaporization chamber which may be equipped with a stream splitter.

Injections of vapour phase may be effected by static or dynamic head-space injection systems.

Dynamic head-space (purge and trap) injection systems include a sparging device by which volatile substances in solution are swept into an absorbent column maintained at a low temperature. Retained substances are then desorbed into the mobile phase by rapid heating of the absorbent column.

Static head-space injection systems include a thermostatically controlled sample heating chamber in which closed vials containing solid or liquid samples are placed for a fixed period of time to allow the volatile components of the sample to reach equilibrium between the non-gaseous phase and the vapour phase. After equilibrium has been established, a predetermined amount of the head-space of the vial is flushed into the gas chromatograph.

Stationary Phases

Stationary phases are contained in columns, which may be:

- a capillary column of fused-silica close wall is coated with the stationary phase.
- a column packed with inert particles impregnated with the stationary phase.
- a column packed with solid stationary phase.

Capillary columns are 0.1 mm to 0.53 mm in internal diameter (Φ) and 5 to 6 m in length. The liquid or stationary phase, which may be chemically bonded to the inner surface, is a film 0.1 µm to 5.0 µm thick.

Packed columns, made of glass or metal, are usually 1 m to 3 m in length with an internal diameter (Φ) of 2 mm to 4 mm. Stationary phases usually consist of porous polymers or solid supports impregnated with liquid phase.

Supports for analysis of polar compounds on columns packed with low-capacity, low-polarity stationary phase must be inert to avoid peak tailing. The reactivity of support materials can be reduced by silanising prior to coating with liquid phase. Acid-washed, flux-calcinated diatomaceous earth is often used. Materials are available in various particle sizes, the most commonly used particles are in the ranges of 150 µm to 180 µm and 125 µm to 150 µm.

Mobile Phases

Retention time and peak efficiency depend on the carrier gas flow rate; retention time is directly proportional to column length and resolution is proportional to the square root of the column length. For packed columns, the carrier gas flow rate is usually expressed in milliliters per minute at atmospheric pressure and room temperature, flow rate is measured at the detector outlet, either with a calibrated mechanical device or with a

bubble tube, while the column is at operating temperature. The linear velocity of the carrier gas through a packed column is inversely proportional to the square root of the internal diameter of the column for a given flow volume. Flow rates of 60 ml/min in a 4 mm internal diameter column and 15 ml/min in a 2 mm internal diameter column, give identical linear velocities and thus similar retention times.

Helium or nitrogen is usually employed as the carrier gas for packed columns, whereas commonly used carrier gases for capillary columns are nitrogen, helium and hydrogen.

Detectors

Flame-ionisation detectors are usually employed but additional detectors which may be used include: electron-capture, nitrogen-phosphorus, mass spectrometric, thermal conductivity, Fourier transform infrared spectrophotometric and others, depending on the purpose of the analysis.

Method

Equilibrate the column, the injector and the detector at the temperatures and the gas flow rates specified in the monograph until a stable baseline is achieved. Prepare the test solution (s) and the reference solutions (s) as prescribed. The solutions must be free from solid particles.

Criteria for assessing the suitability of the system are described in the chapter on *Chromatographic separation techniques.* The extent to which adjustments of parameters of the chromatographic system can be made to satisfy the criteria of system suitability are also given in this chapter.

2.7. - Test for Aflatoxins:

Caution: Aflatoxins are highly dangerous and extreme care should be exercised in handling aflatoxin materials.

This test is provided to detect the possible presence of aflatoxins B_1, B_2, G_1 and G_2 in any material of plant origin. Unless otherwise specified in the individual monograph, use the following method.

Zinc Acetate – Aluminum Chloride Reagent: Dissolve 20 g of *zinc acetate* and 5 g of *aluminum chloride* in sufficient water to make 100 ml.

Sodium Chloride Solution: Dissolve 5 g of *sodium chloride* in 50 ml of purified water.

Test Solution 1: Grind about 200 g of plant material to a fine powder. Transfer about 50 g of the powdered material, accurately weighed, to a glass-stoppered flask. Add 200 ml of a mixture of *methanol* and *water* (17: 3). Shake vigorously by mechanical means for not less than 30 minutes and filter. [Note – If the solution has interfering plant pigments, proceed as directed for Test Solution 2.] Discard the first 50 ml of the filtrate and collect the next 40

ml portion. Transfer the filtrate to a separatory funnel. Add 40 ml of sodium chloride solution and 25 ml of *hexane* and shake for 1 minute. Allow the layers to separate and transfer the lower aqueous layer to a second separatory funnel. Extract the aqueous layer in the separatory funnel twice, each time with 25 ml of *methylene chloride*, by shaking for 1 minute. Allow the layers to separate each time, separate the lower organic layer and collect the combined organic layers in a 125 ml conical flask. Evaporate the organic solvent to dryness on a water bath. Cool the residue. If interferences exist in the residue, proceed as directed for *Cleanup Procedure;* otherwise, dissolve the residue obtained above in 0.2 ml of a mixture of *chloroform* and *acetonitrile* (9.8 : 0.2) and shake by mechanical means if necessary.

Test Solution 2: Collect 100 ml of the filtrate from the start of the flow and transfer to a 250 ml beaker. Add 20 ml of *Zinc Acetate-Aluminum Chloride Reagent* and 80 ml of water. Stir and allow to stand for 5 minutes. Add 5 g of a suitable filtering aid, such as diatomaceous earth, mix and filter. Discard the first 50 ml of the filtrate, and collect the next 80 ml portion. Proceed as directed for *Test Solution 1*, beginning with "Transfer the filtrate to a separatory funnel."

Cleanup Procedure: Place a medium-porosity sintered-glass disk or a glass wool plug at the bottom of a 10 mm x 300 mm chromatographic tube. Prepare slurry of 2 g of silica gel with a mixture of *ethyl ether* and *hexane* (3: 1), pour the slurry into the column and wash with 5 ml of the same solvent mixture. Allow the absorbent to settle and add to the top of the column a layer of 1.5 g of *anhydrous sodium sulfate*. Dissolve the residue obtained above in 3 ml of *methylene chloride* and transfer it to the column. Rinse the flask twice with 1 ml portions of *methylene chloride*, transfer the rinses to the column and elute at a rate not greater than 1 ml per minute. Add successively to the column 3 ml of *hexane*, 3 ml of *diethyl ether* and 3 ml of *methylene chloride*; elute at a rate not greater than 3 ml per minute; and discard the eluates. Add to the column 6 mL of a mixture of *methylene chloride* and *acetone* (9 : 1) and elute at a rate not greater than 1 ml per minute, preferably without the aid of vacuum. Collect this eluate in a small vial, add a boiling chip if necessary and evaporate to dryness on a water bath. Dissolve the residue in 0.2 ml of a mixture of *chloroform* and *acetonitrile* (9.8 : 0.2) and shake by mechanical means if necessary.

Aflatoxin Solution: Dissolve accurately weighed quantities of aflatoxin B_1, aflatoxin B_2, aflatoxin G_1 and aflatoxin G_2 in a mixture of *chloroform* and *acetonitrile* (9.8: 0.2) to obtain a solution having concentrations of 0.5 µg /per ml each for aflatoxin B_1 and G_1 and 0.1µg per ml each for aflatoxins for B2 and G_2.

Procedure: Separately apply 2.5 µl, 5 µl, 7.5 µl and 10 µl of the Aflatoxin Solution and three 10 µl applications of either *Test Solution 1* or *Test Solution 2* to a suitable thin-layer chromatographic plate coated with a 0.25-mm layer of chromatographic silica gel mixture. Superimpose 5 µl of the *Aflatoxin Solution* on one of the three 10 µl applications of the *Test Solution.* Allow the spots to dry and develop the chromatogram in an unsaturated chamber containing a solvent system consisting of a mixture of *chloroform, acetone* and *isopropyl alcohol* (85:10:5) until the solvent front has moved not less than 15 cm from the origin. Remove the plate from the developing chamber, mark the solvent front and allow the plate to air-dry. Locate the spots on the plate by examination under UV light at 365 nm: the four applications of the *Aflatoxin Solution* appear as four clearly separated blue

fluorescent spots; the spot obtained from the *Test Solution* that was superimposed on the *Aflatoxin Solution* is no more intense than that of the corresponding *Aflatoxin Solution;* and no spot from any of the other *Test Solutions* corresponds to any of the spots obtained from the applications of the *Aflatoxin Solution.* If any spot of aflatoxins is obtained in the *Test Solution*, match the position of each fluorescent spot of the *Test Solution* with those of the *Aflatoxin Solution* to identify the type of aflatoxin present. The intensity of the aflatoxin spot, if present in the *Test Solution*, when compared with that of the corresponding aflatoxin in the *Aflatoxin Solution* will give an approximate concentration of aflatoxin in the *Test Solution.*

Table14 - Permissible Limit of Aflatoxins*

S.No	Aflatoxins	Permissible Limit
1.	B_1	0.5 ppm
2.	G_1	0.5 ppm
3.	B_2	0.1 ppm
4.	G_2.	0.1 ppm

*For Domestic use only

2.8. -Test for the Absence of Methanol:-

Take 1 drop of the sample in a 15 ml test tube. Add 1 drop of water with 1-drop dilute phosphoric acid (10 % w/v of water) followed by 1 drop of potassium permanganate solution (1% w/v of water). Add sodium bisulphate solution dropwise until the permanganate color is discharged. If brown color remains add 1 drop of dilute phosphoric acid followed by 5 ml of chromotropic acid solution (5 mg chromotropic acid Na salt in 10 ml mixture of 9 ml H_2SO_4 & 4 ml water) and heat to 60^0 C for 10 minutes. If no violet color is produced indicates the absence of *methanol*.

APPENDIX - 3

PHYSICAL TESTS AND DETERMINATIONS

3.1. - Refractive Index:

The refractive index (η) of a substance with reference to air is the ratio of the sine of the angle of incidence to the sine of the angle of refraction of a beam of light passing from air into the substance. It varies with the wavelength of the light used in its measurement.

Unless otherwise prescribed, the refractive index is measured at 25^0 (±0.5) with reference to the wavelength of the D line of sodium (λ 589.3 nm). The temperature should be carefully adjusted and maintained since the refractive index varies significantly with temperature.

The Abbe's refractometer is convenient for most measurements of refractive index but other refractometer of equal or greater accuracy may be used. Commercial refractometers are normally constructed for use with white light but are calibrated to give the refractive index in terms of the D line of sodium light.

To achieve accuracy, the apparatus should be calibrated against *distilled water* which has a refractive index of 1.3325 at 25^0 or against the reference liquids given in the following table.

Table 15

Reference Liquid	$\eta_D^{20°}$	**Temperature Co-efficient Δn/Δt**
Carbon tetrachloride	1.4603	-0.00057
Toluene	1.4969	-0.00056
α-Methylnaphthalene	1.6176	-0.00048

* Reference index value for the D line of sodium, measured at 20^0

The cleanliness of the instrument should be checked frequently by determining the refractive index of distilled water, which at 25^0 is 1.3325.

3.2. - Weight per Millilitre and Specific Gravity:

A. Weight per millilitre: The weight per millilitre of a liquid is the weight in g of 1 ml of a liquid when weighed in air at 25^0, unless otherwise specified.

Method

Select a thoroughly clean and dry pycnometer. Calibrate the pycnometer by filling it with recently boiled and cooled *water* at 25^{0} and weighing the contents. Assuming that the weight of 1 ml of *water* at 25^{0} when weighed in air of density 0.0012 g per ml, is 0.99602 g. Calculate the capacity of the pycnometer. (Ordinary deviations in the density of air from the value given do not affect the result of a determination significantly). Adjust the temperature of the substance to be examined, to about 20^{0} and fill the pycnometer with it. Adjust the temperature of the filled pycnometer to 25^{0}, remove any excess of the substance and weigh. Substract the tare weight of the pycnometer from the filled weight of the pycnometer. Determine the weight per milliliter dividing the weight in air, expressed in g, of the quantity of liquid which fills the pycnometer at the specified temperature, by the capacity expressed in ml, of the pycnometer at the same temperature.

B. Specific gravity: The specific gravity of a liquid is the weight of a given volume of the liquid at 25^{0} (unless otherwise specified) compared with the weight of an equal volume of water at the same temperature, all weighing being taken in air**.**

Method

Proceed as described under wt. per ml. Obtain the specific gravity of the liquid by dividing the weight of the liquid contained in the pycnometer by the weight of water contained, both determined at 25^{0} unless otherwise directed in the individual monograph.

3.3. - Determination of *p*H Values:

The *p*H value of an aqueous liquid may be defined as the common logarithum of the reciprocal of the hydrogen ion concentration expressed in g per litre. Although this definition provides a useful practical means for the quantitative indication of the acidity or alkalinity of a solution, it is less satisfactory from a strictly theoretical point of view. No definition of *p*H as a measurable quantity can have a simple meaning, which is also fundamental and exact.

The *p*H value of a liquid can be determined potentiometrically by means of the glass electrode, a reference electrode and a pH meter either of the digital or analogue type.

3.4. - Determination of Melting Range and Congealing Range:

3.4.1. Determination of Melting Range:

The melting-range of a substance is the range between the corrected temperature at which the substance begins to form droplets and the corrected temperature at which it completely melts, as shown by formation of a meniscus.

Apparatus:

(a) A capillary tube of soft glass, closed at one end, and having the following dimensions:
(i) thickness of the wall, about 0.10 to 0.15 mm.
(ii) length about 10 cm or any length suitable for apparatus used.
(iii) internal diameter 0.9 to 1.1 mm for substances melting below 100^0 or 0.8 to
1.2 mm for substances melting above 100^0.

Thermometers:

Accurately standardized thermometers covering the range 10^0 to 300^0 the length of two degrees on the scale being not less than 0.8 mm. These thermometers are of the mercury-in-glass, solid-stem type; the bulb is cylindrical in shape, and made of approved thermometric glass suitable for the range of temperature covered; each thermometer is fitted with a safety chamber. The smallest division on the thermometer scale should vary between 0.1^0 to 1.5^0 according to the melting point of the substance under test.

The following form of heating apparatus is recommended.

A glass heating vessel of suitable, construction and capacity fitted with suitable stiring device, capable of rapidly mixing the liquids.
Suitable liquids for use in the heating vessel:

Glycerin	Upto 150^0
Sulphuric acid to which a small crystal of *potassium nitrate* or 4 Drops of *nitric acid* per 100 ml has been added	Upto 200^0
A liquid paraffin of sufficiently high boiling range	Upto 250^0
Seasame oil	Upto 300^0
30 parts of *potassium sulphate*, dissolved by heating in 70 parts of *sulphuric acid*	Upto 300^0

Any other apparatus or method, preferably, the electric method may be used subject to a check by means of pure substances having melting temperature covering the ranges from 0^0 to 300^0 and with suitable intervals.

The following substances are suitable for this purpose.

Substance	Melting range
Vanillin	81^0 to 83^0
Acetanilide	114^0 to 116^0
Phenacetin	134^0 to 136^0
Sulphanilamide	164^0 to 166.5^0
Sulphapyridine	191^0 to 193^0
Caffeine (Dried at 100^0)	234^0 to 237^0

Procedure

Method I: Transfer a suitable quantity of the powdered and thoroughly dried substance to a dry capillary tube and pack the powder by tapping the tube on a hard surface so as to form a tightly packed column of 2 to 4 mm in height. Attach the capillary tube and its contents to a standardized thermometer so that the closed end is at the level of the middle of the bulb; heat in a suitable apparatus (preferably a round-bottom flask) fitted with an auxiliary thermometer regulating the rise of temperature in the beginning to 3^0 per minute. When the temperature reached is below the lowest figure of the range for the substance under examination, the heating of the apparatus is adjusted as desired; if no other directions are given, the rate of rise of temperature should be kept at 1^0 to 2^0 per minute. The statement 'determined by rapid heating' means that the rate of rise of temperature is 5^0 per minute during the entire period of heating.

Unless otherwise directed, the temperature at which the substance forms droplets against the side of the tube and the one at which it is completely melted as indicated by the formation of a definite meniscus, are read.

The following emergent stem corrections should be applied to the temperature readings.

Before starting the determination of the melting temperature the auxiliary thermometer is attached so that the bulb touches the standard thermometer at a point midway between the graduation for the expected melting temperature and the surface of the heating material. When the substance has melted, the temperature is read on the auxiliary thermometer. The correction figure to be added to the temperature reading of the standardized thermometer is calculated from the following formula

$$0.00015\ N\ (T—t)$$

Where 'T' is the temperature reading of the standardized thermometer.

't' is the temperature reading of the auxiliary thermometer.

'N' is the number of degrees of the scale of the standardized thermometer between the surface of the heating material and level of mercury.

The statement "melting range, a^0 to b^0" means that the corrected temperature at which the material forms droplets must be at least a^0, and that the material must be completely melted at the corrected temperature, b^0.

Method II: The apparatus employed for this test is the same as described for method I except for such details as are mentioned in the procedure given below

Procedure: A capillary tube open at both ends is used for this test. Melt the material under test at as low a temperature as possible. Draw into the capillary a column of the material about 10 mm high. Cool the charged tube in contact with ice for at least 2 hours. Attach the tube to the thermometer by means of rubber band and adjust it in the heating vessel

containing water so that the upper edge of the material is 10 mm below the water level. Heat in the manner as prescribed in Method I until the temperature is about 5^0 below the expected melting point and then regulate the rate of rise of temperature to between 0.5^0 to 1^0 per minute. The temperature at which the material is observed to rise in the capillary tube is the melting temperature of the substance.

3.4.2. - Determination of Congealing Range:

The congealing temperature is that point at which there exists a mixture of the liquid (fused) phase of a substance and a small but increasing proportion of the solid phase. It is distinct from the freezing point which is the temperature at which the liquid and solid phase of a substance are in equilibrium. In certain cases, this may happen over a range of temperatures.

The temperature at which a substance solidifies upon cooling is a useful index of its purity if heat is liberated when solidification takes place.

The following method is applicable to substances that melt between -20^0 and 150^0.

Apparatus

A test-tube (About 150 mm × 25 mm) placed inside another test-tube (about 160 mm × 40 mm) the inner tube is closed by a stopper that carries a stirrer and a thermometer (About 175 mm long and with 0.2^0 graduations) fixed so that the bulb is about 15 mm above the bottom of the tube. The stirrer is made from a glass rod or other suitable material formed at one end into a loop of about 18 mm overall diameter at right angles to the rod. The inner tube with its jacket is supported centrally in a 1-litre baker containing a suitable cooling liquid to within 20 mm of the top. The thermometer is supported in the cooling bath.

Method

Melt the substance, if a solid, at a temperature not more than 20^0 above its expected congealing point, and pour it into the inner test-tube to a height of 50 to 57 mm. Assemble the apparatus with the bulb of the thermometer immersed half-way between the top and bottom of the sample in the test-tube. Fill the bath to almost 20 mm from the top of the tube with a suitable fluid at a temperature 4^0 to 5^0 below the expected congealing point. If the substance is a liquid at room temperature, carry out the determination using a bath temperature about 15^0 below the expected congealing point. When the sample has cooled to about 5^0 above its expected congealing point stir it continuously by moving the loop up and down between the top and bottom of the sample at a regular rate of 20 complete cycles per minute. If necessary, congelation may be induced by scratching the inner walls of the test-tube with the thermometer or by introducing a small amount of the previously congealed substance under examination. Pronounced supercooling may result in deviation from the normal pattern of temperature changes. If it happens, repeat the test introducing small fragments of the solid substance under examination at 1^0 intervals when the temperature approaches the expected congealing point.

Record the reading of the thermometer every 30 seconds and continue stirring only so long as the temperature is falling. Stop the stirring when the temperature is constant to starts to

rise slightly. Continue recording the temperature for at least 3 minutes after the temperature again begins to fall after remaining constant.

The congealing point will be mean of not less than four consecutive readings that lie within a range of 0.2^0.

3.5. - Determination of Boiling Range:

The boiling-range of a substance is the range of temperature within which the whole or a specified portion of the substance distils.

Apparatus

The boiling-range is determined in a suitable apparatus, the salient features of which are described below:

(a) **Distillation flask:** The flask shall be made of colourless transparent heat-resistant glass and well annealed. It should have a spherical bulb having a capacity of about 130 ml. The side tube slopes downwards in the same plane as the axis of the neck at angle of between 72^0 to 78^0. Other important dimensional details are as under:

Internal diameter of neck	15 to 17 mm
Distance from top of neck to center of side tube	72 to 78 mm
Distance from the center of the side tube to surface of the Liquid when the flask contains 100 ml liquid	87 to 93 mm
Internal diameter of side tube	3.5 to 4.5 mm
Length of side tube	97 to 103 mm

(b) **Thermometer**: Standardised thermometers calibrated for 100 mm immersion and suitable for the purpose and covering the boiling range of the substance under examination shall be employed; the smallest division on the thermometer scale may vary between 0.2^0 to 1^0 according to requirement.

(c) **Draught Screen**: suitable draught screen, rectangular in cross section with a hard asbestos board about 6 mm thick closely fitting horizontally to the sides of the screen, should be used. The asbestos board shall have a centrally cut circular hole, 110 mm in diameter. The asbestos board is meant for ensuring that hot gases from the heat source do not come in contact with the sides or neck of the flask.

(d) **Asbestos Board:** A 150 mm square asbestos board 6 mm thick provided with a circular hole located centrally to hold the bottom of the flask, shall be used. For distillation of liquids boiling below 60^0 the hole shall be 30 mm in diameter; for other liquid it should be 50 mm in diameter. This board is to be placed on the hard asbestos board of the draught screen covering its 110 mm hole.

(e) **Condenser:** A straight water-cooled glass condenser about 50 cm long shall be used.

Procedure: 100 ml of the liquid to be examined is placed in the distillation flask, and a few glass beads or other suitable substance is added. The bulb of the flask is placed centrally over a circular hole varying from 3 to 5 cm in diameter (according to the boiling range of the substance under examination), in a suitable asbestos board. The thermometer is held concentrically in the neck of the flask by means of a well fitting cork in such a manner that the bulb of the thermometer remains just below the level of the opening of the side-tube. Heat the flask slowly in the beginning and when distillation starts, adjust heating in such a manner that the liquid distils at a constant rate of 4 to 5 ml per minute. The temperature is read when the first drop runs from the condenser, and again when the last quantity of liquid in the flask is evaporated.

The boiling ranges indicated, apply at a barometric pressure of 760 mm of mercury. If the determination is made at some other barometric pressure, the following correction is added to the temperatures read:

K- (760—p)

Where p is the barometric pressure (in mm) read on a mercury barometer, without taking into account the temperature of the air;

K is the boiling temperature constant for different liquids having different boiling ranges as indicated below:—

Observed Boiling range	'K'
Below 100^0	0.04
100^0 to 140^0	0.045
141^0 to 190^0	0.05
191^0 to 240^0	0.055
above 240^0	0.06

If the barometric pressure is below 760 mm of mercury the correction is added to the observed boiling-range; if above, the correction is subtracted.

The statement 'distils between a^0 and $b^{0,}$, means that temperature at which the first drop runs from the condenser is not less than a^0 and that the temperature at which the liquid is completely evaporated is not greater than b^0.

Micro-methods of equal accuracy may be used.

3.6. - Determination of Optical Rotation and Specific Optical Rotation:

A. Optical Rotation :Certain substances, in a pure state, in solution and in tinctures posses the property of rotating the plane of polarized light, i.e., the incident light emerges in a plane forming an angle with the plane of the incident light. These substances are said to be optically active and the property of rotating the plane of polarized light is known as optical

rotation. The optical rotation is defined as the angle through which the plane of polarized light is rotated when polarized light obtained from sodium or mercury vapour lamp passes through one decimeter thick layer of a liquid or a solution of a substance at a temperature of 25º unless as otherwise stated in the monograph. Substances are described as dextrorotatory or laevoretatory according to the clockwise or anticlockwise rotation respectively of the plane of polarized light. Dextrorotation is designated by a plus (+) sign and laevorotation by a minus (-) sign before the number indicating the degrees of rotation.

Apparatus: A polarimeter on which angular rotation accurate 0.05^0 can be read may be used.

Calibration: The apparatus may be checked by using a solution of previously dried *sucrose* and measuring the optical rotation in a 2-din tube at 25^0 and using the concentrations indicated in Table.

Concentration (g/100 ml)	Angle of Rotation (+) at 25^0
10.0	13.33
20.0	26.61
30.0	39.86
40.0	53.06
50.0	66.23

Procedure: For liquid substances, take a minimum of five readings of the rotation of the liquid and also for an empty tube at the specified temperature. For a solid dissolve in a suitable solvent and take five readings of the rotation of the solution and the solvent used. Calculate the average of each set of five readings and find out the corrected optical rotation from the observed rotation and the reading with the blank (average).

B. Specific Rotation : The apparatus and the procedure for this determination are the same as those specified for optical rotation.

Specific rotation is denoted by the expression

$$[\alpha]^t_x$$

t denotes the temperature of rotation; α denotes the wave length of light used or the characteristic spectral line. Specific rotations are expressed in terms of sodium light of wave length 589.3 mw (D line) and at a temperature of 25^0, unless otherwise specified.

Specific rotation of a substance may be calculated from the following formulae:
For liquid substances

$$[\alpha]^t = \frac{a}{ld}$$

For solutions of substances

$$[\alpha]^t \longleftrightarrow = \frac{a \times 100}{lc.}$$

Where a is the corrected observed rotation in degrees
1 is the length of the polarimeter tube in decimeters.

D is the specific gravity of the liquid C is the concentration of solution expressed as the number of g of the substance in 100 ml of solution.

3.7. - Determination of Viscosity:

Viscosity is a property of a liquid, which is closely related to the resistance to flow.

In C.G.S. system, the dynamic viscosity (n) of a liquid is the tangential force in dryness per square centimeter exerted in either of the two parallel planes placed, 1 cm apart when the space between them is filled with the fluid and one of the plane is moving in its own plane with a velocity of 1 cm per second relatively to the other. The unit of dynamic viscosity is the poise (abbreviated p). The centi poise (abbreviated cp) is $1/100^{th}$ of one poise.

While on the absolute scale, viscosity is measured in poise or centi poise, it is mot convenient to use the kinematic scale in which the units are stokes (abbreviated S) and centi-stokes (abbreviated CS). The centistokes is $1/100^{th}$ of one stoke. The kinematic viscosity of a liquid is equal to the quotient of the dynamic viscosity and the density of the liquid at the same temperature, thus :

$$\text{Kinematic Viscosity} = \frac{\text{Dynamic Viscosity}}{\text{Density}}$$

Viscosity of liquid may be determined by any method that will measure the resistance to shear offered by the liquid.

Absolute viscosity can be measured directly if accurate dimensions of the measuring instruments are known but it is more common practice to calibrate the instrument with a liquid of known viscosity and to determine the viscosity of the unknown fluid by comparison with that of the known.

Procedure: The liquid under test is filled in a U tube viscometer in accordance with the expected viscosity of the liquid so that the fluid level stands within 0.2 mm of the filling mark of the viscometer when the capillary is vertical and the specified temperature is attained by the test liquid. The liquid is sucked or blown to the specified weight of the viscometer and the time taken for the meniscus to pass the two specified marks is measured. The kinematic viscosity in centistokes is calculated from the following equation:

Kinematic viscosity = kt

Where k = the constant of the viscometer tube determined by observation on liquids of known kinematic viscosity; t = time in seconds for meniscus to pass through the two specified marks.

3.8. - Determination of Total Solids:

Determination of total solids in Asava/ Aristha is generally required. Asava/ Aristha containing sugar or honey should be examined by method 1, sugar or honey free Asava/ Aristha and other material should be examined by method 2.

Method 1: Transfer accurately 50 ml of the clear Asava/ Aristha an evaporable dish and evaporate to a thick extract on a water bath. Unless specified otherwise, extract the residue with 4 quantities, each of 10 ml, of dehydrated ethanol with stirring and filter. Combine the filtrates to another evaporating dish which have been dried to a constant weight and evaporate nearly to dryness on a water bath, add accurately 1 g of diatomite (dry at 105^0 for 3 hours and cooled in a desiccator for 30 min), stir thoroughly, dry at 105^0 for 3 hours, cool the dish in a desiccator for 30 min, and weigh immediately. Deduct the weight of diatomite added, the weight of residue should comply with the requirements stated under the individual monograph.

Method 2: Transfer accurately 50 ml of the clear Asava/ Aristha to an evaporable dish, which has been dried to a constant weight and evaporate to dryness on a water bath, then dry at 105^0 for 3 hours. After cooling the dish containing the residue in a desiccator for 30 min, weigh it immediately. The weight of residue should comply with the requirements stated under the individual monograph.

3.9. - Solubility in Water:

Take 100 ml of distil water in a *Nessler cylinder* and add air-dried and coarsely powdered drug up to saturation. Then stir the sample continuously by twirling the spatula (rounded end of a microspatula) rapidly. After 1 minute, filter the solution using Hirsch funnel, evaporate the filtrate to dryness in a tared flat bottomed shallow dish and dry at 105^0 to constant weight and calculate the solubility of the drug in water (wt. in mg/100ml).

3.10. - Determination of Saponification Value:

The saponification value is the number of mg of potassium hydroxide required to neutralize the fatty acids, resulting from the complete hydrolysis of 1 g of the oil or fat, when determined by the following method :

Dissolve 35 to 40 g of potassium hydroxide in 20 ml water, and add sufficient alcohol to make 1,000 ml. Allow it to stand overnight, and pour off the clear liquor.

Weigh accurately about 2 g of the substance in a tared 250 ml flask, add 25 ml of the alcoholic solution of potassium hydroxide, attach a reflux condenser and boil on a water-bath for one hour, frequently rotating the contents of the flask cool and add 1 ml of

solution of phenolphthalein and titrate the excess of alkali with 0.5 N hydrochloric acid. Note the number of ml required (a). Repeat the experiment with the same quantities of the same reagents in the manner omitting the substance. Note the number of ml required (b) Calculate the saponification value from the following formula:—

$$\text{Saponification Value} = \frac{(b-a) \times 0.02805 \times 1.000}{W}$$

Where 'W' is the weight in g of the substance taken.

3.11. - Determination of Iodine Value:

The Iodine value of a substance is the weight of iodine absorbed by 100 part by weight of the substance, when determined by one of the following methods:-

Iodine Flasks—The Iodine flasks have a nominal capacity of 250 ml.

A. Iodine Monochloride Method—Place the substance accurately weighed, in dry iodine flask, add 10 ml of *carbon tetrachloride*, and dissolve. Add 20 ml of iodine monochloride solution, insert the stopper, previously moistened with solution of potassium iodine and allow to stand in a dark place at a temperature of about 17^0 or thirty minutes. Add 15 ml of solution of potassium iodine and 100 ml water; shake, and titrate with 0.1 N sodium thiosulphate, using solution of starch as indicator. Note the number of ml required (a). At the same time carry out the operation in exactly the same manner, but without the substance being tested, and note the number of ml of *0.1 N sodium thiosulphate* required (b).

Calculate the iodine value from the formula:—

$$\text{Iodine value} = \frac{(b-a) \times 0.01269 \times 100}{W}$$

Where 'W' is the weight in g of the substance taken.

The approximate weight, in g, of the substance to be taken may be calculated by dividing 20 by the highest expected iodine value. If more than half the available halogen is absorbed, the test must be repeated, a smaller quantity of the substance being used.

Iodine Monochloride Solution: The solution may be prepared by either of the two following methods:

(1) Dissolve 13 g of iodine in a mixture of 300 ml of carbon tetrachloride and 700 ml of glacial acetic acid. To 20 ml of this solution, add 15 ml of *solution of potassium iodide* and 100 ml of *water*, and titrate the solution with *0.1 N sodium thiosulphate*. Pass chlorine, washed and dried, through the remainder of the iodine solution until the amount of 0.1 N sodium thiosulphate required for the titration is approximately, but more than, doubled.

(2)	Iodine trichloride	8 g
	Iodine	9 g
	Carbon tetrachloride	300 ml
	Glacial acetic acid, sufficient to produce	1000 ml

Dissolve the iodine trichloride in about 200 ml of glacial acetic acid, dissolve the iodine in the carbon tetrachloride, mix the two solutions, and add sufficient glacial acetic acid to produce 1000 ml. Iodine Monochloride Solution should be kept in a stoppered bottle, protected from light and stored in a cool place.

B. Pyridine Bromide Method—Place the substance, accurately weighed, in a dry iodine flask, add 10 ml of *carbon tetrachloride* and dissolve. Add 25 ml of pyridine bromide solution, allow to stand for ten minutes in a dark place and complete the determination described under iodine monochloride method, beginning with the words. Add 15 ml.

The approximate weight in gram, of the substance to be taken may be calculated by dividing 12.5 by the highest expected iodine value. If more than half the available halogen is absorbed the test must be repeated, a small quantity of the substance being used.

Pyridine bromide Solution: Dissolve 8 g pyridine and 10 g of *sulphuric acid* in 20 ml of *glacial acetic acid*, keeping the mixture cool. Add 8 g of *bromine* dissolved in 20 ml of *glacial acetic acid* and dilute to 100 ml with *glacial acetic acid*.

Pyridine bromide Solution should be freshly prepared.

3.12. - Determination of Acid Value:

The acid value is the number of mg of *potassium hydroxide* required to neutralize the free acids in 1 g of the substance, when determined by the following method:

Weigh accurately about 10 g of the substance (1 to 5) in the case of a resin into a 250 ml flask and add 50 ml of a mixture of equal volumes of alcohol and solvent ether, which has been neutralized after the addition of 1 ml of solution of phenolphthalein. Heat gently on a water-bath, if necessary until the substance has completely melted, titrate with *0.1 N potassium hydroxide*, shaking constantly until a pink colour which persists for fifteen seconds is obtained. Note the number of ml required. Calculate the acid value from the following formula:

$$\text{Acid Value} = \frac{a \times 0.00561 \times 1000}{W}$$

Where ‘a’ is the number of ml of *0.1 N potassium hydroxide* required and ‘W’ is the weight in g of the substance taken.

3.13. - Determination of Peroxide Value:

The peroxide value is the number of milliequivalents of active oxygen that expresses the amount of peroxide contained in 1000 g of the substance.

Method

Unless otherwise specified in the individual monograph, weigh 5 g of the substance being examined, accurately weighed, into a 250-ml glass-stoppered conical flask, add 30 ml of a mixture of 3 volumes of *glacial acetic acid* and 2 volumes of *chloroform,* swirl until dissolved and add 0.5ml volumes of saturated *potassium iodide soluton.* Allow to stand for exactly 1 minute, with occasional shaking, add 30 ml of *water* and titrate gradually, with continuous and vigorous shaking, with *0.01M sodium thiosulphate* until the yellow colour almost disappears. Add 0.5 ml of *starch solution* and continue the titration, shaking vigorously until the blue colour just disappears (a ml). Repeat the operation omitting the substance being examined (b ml). The volume of *0.01M sodium thiosulphate* in the blank determination must not exceed 0.1 ml.

Calculate the peroxide value from the expression

Peroxide value = 10 (a – b)/*W*

Where *W* = weight, in g, of the substance.

3.14. - Determination of Unsaponifiable Matter:

The unsaponifiable matter consists of substances present in oils and fats, which are not saponifiable by alkali hydroxides and are determined by extraction with an organic solvent of a solution of the saponified substance being examined.

Method

Unless otherwise specified in the individual monograph, introduce about 5 g of the substance being examined, accurately weighed, into a 250-ml flask fitted with a reflux condenser. Add a solution of 2 g of *potassium hydroxide* in 40 ml of *ethanol (95per cent)* and heat on a water-bath for 1 hour, shaking frequently. Transfer the contents of the flask to a separating funnel with the aid of 100 ml of hot water and, while the liquid is still warm, shake very carefully with three quantities, each of 100 ml, of *peroxide-free ether.* Combine the ether extracts in a second separating funnel containing 40 ml of water, swirl gently for a few minute, allow to separate and reject the lower layer. Wash the ether extract with two quantities, each of 40 ml, of water and with three quantities, each of 40 ml, of a 3 per cent w/v solution of *potassium hydroxide,* each treatment being followed by a washing with 40 ml of water. Finally, wash the ether layer with successive quantities, each of 40 ml, of water until the aqueous layer is not alkaline to *phenolphthalein solution.* Transfer the ether layer to a weighed flask, washing out the separating funnel with *peroxide-free ether.* Distil off the ether and add to the residue 6 ml of *acetone.* Remove the solvent completely from the flask with the aid of a gentle current of air. Dry at 100^0 to 105^0 for 30 minutes. Cool in a desiccator and weigh the residue. Calculate the unsaponifiable matter as per cent w/w.

Dissolve the residue in 20 ml of *ethanol (95per cent),* previously neutralised to *phenolphthalein solution* and titrate with *0.1M ethanolic potassium hydroxide.* If the volume of *0.1M ethanolic potassium hydroxide* exceeds 0.2 ml, the amount weighed cannot be taken as the unsaponifiable matter and the test must be repeated.

3.15. - Detection of Mineral Oil (Holde's Test):

Take 22 ml of the alcoholic potassium hydroxide solution in a conical flask and add 1ml of the sample of the oil to be tested. Boil in a water bath using an air or water cooled condenser till the solution becomes clear and no oily drops are found on the sides of the flask. Take out the flask from the water bath, transfer the contents to a wide mouthed warm test tube and carefully add 25ml of boiling distilled water along the side of the test tube. Continue shaking the tube lightly from side to side during the addition. The turbidity indicates presence of mineral oil, the depth of turbidity depends on the percentage of mineral oil present.

3.16. - Rancidity Test (Kreis Test):

The test depends upon the formation of a red colour when oxidized fat is treated with conc. *hydrochloric acid* and a solution of phloroglucinol in ether. The compound in rancid fats responsible for the colour reaction is epihydrin aldehyde. All oxidized fats respond to the Kreis test and the intensity of the colour produced is roughly proportional to the degree of oxidative rancidity.

Procedure

Mix 1 ml of melted fat and 1 ml of conc. *hydrochloric acid* in a test tube. Add 1 ml of a 1 per cent solution of phloroglucinol in *diethyl ether* and mix thoroughly with the fat-acid mixture. A pink colour formation indicates that the fat is slightly oxidized while a red colour indicates that the fat is definitely oxidized.

3.17. - Determination of Alcohol Content:

The ethanol content of a liquid is expressed as the number of volumes of ethanol contained in 100 volumes of the liquid, the volumes being measured at 24.9^0 to 25.1^0. This is known as the "percentage of ethanol by volume". The content may also be expressed in g of ethanol per 100 g of the liquid. This is known as the 'percentage of ethanol by weight".

Use Method I or Method II, as appropriate, unless otherwise specified in the individual monograph.

Method I

Carry out the method for gas chromatography, using the following solutions. Solution (1) contains 5.0 per cent v/v of ethanol and 5.0 per cent v/v of 1-propanol (internal standard). For solution (2) dilute a volume of the preparation being examined with water to contain between 4.0 and 6.0 per cent v/v of ethanol. Prepare solution (3) in the same manner as solution (2) but adding sufficient of the internal standard to produce a final concentration of 5.0 per cent v/v.

The chromatographic procedure may be carried out using a column (1.5 m x 4 mm) packed with porous polymer beads (100 to 120 mesh) and maintained at 150^0, with both the inlet port and the detector at 170^0, and nitrogen as the carrier gas.

Calculate the percentage content of ethanol from the areas of the peaks due to ethanol in the chromatogram obtained with solutions (1) and (3).

Method II

For preparations where the use of Industrial Methylated Spirit is permitted in the monograph, determine the content of ethanol as described in Method I but using as solution (2) a volume of the preparation being examined diluted with water to contain between 4.0 and 6.0 per cent v/v of total ethanol and methanol.

Determine the concentration of methanol in the following manner. Carry out the chromatographic procedure described under Method I but using the following solutions. Solution (1) contains 0.25 per cent v/v of methanol and 0.25 per cent v/v of 1-propanol (internal standard). For solution (2) dilute a volume of the preparation being examined with water to contain between 0.2 per cent and 0.3 per cent v/v of methanol. Prepare solution (3) in the same manner as solution (2) but adding sufficient of the internal standard to produce a final concentration of 0.25 per cent v/v.

The sum of the contents of ethanol and methanol is within the range specified in the individual monograph and the ration of the content of methanol to that of ethanol is commensurate with Industrial Methylated Spirit having been used.

Method III

This method is intended only for certain liquid preparations containing ethanol. Where the preparation contains dissolved substances that may distil along with ethanol Method III B or III C must be followed.

Apparatus

The apparatus (see Fig. 3) consists of a round-bottomed flask (A) fitted with a distillation head (B) with a steam trap and attached to a vertical condenser (C). A tube is fitted to the lower part of the condenser and carries the distillate into the lower part of a 100-ml or 250-ml volumetric flask (D). The volumetric flask is immersed in a beaker (E) containing a mixture of ice and water during the distillation. A disc with a circular aperture, 6 cm in diameter, is placed under the distillation flask (A) to reduce the risk of charring of any dissolved substances.

Method III A

Transfer 25 ml of the preparation being examined, accurately measured at 24.9^0 to 25.1^0, to the distillation flask. Dilute with 150 ml of water and add a little pumice powder. Attach the distillation head and condenser. Distil and collect not less than 90 ml of the distillate into a 100-ml volumetric flask. Adjust the temperature to 24.9^0 to 25.1^0 and dilute to volume with distilled water at 24.9^0 to 25.1^0. Determine the relative density at 24.9^0 to 25.1^0. The values indicated in column 2 of Table 17 are multiplied by 4 in order to obtain the percentage of ethanol by volume contained in the preparation. If the specific gravity is found to be between two values, the percentage of ethanol should be obtained by

interpolation. After calculation of the ethanol content, report the result to one decimal place.

NOTE – (1) If excessive frothing is encountered during distillation, render the solution strongly acid with phosphoric acid or treat with a small amount of liquid paraffin or silicone oil.

(2) The distillate should be clear or not more than slightly cloudy. If it is turbid or contains oily drops, follow Method IIIC. When steam-volatile acids are present, make the solution just alkaline with *1M sodium hydroxide* using solid *phenolphthalein* as indicator before distillation.

Method III B

Follow this method or the following one if the preparation being examined contains appreciable proportions of volatile materials other than ethanol and water.

Mix 25 ml of the preparation, accurately measured at 24^0 to 25.1^0, with about 100 ml of water in a separating funnel. Saturate this mixture with sodium chloride, add about 100 ml of *hexane* and shake vigorously for 2 to 3 minutes. Allow the mixture to stand for 15 to 20 minutes. Run the lower layer into the distillation flask, wash the *hexane* layer in the separating funnel by shaking vigorously with about 25 ml of *sodium chloride* solution, allow to separate and run the wash liquor into the first saline solution. Make the mixed solutions just alkaline with 1M sodium hydroxide using solid phenolphthalein as indicator, add a little pumice powder and 100 ml of water, distil 90 ml and determine the percentage v/v of ethanol by Method IIIA beginning at the words "Adjust the temperature…".

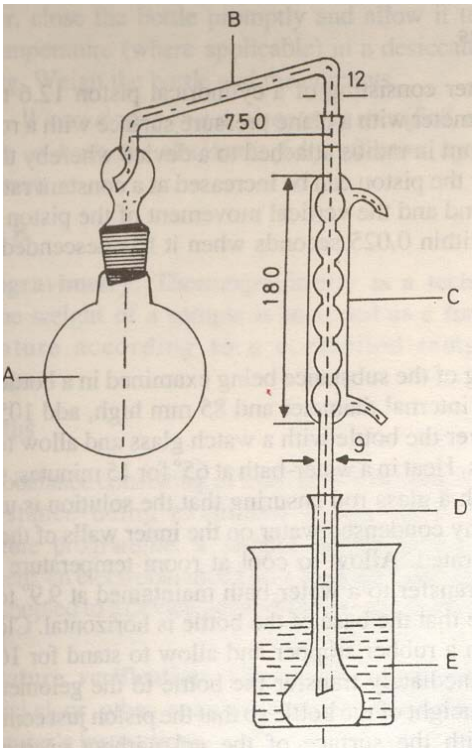


Fig.3 Apparatus for Determination of Ethanol by Distillation Method

Table-17

Specific gravity at 25^0	Ethanol content*
1.0000	0
0.9985	1
0.9970	2
0.9956	3
0.9941	4
0.9927	5
0.9914	6
0.9901	7
0.9888	8
0.9875	9
0.9862	10
0.9850	11
0.9838	12
0.9826	13
0.9814	14
0.9802	15
0.9790	16
0.9778	17
0.9767	18
0.9756	19
0.9744	20
0.9733	21
0.9721	22
0.9710	23
0.9698	24
0.9685	25

* per cent v/v at 15.56^0.

Method III C

Transfer 25 ml of the preparation, accurately measured at 24.9^0 to 25.1^0, to the distillation flask. Dilute with 150 ml of water and add a little pumice powder. Attach the distillation head and condenser. Distil and collect about 100 ml. Transfer to a separating funnel and determine the percentage v/v of ethanol by Method III B beginning at the words “Saturate this mixture…”.

APPENDIX – 4

REAGENTS AND SOLUTIONS

Acetic Acid – Contains approximately 33 per cent w/v of $C_2H_4O_2$. Dilute 315 ml of glacial acetic acid to 1000 ml with *water*.

Acetic Acid, Glacial – CH_3COOH =60.05.

Contains not less than 99.0 per cent w/w of $C_2H_4O_2$. About 17.5 N in strength.

Description **–** At temperature above its freezing point a clear colourless liquid, odour, pungent and characteristic; crystallises when cooled to about 10^0 and does not completely re-melt until warmed to about 15^0.

Solubility – Miscible with *water*, with *glycerin* and most fixed and volatile oils.

Boiling range –Between 117^0 and 119^0.

Congealing temperature –Not lower than 14.8^0.

Wt. per ml –At 25^0about 1.047 g.

Heavy metals –Evaporate 5 ml to dryness in a porcelain dish on water-bath, warm the residue with 2 ml of 0.1 *N hydrochloric acid* and water to make 25 ml; the limit of heavy metals is 10 parts per million, Appendix 2.3.3.

Chloride –5 ml complies with the limit test for chlorides, Appendix 2.3.2.

Sulphate –5 ml complies with the limit test for sulphates,

Certain aldehydic substances – To 5 ml add 10 ml of *mercuric chloride solution* and make alkaline with *sodium hydroxide solution*, allow to stand for five minutes and acidify with dilute *sulphuric acid*; the solution does not show more than a faint turbidity.

Formic acid and oxidisable impurities – Dilute 5 ml with 10 ml of water, to 5 ml of this solution add 2.0 ml of 0.1 *N* potassium dichromate and 6 ml of sulphuric acid, and allow to stand for one minute, add 25 ml of water, cool to 15^0, and add 1 ml of freshly prepared potassium iodide solution and titrate the liberated iodine with 0.1 *N* sodium thiosulphate, using starch solution as indicator. Not less than 1 ml of 0.*N sodium thiosulphate* is required.

Odorous impurities –Neutralise 1.5 ml with *sodium hydroxide solution*; the solution has no odour other than a faint acetous odour.

Readily oxidisable impurities – To 5 ml of the solution prepared for the test for Formic Acid and Oxidisable Impurities, add 20 ml of water and 0.5 ml of 0.1 *N potassium permanganate;* the pink colour does not entirely disappear within half a minute.

Non-volatile matter – Leaves not more than 0.01 per cent w/w of residue when evaporated to dryness and dried to constant weight at 105^0.

Assay –Weigh accurately about 1 g into a stoppered flask containing 50 ml of *water* and titrate with *N sodium hydroxide*, using *phenolphthalein solution* as indicator. Each ml of *sodium hydroxide* is equivalent to 0.06005 g of $C_2H_4O_2$.

Acetic Acid, Lead-Free –Acetic acid which complies with following additional test, boil 25 ml until the volume is reduced to about 15 ml, cool make alkaline with lead-free ammonia solution, add 1 ml of lead free *potassium cyanide solution, dilute* to 50 ml with water, add 2 drops of *sodium sulphide solution;* no darkening is produced.

Acetone – Propan-2-one; $(CH_3)_2CO$ = 58.08

Description – Clear, colourless, mobile and volatile liquid; taste, pungent and sweetish; odour characteristic; flammable.

Solubility –Miscible with *water*, with alcohol, with *solvent ether*, and with *chloroform*, forming clear solutions.

Distillation range – Not less than 96.0 per cent distils between 55.5^0 and 57^0.

Acidity– 10 ml diluted with 10 ml of freshly boiled and cooled water; does not require for neutralisation more than 0.2 ml of 0.1 *N sodium hydroxide*, using phenolphthalein solution as indicator.

Alkalinty – 10 ml diluted with 10 ml of freshly boiled and cooled water, is not alkaline to litmus solution.

Methyl alcohol –Dilute 10 ml with water to 100 ml. To 1 ml of the solution add 1 ml of *water* and 2 ml of *potassium permanganate* and *phosphoric acid solution.* Allow to stand for ten minutes and add 2 ml of *oxalic acid* and *sulphuric acid solution;* to the colourless solution add 5 ml of *decolorised magenta solution* and set aside for thirty minutes between 15^0 and 30^0; no colour is produced.

Oxidisable substances –To 20 ml add 0.1 ml of 0.1 *N potassium permanganate*, and allow to stand for fifteen minutes; the solution is not completely decolorised.

Water – Shake 10 ml with 40 ml of *carbon disulphide*; a clear solution is produced.

Non-volatile matter –When evaporated on a water-bath and dried to constant weight at 105^0, leaves not more than 0.01 per cent w/v residue.

Acetone Solution, Standard – A 0.05 per cent v/v solution of acetone in water.

Alcohol –

Description – Clear, colourless, mobile, volatile liquid, odour, characteristic and spirituous; taste, burning, readily volatilised even at low temperature, and boils at about 78^0, flammable. Alcohol containing not less than 94.85 per cent v/v and not more than 95.2 per cent v/v of C_2H_5OH at 15.56^0.

Solubility –Miscible in all proportions with *water,* with *chloroform* and with *solvent ether.*

Acidity or alkalinity – To 20 ml add five drops of *phenolphthalein solution*; the solution remains colourless and requires not more than 2.0 ml of 0.1*N sodium hydroxide* to produce a pink colour.

Specific gravity –Between 0.8084 and 0.8104 at 25^0.

Clarity of solution –Dilute 5 ml to 100 ml with *water* in glass cylinder; the solution remains clear when examined against a black background. Cool to 10^0 for thirty minutes; the solution remains clear.

Methanol – To one drop add one of water, one drop of *dilute phosphoric acid,* and one drop of *potassium permanganate solution.* Mix, allow to stand for one minute and add sodium bisulphite solution dropwise, until the permanganate colour is discharged. If a brown colour remains, add one drop of *dilute phosphoric* acid. To the colourless solution add 5 ml of freshly prepared *chromotropic acid* solution and heat on a water-bath at 60^0 for ten minutes; no violet colour is produced.

Foreign organic substances – Clean a glass-stoppered cylinder thoroughly with *hydrochloric acid,* rinse with water and finally rinse with the alcohol under examination. Put 20 ml in the cylinder, cool to about 15^0 and then add from a carefully cleaned pipette 0.1 ml 0.1 *N potassium permanganate.* Mix at once by inverting the stoppered cylinder and allow to stand at 15^0 for five minutes; the pink colour does not entirely disappear.

Isopropyl alcohol and t-butyl alcohol – To 1 ml add 2 ml of water and 10 ml of *mercuric sulphate solution* and heat in a boiling water-bath; no precipitate is formed within three minutes.

Aldehydes and ketones – Heat 100 ml of *hydroxylamine hydrochloride solution* in a loosely stoppered flask on a water-bath for thirty minutes, cool, and if necessary, add sufficient 0.05 *N sodium hydroxide* to restore the green colour. To 50 ml of this solution add 25 ml of the alcohol and heat on a water bath for ten minutes in a loosely stoppered flask. Cool, transfer to a *Nesseler cylinder,* and titrate with 0.05 *N sodium hydroxide* until the colour matches that of the remainder of the *hydroxylamine hydrochloride solution* contained in a similar cylinder, both solutions being viewed down the axis of the cylinder. Not more than 0.9 ml of 0.05 *N sodium hydroxide* is required.

Fusel oil constituents – Mix 10 ml with 5 ml of *water* and 1 ml of *glycerin* and allow the mixture to evaporate spontaneously from clean, odourless absorbent paper; no foreign odour is perceptible at any stage of the evaporation.

Non-volatile matter – Evaporate 40 ml in a tared dish on a water-bath and dry the residue at 105º for one hour; the weight of the residue does not exceed 1 mg.

Storage – Store in tightly-closed containers, away from fire.

Labelling – The label on the container states "Flammable".

Alcohol, Aldehyde-free. –Alcohol which complies with the following additional test :

Aldehyde – To 25 ml, contained in 300 ml flask, add 75 ml of *dinitrophenyl hydrazine solution,* heat on a water bath under a reflux condenser for twenty four hours, remove the alcohol by distillation, dilute to 200 ml with a 2 per cent v/v solution of sulphuric acid, and set aside for twenty four hours; no crystals are produced.

Alcohol, Sulphate-free. –Shake alcohol with an excess of anion exchange resin for thirty minutes and filter.

Anisaldehyde-sulphuric acid reagent(AS) - Mix 0.5 ml Anisaldehyde with 10 ml glacial acetic acid, followed by 85 ml *methanol* and 5 ml concentrated sulphuric acid.

Ammonia, XN. –Solutions of any normality xN may be prepared by diluting 75 x ml of strong ammonia solution to 1000 ml with water.

Ammonia Solution, Iron-free –Dilute ammonia solution which complies with the following additional test :-

Evaporate 5 ml nearly to dryness on a water-bath add 40 ml of water, 2 ml of 20 per cent w/v *solution of iron free citric acid* and 2 drops of *thioglycollic acid*, mix, make alkaline with *iron-free ammonia solution and dilute* to 50 ml with *water*, no pink colour is produced.

Ammonium Chloride Solution –A 10.0 per cent w/v solution of *ammonium chloride* in water.

Ammonium molybdate- $NH_4Mo_7O_{24}.4H_2O$=1235.86
Analytical reagent grade of commerce.
White crystal or crystalline masses, sometimes with a yellowish or green tint.

Ammonium Thiocyanate – NH_4SCN = 76.12.

Description –Colourless crystals.

Solubility – Very soluble in water, forming a clear solution, readily soluble in alcohol.

Chloride –Dissolve 1 g in 30 ml of solution of hydrogen peroxide, add 1 g of *sodium hydroxide*, warm gently, rotate the flask until a vigorous reaction commences and allow to stand until the reaction is complete; add a further 30 ml of *hydrogen peroxide solution* boil for two minutes, cool, and add 10 ml of *dilute nitric acid* and 1 ml of *silver nitrate solution*;

any opalescence produced is not greater than that obtained by treating 0.2 ml of 0.01 *N hydrochloric acid* in the same manner.

Sulphated ash –Moisten 1 g with *sulphuric acid* and ignite gently, again moisten with sulphuric acid and ignite; the residue weighs not more than 2.0 mg.

Ammonium Thiocyanate, 0.1N – NH_4SCN = 76.12; 7.612 in 1000 ml. Dissolve about 8 g of *ammonium thiocyanate* in 100o ml of water and standardise the solution as follows :

Pipette 30 ml of standardised 0.1 *N silver nitrate* into a glass stoppered flask, dilute with 50 ml of *water* then add 2 ml of *nitric acid* and 2 ml of *ferric ammonium sulphate solution* and titrate with the *ammonium thiocyanate solution* to the first appearance of a red brown colour. Each ml of 0.1N *silver nitrate* is equivalent to 0.007612 g of NH_4SCN.

Ammonium Thiocyanate Solution – A 10.0 per cent w/v solution of *ammonium thiocyanate solution*.

Anisaldehyde-Sulphuric Acid Reagent – 0.5 ml *anisaldehyde* is mixed with 10 ml *glacial acetic acid*, followed by 85 ml methanol and 5 ml concentrated *sulphuric acid* in that order.

The reagent has only limited stability and is no longer usable when the colour has turned to redviolet.

Arsenomolybdic Acid Reagent- 250 mg of ammonium molybdate was dissolved in 45 ml of distilled water. To this, 2.1 ml of concentrated H_2SO_4 was added and mixed well. To this solution, 3mg of $Na_2ASO_4.7\ H_2O$ dissolved in 25 ml of distilled water, mixed well and placed in incubator maintained at 37^0 C for 24 h.

Borax - Sodium Tetraborate, $Na_2B_4O_7.\ 10H_2O$ = 381.37.
Contains not less than 99.0 per cent and not more than the equivalent of 103.0 per cent of $Na_2B_4O_7.\ 10H_2O$.

Description –Transparent, colourless crystals, or a white, crystalline powder; odourless, taste, saline and alkaline. Effloresces in dry air, and on ignition, loses all its water of crystallisation.

Solubility –Soluble in water, practically insoluble in alcohol.

Alkalinity –A solution is alkaline to litmus solution.

Heavy metals – Dissolve 1 g in 16 ml of water and 6 ml of *N hydrochloric acid* and add *water* to make 25 ml; the limit of heavy metals is 20 parts per million, Appendix 2.3.3.

Iron –0.5 g complies with the *limit test for iron,* Appendix 2.3.4.

Chlorides –1 g complies with the *limit test for chlorides,* Appendix 2.3.2.

Sulphates –1g complies with the *limit test for sulphates*, Appendix 2.3.6.

Assay –Weigh accurately about 3 g and dissolve in 75 ml of *water* and titrate with 0.5 *N hydrochloric acid*, using *methyl red solution* as indicator. Each ml of 0.5 *N* hydrochloric acid is equivalent to 0.09534 g of $Na_2B_4O_7.10H_2O$.

Storage – Preserve Borax in well-closed container.

Bromine – Br_2 =159.80.

Description –Reddish-brown, fuming, corrosive liquid.

Solubility –Slightly soluble in *water*, soluble in most organic solvents.

Iodine –Boil 0.2 ml with 20 ml of *water*, 0.2 ml of *N sulphuric acid* and a small piece of marble until the liquid is almost colourless. Cool, add one drop of *liquefied phenol*, allow to stand for two minutes, and then add 0.2 g of *potassium iodide* and 1 ml of *starch solution*; no blue colour is produced.

Sulphate –Shake 3 ml with 30 ml of *dilute ammonia solution* and evaporate to dryness on a water bath, the residue complies with the *limit test for sulphates*, Appendix 2.3.6.

Bromine Solution – Dissolve 9.6 ml of *bromine* and 30 g of *potassium bromide* in sufficient *water* to produce 100 ml.

Canada Balsam Reagent –General reagent grade of commerce.

Carbon Tetrachloride – CCl_4 = 153.82

Description –Clear, colourless, volatile, liquid; odour, characteristic.

Solubility –Practically insoluble in water; miscible with ethyl alcohol, and with solvent ether.

Distillation range –Not less than 95 per cent distils between 76^0 and 77^0.

Wt. per ml – At 20^0, 1.592 to 1.595 g.

Chloride, free acid –Shake 20 ml with 20 ml of freshly boiled and cooled water for three minutes and allow separation to take place; the aqueous layer complies with the following test :

Chloride – To 10 ml add one drop of nitric acid and 0.2 ml of *silver nitrate solution*; no opalescence is produced.

Free acid –To 10 ml add a few drops of *bromocresol purple solution;* the colour produced does not indicate more acidity than that indicated by the addition of the same quantity of the indicator to 10 ml of freshly boiled and cooled *water.*

Free chlorine –Shake 10 ml with 5 ml of *cadmium iodide solution* and 1 ml *of starch solution*, no blue colour is produced.

Oxidisable impurities –Shake 20 ml for five minutes with a cold mixture of 10 ml of *sulphuric acid* and 10 ml of 0.1 *N potassium dichromate,* dilute with 100 ml of water and add 3 g of *potassium iodide* : the liberated iodine requires for decolourisation not less than 9 ml of 0.1 *N sodium thiosulphate.*

Non-volatile matter –Leaves on evaporation on a water-bath and drying to constant weight at 105^0 not more than 0.002 per cent w/v of residue.

Caustic Alkali Solution, 5 per cent – Dissolve 5 g of *potassium or sodium hydroxide* in *water* and dilute to 100 ml.

Charcoal, Decolourising –General purpose grade complying with the following test.

Decolourising powder –Add 0.10 g to 50 ml of 0.006 per cent w/v solution of *bromophenol blue* in ethanol (20 per cent) contained in a 250 ml flask, and mix. Allow to stand for five minutes, and filter; the colour of the filtrate is not deeper than that of a solution prepared by diluting 1 ml of the *bromophenol blue solution* with *ethanol* (20 per cent) to 50 ml.

Chloral Hydrate –$CCl_3.CH(OH)_2$ = 165.40.

Description –Colourless, transparent crystals, odour, pungent but not acrid; taste, pungent and slightly bitter, volatilises slowly on exposure to air.

Solubility –Very soluble in *water,* freely soluble in *alcohol*, in chloroform and in *solvent ether*.

Chloral alcoholate – Warm 1 g with 6 ml of *water* and 0.5 ml of *sodium hydroxide solution* : filter, add sufficient 0*.1 N iodine* to impart a deep brown colour, and set aside for one hour; no yellow crystalline precipitate is produced and no smell of iodoform is perceptible.

Chloride – 3 g complies with the limit test for chlorides, Appendix 2.3.2.

Assay – Weigh accurately about 4 g and dissolve in 10 ml of *water* and add 30 ml of *N sodium hydroxide.* Allow the mixture to stand for two minutes, and then titrate with *N sulphuric acid* using *phenolphthalein solution* as indicator. Titrate the neutralised liquid with 0.1 *N silver nitrate* using solution of *potassium chromate* as indicator. Add two-fifteenth of the amount of 0.1 *N silver nitrate* used to the amount of *N sulphuric acid* used in the first titration and deduct the figure so obtained from the amount of *N sodium hydroxide* added. Each ml of *N sodium hydroxide,* obtained as difference; is equivalent to 0.1654 g of $C_2H_3Cl_3O_2$.

Storage – Store in tightly closed, light resistant containers in a cool place.

Chloral Hydrate Solution –Dissolve 20 g of *chloral hydrate* in 5 ml of water with warming and add 5 ml of *glycerin*.

Chloral Iodine Solution –Add an excess of crystalline *iodine with* shaking to the *chloral hydrate solution,* so that crystals of undissolved iodine remain on the bottom of bottle.

Shake before use as the iodine dissolves, and crystals of the iodine to the solution. Store in a bottle of amber glass in a place protected from light.

Chloroform – $CHCl_3$ = 119.38

Description –Colourles, volatile liquid; odour, characteristic. Taste, sweet and burning.

Solubility –Slightly soluble in water; freely miscible with ethyl alcohol and with solvent ether.

Wt. per ml. : Between 1.474 and 1.478 g.

Boiling range – A variable fraction, not exceeding 5 per cent v/v, distils below 60^0 and the remainder distils between 50^0 to 62^0.

Acidity –Shake 10 ml with 20 ml of freshly boiled and cooled water for three minutes, and allow to separate. To a 5 ml portion of the aqueous layer add 0.1 ml of *litmus solution*; the colour produced is not different from that produced on adding 0.1 ml of *litmus solution* to 5 ml of freshly boiled and cooled water.

Chloride –To another 5 ml portion of the aqueous layer obtained in the test for Acidity, add 5 ml of water and 0.2 ml of *silver nitrate solution*; no opalescence is produced.

Free chlorine –To another 10 ml portion of the aqueous layer, obtained in the test for Acidity, add 1 ml of *cadmium iodide solution* and two drops of starch solution; no blue colour is produced.

Aldehyde –Shake 5 ml with 5 ml of water and 0.2 ml of *alkaline potassium mercuri-iodide solution* in a stoppered bottle and set aside in the dark for fifteen minutes; not more than a pale yellow colour is produced.

Decomposition products – Place 20 ml of the *chloroform* in a glass-stoppered flask, previously rinsed with *sulphuric acid,* add 15 ml of *sulphuric acid* and four drops of *formaldehyde solution*, and shake the mixture frequently during half an hour and set aside for further half an hour, the flask being protected from light during the test; the acid layer is not more than slightly coloured.

Foreign organic matter – Shake 20 ml with 10 ml of *sulphuric* acid in a stoppered vessel previously rinsed with *sulphuric acid* for five minutes and set aside in the dark for thirty minutes, both the acid and chloroform layers remain colourless. To 2 ml of the acid layer add 5 ml of water; the liquid remains colourless and clear, and has no unpleasent odour. Add a further 10 ml of water and 0.2 ml of *silver nitrate solution*; no opalescence is produced.

Foreign odour –Allow 10 ml to evaporate from a large piece of filter paper placed on a warm plate; no foreign odour is detectable at any stage of the evaporation.

Non volatile matter – Not more than 0.004 per cent w/v determined on 25 ml by evaporation and drying at 105^0.

Storage : Store in tightly-closed, glass-stoppered, light-resistant bottles.

Copper Sulphate – $CuSO_4.5H_2O$ = 249.68

Contains not less than 98.5 per cent and not more than the equivalent of 101.0 per cent of $CuSO_4.5H_2O$.

Description –Blue triclinic prisms or a blue, crystalline powder.
Solubility –Soluble in *water*, very solube in boiling water, almost insoluble in *alcohol*; very slowly soluble in glycerin.

Acidity and clarity of solution – 1 g, dissolved in 20 ml of water, forms a clear blue solution, which becomes green on the addition of 0.1 ml of *methyl orange solution*.

Iron – To 5 g, add 25 ml of water, and 2 ml of nitric acid, boil and cool. Add excess of *strong ammonia solution*, filter, and wash the residue with *dilute ammonia solution* mixed with four times its volumes of water. Dissolve the residue, if any, on the filter with 2 ml of *hydrochloric acid*, diluted with 10 ml of water; to the acid solutions add *dilute ammonia solution* till the precipitation is complete; filter and wash; the residue after ignition weighs not more than 7 mg.

Copper Sulphate, Anhydrous – $CuSO_4$ =159.6

Prepared by heating copper sulphate to constant weight at about 230^0.

Copper Sulphate Solution –A10.0 per cent w/v solution of *copper sulphate* in *water*.
Cresol Red – 4,4$^{/}$, –(3H-2, 1-Benzoxathiol-3 ylidene) di-O-cresol SS-dioxide; $C_{12}H_8O_5S$ = 382.4.

Gives a red colour in very strongly acid solutions, a yellow colour in less strongly acid and neutral solutions, and a red colour in moderately alkaline solutions (*p*H ranges, 0.2 to 1.8, and 7.2 to 8.8).

Cresol Red Solution –Warm 50 ml of cresol red with 2.65 ml of 0.05 M sodium hydroxide and 5 ml of ethanol (90 per cent); after solution is effected, add sufficient ethanol (20 per cent) to produce 250 ml.

Sensitivity –A mixitue of 0.1 ml of the solution and 100 ml of *carbon dioxide-free water* to which 0.15 ml of 0.02 M s*odium hydroxide* has been added is purplish-red. Not more than 0.15 ml of 0.02 *M hydrochloric acid* is required to change the colour to yellow.

Disodium Ethylenediamine tetraacetate – (Disodium Acetate) $C_{10}H_{14}N_2Na_2O_8.2H_2O$ = 372.2 , Analytical reagent grade.

Dragendorff Reagent –
Solution 1 –Dissolve 0.85 g of *bismuth oxy nitrate* in 40 ml of water and 10 ml of acetic acid.
Solution 2 –Dissolve 8 g of *potassium iodide* in 20 ml of water.

Mix equal volumes of solution 1 and 2, and to 10 ml of the resultant mixture add 100 ml of water and 20 ml of acetic acid.

Dragendroffs reagent with tartaric acid:
Solution A: 17 g bismuth sub-nitrate and 200 g tartaric acid in 800 ml water
Solution B: 160 g potassium iodide in 400 ml water.
Stock solution: solution A & solution B
Spray reagent: 50 ml stock solution + 500 ml water + 100 g tartaric acid

Dithizone;1,5-Diphenylthiocarbazone;Diphenylthiocarbazone;$C_6H_5N:NCSNHNHC_6H_5$= 56.32
Analytical Reagent grade of commerce.
Almost black powder; mp, about 168^0, with decomposition.
Store in light-resistant containers.

Eosin – Acid Red 87; Tetrabromofluorescein disodium salt; $C_{20}H_6O_5Br_4Na_2$ =691.86.

Description – Red powder, dissolves in water to yield a yellow to *purplish-red* solution with a greenish-yellow fluorescence.

Solubility –Soluble in *water* and in alcohol.

Chloride –Dissolve 50 mg in 25 ml of *water*, add 1 ml of *nitric acid*, and filter; the filtrate complies with *the limit test for chlorides*, Appendix 2.3.2.

*Sulphate*d ash –Not more than 24.0 per cent, calculated with reference to the substance dried at 110^0 for two hours, Appendix 2.2.6.

Eosin Solution –A 0.5 per cent w/v solution of eosin in water.

Eriochrome Black T –Mordant Black 11; Sodium 2(1-hydroxy-2-naphthylazo) 5-nitro-2-naphtol-4-sulphonate; $C_{20}H_{12}N_3NaO_7S$ = 461.38.

Brownish black powder having a faint, metallic sheen, soluble in alcohol, in *methyl alcohol* and in hot water.

Ethyl Acetate –CH_3. $CO_2C_2H_5$ = 88.11.

Analytical reagent grade.

A colourless liquid with a fruity odour; boiling point, about 77^0; weight per ml about 0.90g.

Ethyl Alcohol –C_2H_5OH = 46.07.

Absolute Alcohol; Dehydrated Alcohol.

Description –Clear, colourless, mobile, volatile liquid; odour, characteristic and spirituous; taste, burning; hygroscopic. Readily volatilisable even at low temperature and boils at 78^0 and is flammable.

Solubility –Miscible with water, with solvent ether and with chloroform.

Contains not less than 99.5 per cent w/w or 99.7 per cent v/v of C_2H_5OH.

Identification –Acidity or Alkalinity: Clarity of Solution; Methanol; Foreign organic substances; Isopropyl alcohol and butyl alcohol; Aldehydes and ketones; fusel oil constituents; Non-volatile matter; complies with the requirements described under Alcohol.

Specific gravity –Between 0.7871 and 0.7902, at 25^0.

Storage –Store in tightly closed containers in a cool place away from fire and protected from moisture.

Labelling –The label on the container states "Flammable".

Fehlings Solution –

A. Dissolve 69.278 g of CuSO4. $5H_2O$ in water and make the volume up to 1 litre
B. Dissolve 100 g of sodium hydroxide and 340 g of Sodium potassium tartarate in water and make the volume to 1 litre.

Mix equal volumes of A and B before the experiment.

Formaldehyde Solution –Formalin; HCHO =30.03

Formaldehyde Solution is a solution of formaldehyde in water with *methyl alcohol* added to prevent polymerisation. It contains not less than 34.0 per cent w/w and not more than 38.0 per cent w/w of CH_2O.

Description – Colourless liquid; odour, characteristic, pungent and irritating; taste, burning. A slight white cloudy deposit is formed on long standing, especially in the cold, due to the separation of paraformaldehyde. This white deposit disappears on warming the solution.
Solubility –Miscible with *water*, and with *alcohol*.

Acidity –To 10 ml add 10 ml of *carbon dioxide free water* and titrate with 0.1 *N sodium hydroxide* using *bromothymol blue solutions* as indicator; not more than 5 ml of 0.1 *N sodium hydroxide* is required.

Wt. per ml – At 20^0, 1.079 to 1.094 g.

Assay –Weigh accurately about 3 g and add to a mixture of 50 ml of *hydrogen peroxide solution* and 50 ml of *N sodium hydroxide*, warm on a water-bath until effervescence ceases and titrate the excess of alkali with *N sulphuric acid* using *phenolphthalein solution* as indicator. Repeat the experiment with the same quantities of the same reagents in the same manner omitting the formaldehyde solution. The difference between the titrations represents the sodium hydroxide required to neutralise the formic acid produced by the oxidation of the formaldehyde. Each ml of N sodium hydroxide is equivalent to 0.03003 g of CH_2O.

Storage–Preserve Formaldehyde Solution in well-closed container preferably at a temperature not below 15^0.

Formaldehyde Solution, Dilute –

Dilute 34 ml of *formaldehyde solution* with sufficient water to produce 100 ml.

Folin Ciocalteu reagent- Dilute commercially available Folin-Ciocalteu reagent (2N) with an equal volume of distilled water. Transfer it in a brown bottle and store in a refrigerator (4^0). It should be goldern in colour. Do not use it if it turns olive green.

Formic acid- HCOOH = 46.03

Description:-Colourless liquid, odour, very pungent, highly corrosive; wt per ml. about 1.20 g, contains about 90.0 per cent of HCOOH and is about 23.6 M in strength.

Assay:- Weigh accurately, a conical flask containing 10ml of water, quickly add about 1ml of the reagent being examined and weigh again. Add 50ml of water and titrate with *1M sodium hydroxide* using 0.5 ml of *phenolphthalein solution* as indicator. Each ml of 1*M sodium hydroxide* is equivalent to 0.04603 g of HCOOH.

Gallic acid

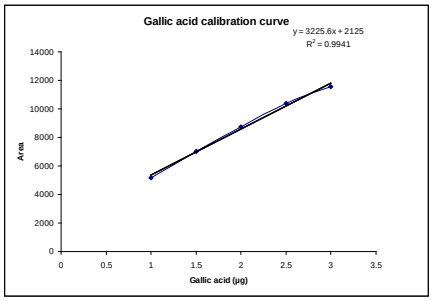
Category**:** Astringent, styptic

Description**:** Off white powder; Needles from absolute methanol or chloroform.

Solubility**:** 1 g dissolves in 87 ml water, 3 ml boiling water, 6 ml alcohol, 100 ml ether, 10 ml glycerol, 5 ml acetone. [Merck Index, 2001, 13th Edn., pp. 722]

Loss on Drying**:** NMT 10 %

Calibration Curve**:** Weigh 25 mg of gallic acid and dissolve in 25 ml of methanol. Perform serial dilutions to make the concentrations of 100 µg/ml, 200 µg/ml, 300 µg/ml, 400 µg/ml, 500 µg/ml and 600 µg/ml. Apply 5 µl of each concentration in triplicate on precoated thin layer chromatographic plate of 0.2 mm thickness. Develop the plate in twin trough TLC chamber (Solvent system: Toluene: Ethyl Acetate: Acetic Acid; 5:4:1 % v/v) upto 8 cm. Spray the plate with Natural Products reagent. Dry the plate in a current of cold air and visualize the plate at 366 nm. Scan the plate densitometrically at 366 nm. Record the peak area under curve and plot the calibration curve for gallic acid.



Assay **:** Contains not less than 0.008 per cent w/v of gallic acid and ethyl gallate, when assayed by the following method:

Glycerine –$C_3H_8O_3$ = 82.09.

Description – Clear, colorless, liquid of syrupy consistency; odourless, taste sweet followed by a sensation of warmth. It is hygroscopic.

Solubility –Miscible with water and with *alcohol*; practically insoluble in chloroform, in solvent ether and in fixed oils.

Acidity –To 50 ml of a 50 per cent w/v solution add 0.2 ml of *dilute phenolphthalein solution*; not more than 0.2 ml of 0.1 *N sodium hydroxide* is required to produce a pink colour.

Wt. per ml –Between 1.252 g and 1.257 g, corresponding to between 98.0 per cent and 100.0 per cent w/w of $C_3H_8O_3$.

Refractive index –Between 1.470 and 1.475 determined at 20^0.

Arsenic –Not more than 2 parts per million, Appendix 2.3.1.

Copper –To 10 ml add 30 ml of *water*, and 1 ml of *dilute hydrochloric acid*, and 10 ml of *hydrogen sulphide solution*; no colour is produced.

Iron – 10 g complies with the *limit test* for iron, Appendix 2.3.4.

Heavy metals – Not more than 5 parts per million, determined by Method A on a solution of 4 g in 2 ml of 0.1 *N hydrochloric acid* and sufficient water to produce 25 ml, Appendix 2.3.3.

Sulphate –1 ml complies with the *limit test* for sulphates, Appendix 2.3.6.

Chloride –1 ml complies with the *limit test* for chloride, Appendix 2.3.2.

Acraldehyde and glucose –Heat strongly; it assumes not more than a faint yellow, and not a pink colour. Heat further; it burns with little or no charring and with no odour of burnt sugar.

Aldehydes and related substances – To 12.5 ml of a 50 per cent w/v solution in a glass-stoppered flask add 2.5 ml of *water* and 1 ml of *decolorised magenta solution*. Close the flask and allow to stand for one hour. Any violet colour produced is not more intense than that produced by mixing 1.6 ml of 0.1 *N potassium permanganate* and 250 ml of *water*.

Sugar –Heat 5 g with 1 ml of *dilute sulphuric acid* for five minutes on a water-bath. Add 2 ml of *dilute sodium hydroxide solution* and 1 ml of *copper sulphate solution*. A clear, blue coloured solution is produced. Continue heating on the water-bath for five minutes. The solution remains blue and no precipitate is formed.

Fatty acids and esters –Mix 50 ml with 50 ml of freshly boiled *water* and 50.0 ml of 0.5N *sodium hydroxide,* boil the mixture for five minutes. Cool, add a few drops of *phenolphthalein solution* and titrate the excess alkali with 0.5 *N hydrochloric acid*. Perform a blank determination, not more than 1 ml of 0.5 *N sodium hydroxide* is consumed.

*Sulphate*d ash –Not more than 0.01 per cent, Appendix 2.2.6.

Storage –Store in tightly-closed containers.

Glycerin Solution –Dilute 33 ml of *glycerin* to 100 ml with water and add a small piece of camphor or liquid phenol.

***n*- Hexane:-** C_6H_{14},= 86.18

Analytical reagent grade of commerce containing not less than 90.05 of n-*Hexane*

Colourless, mobile, highly flammable liquid, bp 68^0; wt per ml, about 0.674 g

Hydrochloric Acid –HCl = 36.46

Concentrated Hydrochloric Acid

Description –Clear, colourless, fuming liquid; odour, pungent.

Arsenic –Not more than 1 part per million, Appendix 2.3.1.

Heavy metals –Not more than 5 parts per million, determined by Method A on a solution prepared in the following manner : Evaporate 3.5 ml to dryness on a water-bath, add 2 ml of *dilute acetic acid* to the residue, and add water to make 25 ml, Appendix 2.3.3.

Bromide and iodide –Dilute 5 ml with 10 ml of *water*, add 1 ml of *chloroform*, and add drop by drop, with constant shaking, *chlorinated lime solution*; the chloroform layer does not become brown or violet.

Sulphite –Dilute 1 ml with 10 ml of water, and add 5 drops of *barium chloride solution* and 0.5 ml of 0.001 *N iodine*; the colour of the iodine is not completely discharged.

Sulphate –To 5 ml add 10 mg of sodium bicarbonate and evaporate to dryness on a water bath; the residue, dissolved in *water*; complies with the *limit test for sulphates*, Appendix. 2.3.7.

Free chlorine –Dilute 5 ml with 10 ml of freshly boiled and cooled *water*, add 1 ml of cadmium *iodide solution*, and shake with 1 ml of *chloroform*; the chloroform layer does not become violet within one minute.

*Sulphate*d ash –Not more than 0.01 per cent, Appendix 2.2.6.

Assay –Weigh accurately about 4 g into a stoppered flask containing 40 ml of water, and titrare with *N sodium hydroxide*, using *methyl orange solution* as indicator. Each ml of *N sodium hydroxide* is equivalent to 0.03646 g of HCl.

Storage –Store in glass-stoppered containers at a temperature not exceeding 30^0.

Hydrochloric Acid, x N –Solution of any normality x N may be prepared by diluting 84 x ml of *hydrochloric acid* to 1000 ml with *water*.

Hydrochloric Acid –(1 per cent w/v) Dilute 1 g of hydrochloric *acid* to 100 ml with *water.*

Dilute Hydrochloric Acid –

Description –Colourless liquid.

Arsenic, Heavy metals bromoide and iodide, Sulphate, free chlorine –Complies with the tests described under Hydrochloric Acid, when three times the quantity is taken for each test.

Assay –Weigh accurately about 10 g and carry out the Assay described under Hydrochloric Acid.

Storage –Store in stoppered containers of glass or other inert material, at temperature below 30^0.

Hydrochloric Acid, N – HCl = 36.460

36.46 g in 1000 ml

Dilute 85 ml of hydrochloric acid with water to 1000 ml and standardise the solution as follows:

Weigh accurately about 1.5 g of anhydrous sodium carbonate, previously heated at about 270^0 for one hour. Dissolve it in 100 ml of *water* and add two drops of *methyl red solution*. Add the acid slowly from a burette with constant stirring, until the solution becomes faintly pink. Heat again to boiling and titrate further as necessary until the faint pink colour no longer affected by continued boiling. Each 0.5299 g of *anhydrous* sodium carbonate is equivalent to 1 ml of N hydrochloric acid.

Hydrochloric Acid, Iron-Free –Hydrochloric acid, which complies with the following additional test. Evaporate 5 ml on a water-bath nearly to dryness, add 40 ml of water, 2 ml of a 20 per cent w/v solution of citric acid and two drops of thioglycollic acid, mix, make alkaline with *dilute ammonia solution*, and dilute to 50 ml with water; no pink colour is produced.

Hydrogen Peroxide Solution – (20 Vol.) H_2O_2 = 34.02

Analytical reagent grade of commerce or *hydrogen peroxide solution* (100 Vol.) diluted with 4 volumes of water.

A colourless liquid containing about 6 per cent w/v of H_2O_2; weight per ml, about 1.02 g.

Hydroxylamine Hydrochloride; Hydroxylammonium Chloride – $NH_2OH.HCl = 69.49$.

Contains not less than 97.0 per cent w/w of NH_2OH. HCI.

Description –Colourless crystals, or a white, crystalline powder.

Solubility –Very soluble in water; soluble in alcohol.

Free acid –Dissolve 1.0 g in 50 ml of *alcohol*, add 3 drops of *dimethyl yellow solution* and titrate to the full yellow colour with *N sodium hydroxide*; not more than 0.5 ml of *N sodium hydroxide* is required.

Sulphated ash –Not more than 0.2 per cent, Appendix 2.2.6.

Assay –Weigh accurately about 0.1 g and dissolve in 20 ml of water, add 5 g of ferric ammonium sulphate dissolve in 20 ml of water, and 15 ml of *dilute sulphuric acid*, boil for five minutes, dilute with 200 ml of water, and titrate with 0.1 *N potassium permanganate*. Each ml of 0.1 *N potassium permanganate* is equivalent to 0.003475 g of NH_2OH. HCl.

Hydroxylamine Hydrochloride Solution –Dissolve 1 g of *hydroxylamine hydrochloride* in 50 ml of *water* and add 50 ml of *alcohol*, 1 ml of *bromophenol blue solution* and 0.1 *N sodium hydroxide* until the solution becomes green.

Mercuric Chloride –$HgCl_2$ =271.50.

Contains not less than 99.5 per cent of $HgCl_2$;

Description –Heavy, colourless or white, crystalline masses, or a white crystalline powder.

Solubility –Soluble in *water*; freely soluble in *alcohol*.

Non-volatile matter –When volatilised, leaves not more than 0.1 per cent of residue.

Assay –Weigh accurately about 0.3 g and dissolve in 85 ml of *water* in a stoppered-flask, add 10 ml of *calcium chloride solution*, 10 ml of *potassium iodide solution*, 3 ml of *formaldehyde solution and* 15 ml of *sodium hydroxide solution*, and shake continuously for two minutes. Add 20 ml of acetic acid and 35 ml of 0.1 *N iodine*. Shake continuously for about ten minutes, or until the precipitated mercury is completely redissolved, and titrate the excess of iodine with 0.1 *N sodium thiosulphate*. Each ml of 0.1 *N iodine is* equivalent to 0.01357 g of $HgCl_2$.

Mercuric Chloride, 0.2 M – Dissolve 54.30 g of *mercuric chloride* in sufficient water to produce 1000 ml.

Mercuric Chloride Solution –A 5.0 per cent w/v solution of *mercuric chloride* in water.

Mercuric Potassium Iodide Solution – See Potassium - Mercuric Iodide solution.

Methyl Alcohol : Methanol : CH_3OH = 32.04.

Description –Clear, Colourless liquid with a characteristic odour.

Solubility –Miscible with water, forming a clear colourless liquid.

Specific Gravity – At 25^0, not more than 0.791.

Distillation range – Not less than 95 per cent distils between 64.5^0 and 65.5^0.

Refractive Index –At 20^0, 1.328 to 1.329.

Acetone –Place 1 ml in a *Nessler cylinder*, add 19 ml of water, 2 ml of a 1 per cent w/v solution of *2-nitrobenzaldehyde* in *alcohol (50 per cent)*, 1 ml of 30 per cent w/v *solution of sodium hydroxide* and allow to stand in the dark for fifteen minutes. The colour developed does not exceed that produced by mixing 1 ml of standard acetone solution, 19 ml of water, 2 ml of the solution of *2-nitrobenzaldehyde* and 1 ml of the *solution of sodium hydroxide* and allowing to stand in the dark for fifteen minutes.

Acidity –To 5 ml add 5 ml of *carbon dioxide-free water*, and titrate with 0.1 *N sodium hydroxide*, using *bromothymol blue solution* as indicator; not more than 0.1 ml is required.

Non-volatile matter – When evaporated on a water-bath and dried to constant weight at 105º, leaves not more than 0.005 per cent w/v of residue.

Methyl Alcohol, Dehydrated –Methyl alcohol, which complies with the following additional requirement.

Water –Not more than 0.1 per cent w/w.

Methyl Orange – Sodium-*p*-di methylamineazobenzene sulphate, $C_{14}H_{14}O_3N_3SNa$.

An orange-yellow powder or crystalline scales, slightly soluble in cold water; insoluble in alcohol; readily soluble in hot water.

Methyl Orange Solution –Dissolve 0.1 g of methyl orange in 80 ml of water and dilute to 100 ml with alcohol.

Test for sensitivity –A mixture of 0.1 ml of the methyl orange solution and 100 ml freshly boiled and cooled water is yellow. Not more than 0.1 ml of 0.1 N hydrochloric acid is required to change the colour to red.

Colour change – *p*H 3.0 (red) to pH 4.4 (yellow).

Methyl Red – *p*-Dimethylaminoazobenzene-O-carboxylic acid, $C_{15}H_{15}O_2N_3$.

A dark red powder or violet crystals, sparingly soluble in *water*; soluble in alcohol.

Methyl red solution –Dissolve 100 mg in 1.86 ml of 0.1 *N sodium hydroxide* and 50 ml of *alcohol* and dilute to 100 ml with water.

Test for sensitivity –A mixture of 0.1 ml of the *methyl red solution* and 100 ml of freshly boiled and cooled *water* to which 0.05 ml of 0.02 *N hydrochloric acid* has been added is red. Not more than 0.01 ml of 0.02 *N sodium hydroxide* is required to change the colour to yellow.

Colour change – *p*H 4.4 (red) to *p*H 6.0 (yellow).

Molish's Reagent –Prepare two solutions in separate bottles, with ground glass stoppers:

(a) Dissolve 2 g of α-naphthol in 95 per cent alcohol and make upto 10 ml with alcohol (*α*-naphthol can be replaced by thymol or resorcinol). Store in a place protected from light. The solution can be used for only a short period.

(b) *Concentrated sulphuric acid*.

Natural Product Reagent (Natural Product-Polyethylene Reagent) –

Solution A-1% ethyl acetate diphenylboric acid-Bethylaminoester(NP),

Solution B-5%ethyl acetatepolyethylene glycol 4000 (PEG)

Spray the plate with10 ml solution A and 8ml solution B respectively.

Nitric Acid –Contains 70.0 per cent w/w of HNO_3 (limits, 69.0 to 71.0). About 16 N in strength.

Description –Clear, colourless, fuming liquid.

Wt. per ml. – At 20^0, 1.41 to 1.42 g.

Copper and Zinc –Dilute 1 ml with 20 ml of water, and add a slight excess of dilute ammonia solution; the mixture does not become blue. Pass hydrogen sulphide; a precipitate is not produced.

Iron –0.5 ml of complies with the limit test for iron, Appendix 2.3.4.

Lead –Not more than 2 parts per million, Appendix 2.3.5.

Chloride –5 ml neutralised with dilute ammonia solution, complies with the limit test for chlorides, Appendix 2.3.2.

Sulphates –To 2.5 ml add 10 mg of sodium bicarbonate and evaporate to dryness on a water-bath, the residue dissolved in water, complies with the limit test for sulphates, Appendix 2.3.7.
*Sulphate*d ash – Not more than 0.01 per cent w/w, Appendix 2.2.6.

Assay –Weigh accurately about 4 g into a stoppered flask containing 40 ml of water, and titrate with N Sodium hydroxide, using methyl orange solution as indicator. Each ml of N sodium hydroxide is equivalent to 0.06301 g of HNO_3.

Nitric Acid, xN –Solutions of any normality XN may be prepared by diluting 63x ml of nitric acid to 1000 ml with water.

Nitric Acid, Dilute –Contains approximately 10 per cent w/w of HNO_3. Dilute 106 ml of nitric acid to 1000 ml with water.

Petroleum Light – Petroleum Spirit.

Description – Colourless, very volatile, highly flammable liquid obtained from petroleum, consisting of a mixture of the lower members of the paraffin series of hydrocarbons and complying with one or other of the following definitions :

Light Petroleum –(Boiling range, 30^0 to 40^0).

Wt. per ml. –At 20^0, 0.620 to 0.630 g.

Light Petroleum –(Boiling range, 40^0 to 60^0).

Wt. per ml –At 20^0, 0.630 to 0.650 g.

Light Petroleum –(Boiling range, 60^0 to 80^0).

Wt. per ml. –At 20^0, 0.670 to 0.690.

Light Petroleum –(Boiling range, 80^0 to 100^0).

Wt. per ml. –At 20^0, 0.700 to 0.720

Light Petroleum –(Boiling range, 100^0 to 120^0).

Wt. per ml –At 20^0, 0.720 to 0.740 g.

Light Petroleum –(Boiling range, 120^0 to 160^0).

Wt. per ml –At 20^0, about 0.75 g.

Non-volatile matter –When evaporated on a water-bath and dried at 105^0, leaves not more than 0.002 per cent w/v of residue.

Phenolphthalein –$C_{20}H_{14}O_4$.

A white to yellowish-white powder, practically insoluble in water, soluble in alcohol.

Phenolphthalein Solution –Dissolve 0.10 g in 80 ml of *alcohol* and dilute to 100 ml with water.

Test for sensitivity –To 0.1 ml of the *phenolphthalein solution* add 100 ml of freshly boiled and cooled water, the solution is colourless. Not more than 0.2 ml of 0.02 *N sodium hydroxide* is required to change the colour to pink.

Colour change – *p*H 8.2 (colourless) to pH 10.0 (red)

Phloroglucinol – 1 , 3 , 5 – Trihydroxybenzene , $C_6H_3(OH)_3 . 2H_2O$.

Description – White or yellowish crystals or a crystalline powder.

Solubility –Slightly soluble in water; soluble in *alcohol*, and in *solvent ether*.

Melting range –After drying at 110^0 for one hour, 215^0 to 219^0.

*Sulphate*d ash – Not more than 0.1 per cent, Appendix 2.2.6.

Phloroglucinol should be kept protected from light.

Phosphoric Acid – H_3PO_4 = 98.00.

(Orthophosphoric Acid; Concentrated Phosphoric Acid).

Description –Clear and colourless syrupy liquid, corrosive.

Solubility –Miscible with water and with alcohol.

Phosphoric Acid, x N –

Solutions of any normality, x N may be prepared by diluting 49 x g of *phosphoric acid* with water to 1000 ml.

Phosphoric Acid, Dilute –

Contains approximately 10 per cent w/v of H_3PO_4.

Dilute 69 ml of *phosphoric acid* to 1000 ml with water.

Potassium Chloride –KCl = 74.55

Analytical reagent grade

Potassium Chromate – K_2CrO_4 = 194.2

Analytical reagent grade

Potassium Chromate Solution –A 5.0 per cent w/v solution of potassium chromate. Gives a red precipitate with *silver nitrate* in neutral solutions.

Potassium Cupri-Tartrate Solution –Cupric Tatrate Alkaline Solution: Fehling's Solution.

(1) *Copper Solution* – Dissolve 34.66 g of carefully selected small crystals of *copper sulphate,* showing no trace of efflorescence or of adhering moisture, in sufficient water to make 500 ml. Keep this solution in small, well-stoppered bottles.

(2) *Alkaline Tartrate Solution* – Dissolve 176 g of sodium *potassium tartrate* and 77 g of *sodium hydroxide* in sufficient *water* to produce 500 ml.

Mix equal volumes of the solutions No. 1 and No. 2 at the time of using.

Potassium Dichromate – $K_2Cr_2O_7$ =294.18.

Contains not less than 99.8 per cent of $K_2Cr_2O_7$.

Description – Orange-red crystals or a crystalline powder.

Solubility – Soluble in *water*

Chloride –To 20 ml of a 5 per cent w/v solution in *water* and 10 ml *nitric acid,* warm to about $50^0$and add a few drops of *silver nitrate solution*; not more than a faint opalescence is produced.

Assay –Carry out the assay described under Potassium Chromate, using 2 g. Each ml of 0.1 *N sodium thiosulphate* is equivalent to 0.004904 g of $K_2Cr_2O_7$.

Potassium Dichromate Solution – A 7.0 per cent w/v solution of *potassium dichromate* in *water.*

Potassium Dichromate, Solution 0.1N – $K_2Cr_2O_7$ = 294.18, 4.903 g in 1000 ml.

Weigh accurately 4.903 g of *potassium dichromate* and dissolve in sufficient *water* to produce 1000 ml.

Potassium Dihydrogen Phosphate - KH_2PO_4 = 136.1

Analytical reagent grade of commerce.

Potassium Ferrocyanide – $K_4Fe(CN)_6.3H_2O$ =422.39.

Contains not less than 99.0 per cent of $K_4Fe(CN)_6.3H_2O$.

Description –Yellow, crystalline powder.

Solubility –Soluble in water.

Acidity or Alkalinity –A 10 per cent w/v solution in water is neutral to litmus paper.

Assay –Weigh accurately about 1g and dissolve in 200 ml of *water*, add 10 ml of *sulphuric acid and* titrate with 0.1 *N potassium permanganate.* Each ml of 0.1 *N potassium permanganate* is equivalent to 0.04224 g of $K_4Fe(CN)_6.3H_2O$.

Potassium Ferrocyanide Solution –A 5.0 per cent w/v solution of *potassium ferrocyanide in water.*

Potassium Hydrogen Phthalate – $CO_2H.C_6H_4.CO_2K$ =204.22.

Contains not less than 99.9 per cent and not more than the equivalent of 100.1 per cent of $C_8H_5O_4K$ calculated with reference to the substance dried at 110^0 for one hour.

Description –White, crystalline powder.

Solubility –Slowly soluble in *water,* forming clear, colourless solution.

Acidity –A 2.0 per cent w/v solution in carbon dioxide free water gives with *bromophenol blue solution* the grey colour indicative of *p*H 4.0.

Assay –Weigh accurately about 9 g, dissolve in 100 ml of *water* and titrate with *N sodium hydroxide* using *phenolphthalein solution* as indicator. Each ml of *N Sodium hydroxide* is equivalent to 0.2042 g of $C_8H_5O_4K$.

Potassium Hydrogen Phthalate, 0.02 M – Dissolve 4.084 g of *Potassium hydrogen phthalate* in sufficient *water* to produce 1000 ml.

Potassium Hydrogen Phthalate, 0.2 M – Dissolve 40.84 g of *potassium hydrogen phthalate* in sufficient *water* to produce 1000 ml.

Potassium Hydroxide –Caustic Potash : KOH = 56.11

Contains not less than 85.0 per cent of total alkali, calculated as KOH and not more than 4.0 per cent of K_2CO_3.

Description – Dry white sticks, pellets or fused mass; hard, brittle and showing a crystalline fracture; very deliquescent; strongly alkaline and corrosive.

Solubility –Freely soluble in water, in alcohol and in glycerin; very soluble in boiling *ethyl alcohol*.

Aluminium, iron and matter insoluble in *hydrochloric acid* –Boil 5 g with 40 ml of dilute *hydrochloric acid*, cool, make alkaline with dilute ammonia solution, boil, filter and wash the residue with a 2.5 per cent w/v solution of ammonium nitrate; the insoluble residue, after ignition to constant weight, weighs not more than 5 mg.

Chloride –0.5 g dissolved in water with the additon of 1.6 ml of nitric acid, complies with the limit test for chlorides, Appendix 2.3.2.

Heavy metals –Dissolve 1 g in a mixture of 5 ml of water and 7 ml of dilute hydrochloric acid. Heat to boiling, add 1 drop of phenolphthalein solution and dilute ammonia solution dropwise to produce a faint pink colour. Add 2 ml of acetic acid and water to make 25 ml; the limit of heavy metals is 30 parts per million, Appendix 2.3.3.

Sulphate –Dissolve 1 g in water with the addition of 4.5 ml of hydrochloric acid; the solution complies with the limit test for sulphates, Appendix 2.3.6.

Sodium –To 3 ml of a 10 per cent w/v solution add 1 ml of water, 1.5 ml of alcohol, and 3 ml of potassium antimonate solution and allow to stand; no white crystalline precipitate or sediment is visible to the naked eye within fifteen minutes.

Assay –Weigh accurately about 2 g, and dissolve in 25 ml of water, add 5 ml of barium chloride solution, and titrate with N hydrochloric acid, using phenolphthalein solution as indicator. To the solution in the flask add bromophenol blue solution, and continue the titration with N hydrochloric acid. Each ml of N hydrochloric acid, used in the second titration in equivalent to 0.06911 g of K_2CO_3 . Each ml of N hydrochloric acid, used in the combined titration is equivalent to 0.05611 g of total alkali, calculated as KOH.

Storage –Potassium Hydroxide should be kept in a well-closed container.

Potassium Hydroxide, xN – Solution of any normality, x N, may be prepared by dissolving 56.11x g of potassium hydroxide in water and diluting to 1000 ml.

Potassium Hydroxide Solution –Solution of Potash.

An aqueous solution of potassium hydroxide containing 5.0 per cent w/v of total alkali, calculated as KOH (limits, 4.75 to 5.25).

Assay –Titrate 20 ml with N sulphuric acid, using solution of methyl orange as indicator. Each ml of N sulphuric acid is equivalent to 0.05611 g of total alkali, calculated as KOH.

Storage –Potassium hydroxide solution should be kept in a well-closed container of lead-free glass or of a suitable plastic.

Potassium Iodide –KI = 166.00

Description – Colourless crystals or white powder; odourless, taste, saline and slightly bitter.

Solubility –Very soluble in water and in glycerin; soluble in alcohol.

Arsenic –Not more than 2 parts per million, Appendix 2.3.1.

Heavy metals -Not more than 10 parts per million, determined on 2.0 g by Method A, Appendix 2.3.3.

Barium –Dissolve 0.5 g in 10 ml of water and add 1 ml of dilute sulphuric acid; no turbidity develops within one minute.

Cyanides –Dissolve 0.5 g in 5 ml of warm water, add one drop of ferrous sulphate solution and 0.5 ml of sodium hydroxide solution and acidify with hydrochloric acid; no blue colour is produced.

Iodates –Dissolve 0.5 g in 10 ml of freshly boiled and cooled water, and add 2 drops of dilute sulphuric acid and a drop of starch solution; no blue colour is produced within two minutes.

Assay –Weigh accurately about 0.5 g, dissolve in about 10 ml of water and add 35 ml of hydrochloric acid and 5 ml of chloroform. Titrate with 0.05 M potassium iodate until the purple colour of iodine disappears from the chloroform. Add the last portion of the iodate solution drop-wise and agitate vigorously and continuously. Allow to stand for five minutes. If any colour develops in the chloroform layer continue the titration. Each ml of 0.05 M potassium iodate is equivalent to 0.0166 mg of KI.

Storage –Store in well-closed containers.

Potassium Iodide, M –Dissolve 166.00 g of potassium iodide in sufficient water to produce 1000 ml.

Potassium Iodide and Starch Solution –Dissolve 10 g of potassium iodide in sufficient water to produce 95 ml and add 5 ml of starch solution.

Potassium Iodide and Starch solution must be recently prepared.

Potassium Iodide Solution –A 10 per cent w/v solution of potassium iodide in water.

Potassium Iodobismuthate Solution –Dissolve 100 g of tartaric acid in 400 ml of water and 8.5 g of bismuth oxynitrate. Shake during one hour, add 200 ml of a 40 per cent w/v

Potassium Iodobismuthate Solution, Dilute –Dissolve 100 g of tartaric acid in 500 ml of water and add 50 ml of potassium iodobismuthate solution.

Potassium Mercuric-Iodide Solution –Mayer's Reagent.

Add 1.36 g of mercuric chloride dissolved in 60 ml of water to a solution of 5 g of potassium iodide in 20 ml of water, mix and add sufficient water to produce 100 ml.

Potassium Mercuri-Iodide Solution, Alkaline (Nessler's Reagent)

To 3.5 g of potassium iodide add 1.25 g of mercuric chloride dissolved in 80 ml of water, add a cold saturated solution of mercuric chloride in water, with constant stirring until a slight red precipitate remains. Dissolve 12 g of sodium hydroxide in the solution, add a little more of the cold saturated solution of mercuric chloride and sufficient water to produce 100 ml. Allow to stand and decant the clear liquid.

Potassium Permanganate – $KMnO_4$ = 158.03

Description –Dark purple, slender, prismatic crystals, having a metallic lustre, odourless; taste, sweet and astringent.

Solubility –Soluble in *water*; freely soluble in *boiling water.*

Chloride and *Sulphate* –Dissolve 1 g in 50 ml of boiling *water,* heat on a water-bath, and add gradually 4 ml or a sufficient quantity of *alcohol* until the meniscus is colour-less; filter. A 20 ml portion of the filtrate complies with the limit test for *chloride,* Appendix 2.3.2., and another 20 ml portion of the filtrate complies with the limit test for *sulphates,* Appendix 2.3.7.

Assay –Weigh accurately about 0.8 g, dissolve in water and dilute to 250 ml. Titrate with this solution 25.0 ml of 0.1 *N oxalic acid* mixed with 25 ml of *water* and 5 ml of *sulphuric acid.* Keep the temperature at about 70^0 throughout the entire titration. Each ml of 0.1 *N oxalic acid* is equivalent to 0.00316 g of $KMnO_4$.

Storage –Store in well-closed containers.

Caution –Great care should be observed in handling *potassium permanganate,* as dangerous explosions are liable to occur if it is brought into contact with organic or other readily oxidisable substance, either in solution or in the dry condition.

Potassium Permanganate Solution – A 1.0 per cent w/v solution of *potassium permanganate* in water.

Potassium Permanganate, 0.1 N Solution –158.03. 3.161 g in 1000 ml

Dissolve about 3.3. g of *potassium permanganate* in 1000 ml of *water,* heat on a water-bath for one hour and allow to stand for two days. Filter through glass wool and standardise the solution as follows :

To an accurately measured volume of about 25 ml of the solution in a glass stoppered flask add 2 g of *potassium iodide* followed by 10 ml of *N sulphuric acid.* Titrate the liberated *iodine* with standardised 0.1 *N sodium thiosulphate,* adding 3 ml of *starch solution* as the end point is approached. Correct for a blank run on the same quantities of the same reagents. Each ml of 0.1 *N sodium thiosulphate* is equivalent to 0.003161 g of $KMnO_4$.

Potassium Tellurite: $K_2\ TeO_3$ (approx)
General reagent grade of commerce.

Purified Water –H_2O = 18.02.

Description –Clear, colourless liquid, odourless, tasteless.

Purified water is prepareed from potable water by distillation, ion-exchange treatment, reverse osmosis or any other suitable process. It contains no added substances.

*p*H – Between 4.5 and 7.0 determined in a solution prepared by adding 0.3 ml of a saturated solution of *potassium chloride* to 100 ml of the liquid being examined.

Carbon dioxide –To 25 ml add 25 ml of *calcium hydroxide solution,* no turbidity is produced.

Chloride –To 10 ml add 1 ml of *dilute nitric acid* and 0.2 ml of *silver nitrate solution;* no opalescence is produced, Appendix 2.3.2.
Sulphate –To 10 ml add 0.1 ml of *dilute hydrochloric acid* and 0.1 ml of *barium chloride,* Appendix 2.3.6.

Solution : the solution remains clear for an hour.

Nitrates and Nitrites –To 50 ml add 18 ml of *acetic acid* and 2 ml of *naphthylamine-sulphanilic acid* reagent. Add 0.12 g of *zinc reducing mixture* and shake several times. No pink colour develops within fifteen minutes.

Ammonium – To 20 ml add 1 ml of *alkaline potassium mercuric-iodide solution* and after five minutes view in a Nessler cylinder placed on a white tile; the colour is not more intense than that given on adding 1 ml of *alkaline potassium mercuric-iodide solution* to a solution containing 2.5 ml of *dilute ammonium chloride solution (Nessler's)* 7.5 ml of the liquid being examined.

Calcium –To 10 ml add 0.2 ml of *dilute ammonia solution* and 0.2 ml of *ammonium oxalate solution;* the solution remains clear for an hour.

Heavy metals –Adjust the *p*H of 40 ml to between 3.0 and 4.0 with *dilute acetic acid,* add 10 ml of freshly prepared *hydrogen sulphide solution* and allow to stand for ten minutes; the colour of the solution is not more than that of a mixture of 50 ml of the liquid being examined and the same amount of *dilute acetic acid* added to the sample, Appendix 2.3.3.

Oxidisable matter –To 100 ml add 10 ml of *dilute sulphuric acid* and 0.1 ml of 0.1 *N potassium permanganate* and boil for five minutes. The solution remains faintly pink.

Total Solids –Not more than 0.001 per cent w/v determined on 100 ml by evaporating on a water bath and drying in an oven at 105^0 for one hour.

Storage –Store in tightly closed containers.

Silver Nitrate Solution –

A freshly prepared 5.0 per cent w/v solution of silver nitrate in water.

Silver Nitrate, 0.1 N– $AgNO_3$ = 169. 87; 16.99 g in 1000 ml. Dissolve about 17 g in sufficient *water* to produce 1000 ml and standardise the solution as follows:

Weigh accurately about 0.1 g of *sodium chloride* previously dried at 110^0 for two hours and dissolve in 5 ml of *water.* Add 5 ml of *acetic acid,* 50 ml of *methyl alcohol* and three drops of *eosin solution is* equivalent to 1 ml of 0.1 *N silver nitrate.*
Sodium Bicarbonate – $NaHCO_3$ =84.01

Description –White, crystalline powder or small, opaque, monoclinic crystals; odourless; taste, saline.

Solubility –Freely soluble in *water*; practically insoluble in *alcohol.*

Carbonate –*p*H of a freshly prepared 5.0 per cent w/v solution in *carbon dioxide-free water,* not more than 8.6.

Aluminium, calcium and insoluble matter –Boil 10 g with 50 ml of *water* and 20 ml of *dilute ammonia solution,* filter, and wash the residue with water; the residue, after ignition to constant weight, not more than 1 mg.

Arsenic –Not more than 2 parts per million, Appendix 2.3.1.

Iron –Dissolve 2.5 g in 20 ml of *water* and 4 ml of *iron-free hydrochloric acid,* and *dilute* to 40 ml with *water*; the solution complies with the *limit test for iron,* Appendix 2.3.4.

Heavy metals –Not more than 5 parts per million, determined by Method A on a solution prepared in the following manner:

Mix 4.0 g with 5 ml of *water* and 10 ml of *dilute hydrochloric acid,* heat to boiling, and maintain the temperature for one minute. Add one drop of *phenolphthalein solution* and sufficient *ammonia solution* drop wise to give the solution a faint pink colour. Cool and dilute to 25 ml with *water,* Appendix 2.3.3.

Chlorides –Dissolve 1.0 g in *water* with the addition of 2 ml of *nitric acid;* the solution complies with the *limit test for chlorides,* Appendix 2.3.2.

Sulphates –Dissolve 2 g in *water* with the addition of 2 ml of *hydrochloric acid;* the solution complies with the limit test for *sulphates,* Appendix 2.3.6.

Ammonium compounds –1 g warmed with 10 ml of *sodium hydroxide solution* does not evolve ammonia.

Assay –Weigh accurately about 1 g, dissolve in 20 ml of *water,* and titrate with 0.5 *N sulphuric acid* using *methyl orange solutions* as indicator. Each ml of 0.5 *N sulphuric acid* is equivalent to 0.042 g of $NaHCO_3$.

Storage –Store in well-closed containers.

Sodium Bicarbonate Solution –A 5 per cnet w/v solution of *sodium bicarbonate* in *water.*

Sodium Carbonate – $Na_2CO_3. 10H_2O$ =286.2.

Analytical reagent grade.

Sodium Chloride – NaCl = 58.44
Analytical reagent grade.

Sodium Hydroxide –NaOH = 40.00

Description –White sticks, pellets, fused masses, or scales; dry, hard brittle and showing a crystalline fracture, very deliquescent; strongly alkaline and corrosive.

Solubility –Freely soluble in *water* and in *alcohol.*

Aluminium, iron and matter insoluble in hydrochloric acid –Boil 5 g with 50 ml of dilute hydrochloric acid, cool, make alkaline with *dilute ammonia solution,* boil, filter, and wash with a 2.5 per cent w/v solution of *ammonium nitrate;* the insoluble residue after ignition to constant weight weighs not more than 5 mg.

Arsenic –Not more than 4 parts per million, Appendix 2.3.1.

Heavy metals –Not more than 30 parts per million, determined by Method A, Appendix 2.3.3. in a solution prepared by dissolving 0.67 g in 5 ml of water and 7 ml of 3 *N hydrochloric acid.* Heat to boiling, cool and dilute to 25 ml with water.

Potassium –Acidify 5 ml of a 5 per cent w/v solution with *acetic acid* and add 3 drops of *sodium cobaltnitrite solution;* no preciptitate is formed.

Chloride – 0.5 g dissolved in *water* with the addition of 1.8 ml of *nitric acid,* complies with the limit test for *chlorides,* Appendix 2.3.2.
Sulphates –1 g dissolved in *water* with the addition of 3.5 ml of *hydrochloric acid* complies with the limit test for *sulphates,* Appendix 2.3.6.

Assay –Weigh accurately about 1.5 g and dissolve in about 40 ml of *carbon dioxide-free water.* Cool and titrate with *N sulphuric acid* using *phenolphthalein solution* as indicator. When the pink colour of the solution is discharged, record the volume of acid solution required, add *methyl orange solution* and continue the titration until a persistent pink colour is produced. Each ml of *N sulphuric acid* is equivalent to 0.040 g of total alkali calculated as NaOH and each ml of acid consumed in the titration with *methyl orange* is equivalent to 0.106 g of Na_2CO_3.

Storage –Store in tightly closed containers.

Sodium Hydroxide, xN – Solutions of any normality, xN may be prepared by dissolving 40 x g of *sodium hydroxide* in *water* and diluting to 1000 ml.

Sodium Hydroxide Solution – A 20.0 per cent w/v solution of *sodium hydroxide* in *water.*

Sodium Hydroxide Solution, Dilute –

A 5.0 per cent w/v solution of *sodium hydroxide* in water.

Sodium Potassium Tartrate –Rochelle Salt COONa.CH(OH). CH(OH), COOK. $4H_2O$ = 282.17
Contains not less than 99.0 per cent and not more than the equivalent of 104.0 per cent of $C_4H_4O_6KNa.\ 4H_2O$.

Description –Colourless crystals or a white, crystalline powder; odourless; taste saline and cooling. It effloresces slightly in warm, dry air, the crystals are often coated with a white powder.

Solubility –Soluble in *water;* practically insoluble in alcohol.

Acidity or Alkalinity –Dissolve 1 g in 10 ml of recently boiled and cooled *water,* the solution requires for neutralisation not more than 0.1 ml of 0.1 *N sodium hydroxide* or of 0.1 *N hydrochloric acid,* using *phenolphthalein solution* as indicator.

Iron –0.5 g complies with the *limit test for iron,* Appendix 2.3.4.

Chloride –0.5 g complies with the *limit test for chlorides,* Appendix 2.3.2.

Sulphate –0.5 g complies with the *limit test for sulphate,* Appendix 2.3.6.

Assay –Weigh accurately about 2 g and heat until carbonised, cool, and boil the residue with 50 ml of *water* and 50 ml of 0.5 *N sulphuric acid;* filter, and wash the filter with *water;* titrate the excess of acid in the filtrate and washings with 0.5 N *sodium hydroxide,* using *methyl orange solution* as indicator. Each ml of 0.5 *N sulphuric acid* is equivalent to 0.07056 g of $C_4H_4O_6KNa.\ 4H_2O$.

Sodium Sulphate (anhydrous) – $Na_2SO_4 = 142.04$

Analytical reagent grade of commerce.
White, crystalline powder of granules; hygroscopic.

Sodium Thiosulphate – $Na_2S_2O_3.\ 5H_2O = 248.17$.

Description – Large colourless crystals or coarse, crystalline powder; odourless; taste, saline, deliquescent in moist air and effloresces in dry air at temperature above 33^0.

Solubility – Very soluble in *water*; insoluble in *alcohol.*

pH –Between 6.0 and 8.4, determined in a 10 per cent w/v solution.

Arsenic –Not more than 2 parts per million, Appendix 2.3.1.

Heavy metals –Not more than 20 parts per million, determined by Method A, Appendix 2.3.3. in a solution prepared in the following manner : Dissolve 1 g in 10 ml of *water,* slowly add 5 ml of *dilute hydrochloric acid* and evaporate the mixture to dryness on a water-bath. Gently boil the residue with 15 ml of *water* for two minutes, and filter. Heat the filtrate to boiling, and add sufficient *bromine solution* to the hot filtrate to produce a clear solution and add a slight excess of *bromine solution.* Boil the solution to expel the *bromine* completely, cool to room temperature, then add a drop of *phenolphthalein solution* and *sodium hydroxide solution* until a slight pink colour is produced. Add 2 ml of *dilute acetic acid* and dilute with *water* to 25 ml.

Calcium –Dissolve 1 g in 20 ml of *water,* and add a few ml of *ammonium oxalate solution;* no turbidity is produced.

Chloride –Dissolve 0.25 g in 15 ml of *2N nitric acid* and boil gently for three to four minutes, cool and filter; the filtrate complies with the *limit test for chlorides,* Appendix 2.3.2.

Sulphate and Sulphite –Dissolve 0.25 g in 10 ml of *water*, to 3 ml of this solution add 2 ml of *iodine solution,* and gradually add more *iodine solution*, dropwise until a very faint-persistant yellow colour is procduced; the resulting solution complies with the limit test for sulphates, Appendix 2.3.7.

Sulphide –Dissolve 1 g in 10 ml of *water* and 10.00 ml of a freshly prepared 5 per cent w/v solution of *sodium nitroprusside;* the solution does not become violet.

Assay –Weigh accurately about 0.8 g and dissolve in 30 ml of *water*. Titrate with 0.1 *N iodine,* using 3 ml of *starch solution* as indicator as the end-point is approached. Each ml of 0.1 iodine is equivalent to 0.02482 g of $Na_2S_2O_3.5H_2O$.

Storage –Store in tightly-closed containers.

Sodium Thiosulphate 0.1 N – $Na_2S_2O_3.5H_2O$. = 248.17, 24.82 g in 1000 ml.

Dissolve about 26 g of *sodium thiosulphate* and 0.2 g of *sodium carbonate* in *carbon dioxide-free water* and dilute to 1000 ml with the same solvent. Standardise the solution as follows :

Dissolve 0.300 g of *potassium bromate* in sufficient *water* to produce 250 ml. To 50 ml of this solution, add 2 g of *potassium iodide* and 3 ml of 2 *N hydrochloric acid* and titrate with the *sodium-thiosulphate solution* using *starch solution*, added towards the end of the titration, as indicator until the blue colour is discharged. Each 0.002784 g of *potassium bromate* is equivalent to 1 ml of 0.1*N sodium thiosulphate.* Note: –Re-standardise 0.1 *N sodium thiosulphate* frequently.

Stannous Chloride – $SnCl_2.\ 2H_2O$ =225.63.

Contains not less than 97.0 per cent of $SnCl_2.\ 2H_2O$.

Description –Colourless crystals.

Solubility –Soluble in *dilute hydrochloric acid.*

Arsenic- Dissolve 5.0 g in 10 ml of *hydrochloric acid,* heat to boiling and allow to stand for one hour; the solution shows no darkening when compared with a freshly prepared solution of 5.0 g in 10 ml of *hydrochloric acid.*

Sulphate –5.0 g with the addition of 2 ml of *dilute hydrochloric acid*, complies with the *limit test for sulphates,* Appendix 2.3.7.

Assay –Weigh accurately about 1.0 g and dissolve in 30 ml of *hydrochloric acid* in a stoppered flask. Add 20 ml of *water* and 5 ml of *chloroform* and titrate rapidly with 0.05 *M*

potassium iodate until the *chloroform* layer is colourless. Each ml of 0.05 M potassium iodate is equivalent to 0.02256 g of $SnCl_2$. $2H_2O$.

Stannous Chloride Solution – May be prepared by either of the two methods given below :

Dissolve 330 g of stannous *chloride* in 100 ml of *hydrochloric acid* and add sufficient *water* to produce 1000 ml.

Dilute 60 ml of *hydrochloric acid* with 20 ml of *water*, add 20 g of tin and heat gently until gas ceases to be evolved; add sufficient *water* to produce 100 ml, allowing the undissolved tin to remain in the solution.

Starch Soluble – Starch, which has been treated with *hydrochloric acid* until after being washed, it forms an almost clear liquid solution in hot water.

Description –Fine, white powder.

Solubility –Soluble in hot *water*, usually forming a slightly turbid *solution.*

Acidity or Alkalinity –Shake 2 g with 20 ml of *water* for three minutes and filter; the filtrate is not alkaline or more than fainthy acid to litmus paper.

Sensitivity –Mix 1 g with a little cold *water* and add 200 ml *boiling water.* Add 5 ml of this solution to 100 ml of *water* and add 0.05 ml of 0.1 *N iodine.* The deep blue colour is discharged by 0.05 ml of 0.1 *N sodium thiosulphate.*

Ash – Not more than 0.3 per cent, Appendix 2.3.

Starch Solution –Triturate 0.5 g of *soluble starch*, with 5 ml of *water*, and add this, with constant stirring, to sufficient water to produce about 100 ml. Boil for a few minutes, cool, and filter.

Solution of *starch must be recently prepared.*

Sulphamic Acid –NH_2SO_3H =97.09.

Contains not less than 98.0 per cent of H_3NO_3S.

Description -White crystals or a white crystalline powder.

Solubility –Readily soluble in water. Melting Range –203^0 to 205^0, with decomposition.

Sulphuric Acid – H_2SO_4 = 98.08.

When no molarity is indicated use analytical reagent grade of commerce containing about 98 per cent w/w of *sulphuric acid.* An oily, corrosive liquid weighing about 1.84 g per ml and about 18 M in strength.

When solutions of molarity xM are required, they should be prepared by carefully adding 54 ml of sulphuric acid to an equal volume of water and diluting with water to 1000 ml.

Solutions of sulphuric acid contain about 10 per cent w/v of H_2SO_4 per g mol.

Sulphuric Acid, Dilute –Contains approximately 10 per cent w/w of H_2SO_4.

Dilute 57 ml of sulphuric acid to 1000 ml with water.

Sulphuric Acid, Chlorine-free –Sulphuric acid which complies with the following additional test:

Chloride –Mix 2 ml with 50 ml of water and add 1 ml of solution of *silver nitrate*, no opalescence is produced.

Sulphuric Acid, Nitrogen-free-Sulphuric acid which contains not less than 98.0 per cent w/w of H_2SO_4 and complies with the following additional test :

Nitrate –Mix 45 ml with 5 ml of *water*, cool and add 8 mg of *diphenyl benezidine;* the solution is colourless or not more than very pale blue.

Tartaric Acid –$(CHOH.COOH)_2$ =150.1

Analytical reagent grade.

Thioglycollic Acid – Mercapto acetic acid, – HS. CH_2COOH =92.11.

Contains not less than 89.0 per cent w/w of $C_2H_4O_2S$, as determined by both parts of the Assay described below :

Description –Colourless or nearly colourless liquid; odour strong and upleasant.

Iron –Mix 0.1 ml with 50 ml of water and render alkaline with *strong ammonia solution;* no pink colour is produced.

Assay – Weigh accurately about 0.4 g and dissolve in 20 ml of *water* and titrate with 0.1 *N sodium hydroxide* using *cresol red solution* as indicator. Each ml of 0.1 *N sodium hydroxide is equivalent to* 0.009212 g of $C_2H_4O_2S$.

To the above neutralised solution and 2 g of *sodium bicarbonate* and titrate with 0.1 *N iodine.* Each ml of 0.1 N iodine is equivalent to 0.009212 g of $C_2H_4O_2S$.

Triethanolamine -

Toluene :-Methyl benzene,$C_6H_5.CH_3$ =102.14.

Analytical grade reagent of commerce.

Clear, colourless liquid, odour, characteristic; bp about 110^0, wt per ml, about 0.870 g.

Water –See purified water.

Water, Ammonia-free –Water, which has been boiled vigorously for a few minutes and protected from the atomosphere during cooling and storage.

Xylenol Orange – [3H-2,1-Benzoxathiol–3-ylidene bis – (6-hydroxy-5-methyl-m-phenylene) methylenenitrilo] tetra acetic acid SS-dioxide or its tetra sodium salt.

Gives a reddish-purple colour with mercury, lead, zinc and contain other metal ions in acid solution. When metal ions are absent, for example, in the presence of an excess of *disodium ethylenediamine tetraacetate*, this solution is yellow.

Xylenol Orange Solution –Dissolve 0.1 g of *xylenol orange* with 100 ml of *water* and filter, if necessary.

Zinc, Acetate – analytical grade reagent of commerce.

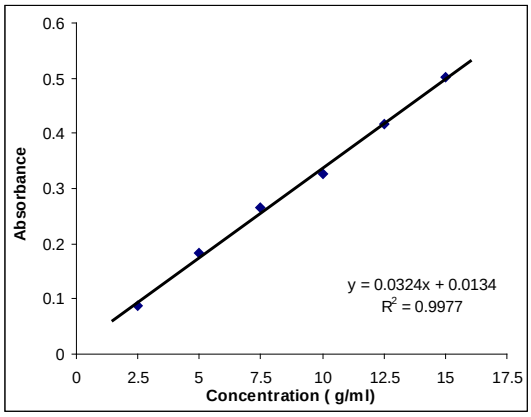
APPENDIX- 5

CHEMICAL TESTS AND ASSAYS

5.1.1. - Estimation of Total Phenolics

Reagents

1. *Folin Ciocalteu reagent (1 N):* Dilute commercially available Folin-Ciocalteu reagent (2 N) with an equal volume of distilled water. Transfer it in a brown bottle and store in a refrigerator (4°C). It should be golden in colour. Do not use it if it turns olive green.
2. *Sodium carbonate (20%):* Weigh 40 g sodium carbonate (x 10 H_2O), dissolve it in about 150 ml distilled water and make up to 200 ml with distilled water.
3. *Standard tannic acid solution (0.1 mg/ml):* Dissolve 1 mg in 10 ml of distilled water (always use a freshly prepared solution). Important: Use standard tannic acid sample (make: Merck) which is found to be the best.



Calibration curve Equation (tannic acid): Y = 0.0324x + 0.0134

Analysis of total phenols

Take suitable aliquots of the tannin-containing extract in test tubes, make up the volume to 0.5 ml with distilled water, and add 0.25 ml of the Folin- Ciocalteu reagent and then 1.25 ml of the sodium carbonate solution. Vortex the tubes and record absorbance at 725 nm after 40 min. Calculate the amount of total phenols as tannic acid equivalent from the above calibration curve equation. Express total phenolic content in (x % w/v).

5.1.2. - Estimation of Total Tannins

Defat 2 g of sample with 25 ml *petroleum ether* for 12 h. Boil the marc for 2 h with 300 ml of *double distilled water*. Cool, dilute up to 500 ml and filter. Measure 25 ml of this infusion into 2-litre porcelain dish; add 20 ml *Indigo solution* and 750 ml *double distilled water*. Titrate it with *0.1N potassium permanganate solution*, 1 ml at a time, until blue solution changes to green. Thereafter add drops wise until solution becomes golden yellow in colour.

Similarly, titrate mixture of 20-ml *Indigo solution* and 750 ml of *double distilled water*. Calculate the difference between two titrations in ml.

Each ml of 0.1*N potassium permanganate solution* is equivalent to 0.004157 g of total tannins.

5.1.3. - Estimation of Sugars

5.1. 3. 1. - Nelson - Somogyi photometric method

Estimate total soluble and reducing sugars according to Nelson - Somogyi photometric method for the determination of glucose.

Preparation of calibration curve for *d*-glucose (Dextrose)

Dissolve accurately weighed 500 mg of dextrose in a 100-ml volumetric flask (5 mg / ml). From the above stock solution pipette out aliquots of 0.05 ml to 0.3 ml in to 10-ml volumetric flask and makeup the volume with *double distilled water*. Add 1 ml of alkaline reagent to each tube (25 parts of Reagent I + 1 part of Reagent II).

Reagent I: Dissolve 25 g of anhydrous *sodium carbonate* 25 g of Rochelle salt or sodium potassium tartrate, 20 g of *sodium bicarbonate* and 200 g of anhydrous *sodium sulphate* in about 800 ml of water and dilute to 1 L.

Reagent II : Add 15 per cent *copper sulphate* containing concentrated *sulphuric acid* per 100 ml to the tube. Mix the contents and heat for 20 min in a boiling water-bath. Then cool the tubes and add the solution 1 ml of *arsenomolybdic acid reagent* (dissolve 250 mg of *ammonium molybdate* in 45 ml of *purified water*. To this, add 2.1 ml of *concentrated sulphuric acid* and mix well. To this solution, dissolve 3 g of *sodium arsenate* in 25 ml of *purified water*, mix well and place in incubator maintained at 37 º C for 24 hr). Dilute the contents of the test tube to 10 ml by adding *purified water* mix well and then read color intensity at 520 nm using a *ultra violet* visible spectrophotometer. Record the absorbance and plot a standard curve of absorbance *vs.* concentration.

Reducing sugars

For reducing sugars, weigh accurately 500 mg of the sample, dissolve in 100 ml of *double distilled water* and make up the volume to 100 ml in a volumetric flask. Then follow method as mentioned for the preparation of calibration curve.

Total sugars

Place 25 ml of the solution from the 100 ml stock solution prepared for the reducing sugars in a 100 ml beaker. To this, add 5 ml of hydrochloric acid: *purified water* (1:1 v/v), mix well and allow to stand at room temperature for 24 hr for inversion. Neutralize the sample with 5 N *sodium hydroxide* and make up to 50 ml with *purified water*. From this diluted sample, use 1 ml of aliquot for the estimation of total soluble sugars using the method described in preparation of calibration curve for dextrose.

5.1. 3. 2. - Reducing and Non -reducing sugars

Non- sugars are determined by subtracting the content of reducing sugars from the amount of total sugars.

Clarifying reagent:

Solution 1: Dissolve 21.9 g of *zinc acetate* and 3 ml of *glacial acetic acid* in *purified water* and make the volume to 100 ml.

Solution II: Dissolve 10.6 g of *potassium ferrocyanide* in water and make up to 100 ml.

Reducing sugars: Take suitable amount of the sample and neutralize with *sodium hydroxide solution* (10per cent in water). Evaporate the neutralized solution to half the volume on a water bath at 50^0 to remove the alcohol. Cool the solution add 10 ml of the clarifying solution I followed by 10 ml of the clarifying solution II. Mix, filter through a dry filter paper and make up the volume to 100 ml. Take 10 ml of the *Fehling's solution* and from a burette and add sugar solution (above prepared sample) in a drop wise manner and heat to boiling over the hot plate (maintained at 80^0) until the mixture of Copper (*Fehling's solution*) appears to be nearly reduced. Add 3-5 drops of 1per cent *methylene blue* and continue the titration till the blue colour is discharged. Note down the readings and calculate the percentage of glucose.

The proportions of invert sugar, equivalent to 10 ml of Fehling's solution, are given in the Table – 18. Calculate the reducing sugar, invert sugar.

Non-reducing sugars: Take suitable amount of the sample and neutralize with *sodium hydroxide solution* (10per cent in water). Evaporate the neutralized solution to half the volume on a water bath at 50^0C to remove the alcohol. Cool the solution add 10 ml of the clarifying solution I followed by 10 ml of the clarifying solution II. Mix, filter through a dry filter paper. To the Filter add 15 ml of 0.1 N *hydrochloric acid*. Cover with stopper and heat to boiling for two minutes. Add *phenolpthlein* and neutralize with *sodium hydroxide* solution (10per cent). Transfer to 100 ml volumetric flask and make the volume to 100 ml and perform the titration as done for the reducing sugars. Calculate the percentage of the total sugars. Subtract the percentage of the reducing sugars from the sugars to obtain non reducing sugars.

Table No. 18

Invert Sugar Table Per 10 ml. Fehling Solution

ml of sugar solution required	No sucrose	Solution containing besides invert sugar:- 1 g sucrose per 100 ml		5 g sucrose per 100 ml		10 g sucrose per 100 ml		25 g sucrose per 100 ml		
	Invert sugar factor	mg invert sugar per 100 ml	Invert sugar factor	mg invert sugar per 100 ml	Invert sugar factor	mg invert sugar per 100 ml	Invert sugar factor	mg invert sugar per 100 ml	Invert sugar factor	mg invert sugar per 100 ml
15	50.5	336	49.9	333	47.6	317	46.1	307	43.4	289
16	50.6	316	50.0	312	47.6	297	46.1	288	43.4	271
17	50.7	298	50.1	295	47.6	280	46.1	271	43.4	255
18	50.8	282	50.1	278	47.6	264	46.1	256	43.3	240
19	50.8	267	50.2	264	47.6	250	46.1	243	43.3	227
20	50.9	254.5	50.2	251.0	47.6	238.0	46.1	230.5	43.2	216
21	51.0	542.9	50.2	239.0	47.6	226.7	46.1	219.5	43.2	206
22	51.0	231.8	50.3	228.2	47.6	216.4	46.1	209.5	43.1	196
23	51.1	222.2	50.3	218.7	47.6	207.0	46.1	200.4	43.1	187
24	51.2	213.3	50.3	209.8	47.6	198.3	46.1	192.1	42.9	179
25	51.2	204.8	50.4	201.6	47.6	190.4	46.0	184.0	42.8	171
26	51.3	197.4	50.4	193.8	47.6	183.1	46.0	176.9	42.8	164
27	51.4	190.4	50.4	186.7	47.6	176.4	46.0	170.4	42.7	158
28	51.4	183.7	50.5	180.2	47.7	170.3	46.0	164.3	42.7	152
29	51.5	177.6	50.5	174.1	47.7	164.5	46.0	158.6	42.6	147
30	51.5	171.7	50.5	168.3	47.7	159.0	46.0	153.3	42.5	142
31	51.6	166.3	50.6	163.1	47.7	153.9	45.9	148.1	45.5	137
32	51.6	161.2	50.6	158.1	47.7	149.1	45.9	143.4	42.4	132
33	51.7	156.6	50.6	153.3	47.7	144.5	45.9	139.1	42.3	128
34	51.7	152.2	50.6	148.9	47.7	140.3	45.8	134.9	42.2	124
35	51.8	147.9	50.7	144.7	47.7	136.2	45.8	130.8	42.2	121
36	51.8	143.9	50.7	140.7	47.7	132.5	45.8	127.1	42.1	117
37	51.9	140.2	50.7	137.0	47.7	128.9	45.7	123.5	42.0	114
38	51.9	136.6	50.7	133.5	47.7	125.5	45.7	120.3	42.0	111
39	52.0	133.3	50.8	130.5	47.7	122.3	45.7	117.1	41.9	107
40	52.0	130.1	50.8	127.0	47.7	119.2	45.6	114.1	41.8	104
41	52.1	127.1	50.8	123.0	47.7	116.3	45.6	111.2	41.8	102
42	52.1	124.2	50.8	121.0	47.7	113.5	45.6	108.5	41.7	99
43	52.2	121.4	50.8	118.2	47.7	110.9	45.5	105.8	41.6	97
44	52.2	118.7	50.9	115.6	47.7	108.4	45.5	103.4	41.5	94
45	52.3	116.1	50.9	113.1	47.7	106.0	45.4	101.0	41.4	92
46	52.3	113.7	50.9	110.6	47.7	103.7	45.4	98.7	41.4	90
47	52.4	111.4	50.9	108.2	47.7	101.5	45.3	96.4	41.3	88
48	52.4	109.2	50.9	106.0	47.7	99.4	45.3	94.3	41.2	86
49	52.5	107.1	51.0	104.0	47.7	97.4	45.2	92.3	41.4	84
50	52.5	105.1	51.0	102.0	47.7	95.4	45.2	90.4	41.0	82

5.1. 4. - Estimation of Curcumin by TLC Densitometer:

Sample solution - Extract 5 g of avaleha with *methanol* (25 ml x 4), filter, pool, concentrate and make up the volume to 25 ml with *methanol.*

Standard solution - Prepare a stock solution of *curcumin* (160 µg/ml) by dissolving 4 mg of accurately weighed curcumin in methanol and making up the volume to 25 ml with methanol. Transfer the aliquots (0.4 – 1.4 ml) of stock solution to 10 ml volumetric flasks and make up the volume with methanol to obtain standard solutions containing 6.4 to 22.4 µg/ml curcumin, respectively.

Calibration curve - Apply 10 µl of the standard solutions (64 to 224 ng) on a precoated TLC plate of uniform thickness. Develop the plate in the solvent system *toluene: ethyl acetate: methanol* (5 : 0.5 : 1) to a distance of 10 cm. Scan the plate densitometrically at 429 nm. Record the peak area and prepare the calibration curve by plotting peak area *vs* concentration of *curcumin* applied.

Estimation of curcumin in the drug - Apply 5 µl of the test solution on a precoated silica gel 60 F_{254} TLC plate. Develop the plate in the solvent system *toluene: ethyl acetate: methanol* (5: 0.5: 1) and record the chromatogram as described above for the calibration curve. Calculate the amount of curcumin present in the sample from the calibration curve of curcumin.

5.2.1 - Determination of Aluminum:

Solutions:

10 per cent sodium hydroxide solution – Dissolve 10 g *sodium hydroxide* in 100 ml purified water.

EDTA solution 0.05 M – Dissolve 18.6120 g of sodium salt of EDTA in purified water and make up to 1000 ml.

Zinc acetate solution 0.05M:- Dissolve 10.9690 g of z*inc acetate* in 50 ml *purified water* and few drops of *glacial acetic acid* and dilute to 1000 ml.

Acetate buffer 5.5 pH – Dissolve 21.5 g of *sodium acetate* (AR) in 300 ml *purified water* containing 2 ml *glacial acetic acid* and dilute to 1000 ml

Xylenol orange indicator –Dissolve 0.2 g of *xylenol orange indicator* in 100 ml *purified water* with 2 ml *acetic acid*.

Procedure:

Take suitable aliquot from the stock solution in 250 ml beaker. Take 50 ml of 10 per cent *sodium hydroxide solution* in another beaker. Neutralize the aliquot with *sodium hydroxide solution*. Transfer the 10 per cent *sodium hydroxide solution* to aliquot with constant stirring. Add a pinch of *sodium carbonate* into the solution. Boil the content on burner. Cool and filter through Whatman 40 No. filter paper with pulp in 600 ml beaker. Wash the precipitate with hot water 6-8 times. Acidify the filtrate with *dil. hydrochloric acid* and adjust pH 5.5. Add, in excess normally 25 ml 0.05M EDTA solution. Add 25 ml *acetate buffer solution*. Boil the solution; cool and again adjust pH 5 – 5.5. Add 5-6 drops of *xylenol orange indicator*. The colour changes from golden yellow to orange red at the

end point. Take 25 m l0.05 M EDTA solution and run a blank. Each of 1M EDTA is equivalent to 0.05098 g of Al_2O_3.

5. 2. 2 - Determination of Borax:

Powder 5-6 g of drug and incinerated at 450^0 for 3 hours to get it ash. Dissolve the ash in 20 ml. of *purified water* and left for 15 minutes, filter, wash the residue with 80 ml of *purified* water for 4-5 washings. If necessary, shake the contents and titrate with *0.5N hydrochloric acid* using solution of m*ethyl orange* as an indicator. Each ml of *0.5N hydrochloric acid* is equivalent to 0.09536 g of $Na_2\ B_4O_7.10H_2O$.

5.2.3 - Determination of Calcium:

Solutions:
20 per cent Potassium hydroxide solution – Dissolve 200 g *potassium hydroxide* in *purified water* and make up to 1000 ml.
Ammonia buffer solutions 9.5 pH – Dissolve 67.5 g *ammonium chloride* in 300 ml *purified water*, add 570 ml *ammonia solution* and dilute to 1000 ml.

EDTA (Ethylene Diethyl Tetra Acetic acid) solution 0.05 M – Dissolve 18.6120 g of solution salt of EDTA and in water and make up to 1000 ml.

Triethanolamine 20per cent Solution – 200 ml of triethanolamine, adds 800 ml water and make up to 1000 ml.

Eriochrome Black T indicator 0.1per cent solution – Dissolve 0.10 g indicator in 100 ml of Methanol.

Patterns & Reeders indicators 0.1per cent solution – Dissolve 0.01g indicator in 100 ml of Methanol.

Procedure:

Take one part of filtrate reserved from Iron (Fe) estimation. Add 5 ml Triethanolamine 20 per cent solution. Add a pinch of *Hydroxylamine hydrochloride*. Add 25-30 ml *potassium hydroxide* 20 per cent solution. Add 4-5 drops of Patterns and Reeders indicator, which imparts rose red colour. Titrate the solution against standard EDTA solution. The colour changes from rose red to Prussian blue mark end point.

Each ml of 1M EDTA solution is equivalent to 0.04008 g Calcium.

5.2.4 - Determination of Copper:

Solutions:

Standard 0.1 N sodium thiosulphate solutions.
Potassium iodide.
Starch 1per cent solution – Dissolve 1 g in water, boil and make up 100ml.

Procedure:

Take suitable aliquot from the stock solution in a beaker. Add approx. 1.0 g sodium fluoride. Add *ammonia solution* and precipitate solution. Add *acetic acid* to dissolve the precipitate. Boil and cool in water bath. Add approx 1.0 g *potassium iodide*. Titrate the liberated iodine against *0.1 N sodium thoisulphate* (hypo) solutions by adding *starch solution* as indicator. The liberated iodine colour blackish brown changes to white at the end point. Calculate copper value against 1 ml of hypo solution titrating against standard 1000 ppm copper solution.

Each ml of 1N $Na_2S_2O_3$ solution is equivalent to 0.06357 g of Copper

5.2.5. - Determination of Iron (Fe)

Preparation of sample solution:

Ignite a suitable quantity of the sample (in the presence of organic matter) in a crucible in a muffle furnace at $500\text{-}550^0$ until the residue is free from organic matter. Moisten with 5-10 ml of hydrochloric acid, boil for two min, add 30 ml of water, heat on the water bath for few min, filter and wash thoroughly the residue with water and make up to volume in a volumentric flask.

Solutions:

Stannous chloride solution – Dissolve 5 g *stannous chloride* (A.R) in 25 ml Conc. *hydrochloric acid* and dilute to 100 ml (5 per cent solution).

Mercuric chloride – saturated solution in water.

Sulphuric acid + orthophosphoric acid mixture – take 60 ml water, add 15 ml conc. *sulphuric acid* and 15 ml H_3PO_4 cool and dilute to 1000ml.

Diphenylamine barium sulphonate – Dissolve 0.25 g in 100 ml water.

0.1 N *Standard potassium dichromate solution*. Dissolve 4.9035 g AR grade in water and dilute to 1000 ml.

Procedure:

Take /withdraw a suitable aliquot from the stock solution in 250 ml in duplicate. Dilute to about 100 ml with distilled water. Add 1-2 drops of *methyl red* indicator. Add 1-2 g *ammonium chloride*. Add dil. Ammonium solution till brown precipitate appears. Boil the solution with ppt. for 4-5 minutes. Cool the content and filter through Whatman 41 no. filter paper. Wash the residue with hot water 4-6 times. Dissolve the residue in dil. HCl in 250 ml beaker. Wash with hot water and make the volume to 100 ml approx. Boil the solution on burner. Reduce the Fe^{3+} to Fe^{2+} by adding *stannous chloride solution* drop wise till solution becomes colourless.

Add 1-2 drops of *stannous chloride solution* in excess. Cool the content in water. Add 10-15 ml 10per cent solution of *mercuric chloride*. Add 25 ml acid mixture. Add 2-3 drops of *diphenylamine barium sulphonate indicator*. Add distilled water, if required. Titrate against standard *potassium dichromate solution*. Appearance of violet colour show end point.

Each ml of 1N $K_2Cr_2O_7$ solution is equivalent to 0.05585 g Iron

Each ml of 1N $K_2Cr_2O_7$ solution is equivalent to 0.7985 g Fe_2O_3

5.2.6.- Determination of Magnesium:

Take another part of filtrate reserved from Fe estimation. Add 5 ml *triethanolamine 20 per cent solution*. Add a pinch of *hydroxylamine hydrochloride*. Add 25-30 ml *ammonia buffer 9.5 pH*. Add 4-5 drops of *eriochrome black* T indicator. The colour changes from rose red to blue marks the end point.

Each ml of 1M EDTA solution is equivalent to 0.0409 g of MgO.

5.2.7. - Determination of Mercury:

Powder 0.5 g drug and treat with 7 ml of conc. *nitric acid* and 15 ml of conc. *sulphuric acid* in a kjeldahl flask; heat under reflux gently at first then strongly for 30 minutes. Cool and add 50 ml conc. *nitric acid* boil so as to remove the brown fumes. Continue the addition of *nitric acid* and boiling until the liquid is colourless; cool, wash the condenser with 100 ml of water, remove the flask and add 1.0 per cent *potassium permangnate* solution drop wise until pink colour persists. Decolourize it by adding 6.0 per cent *hydrogen peroxide* drop wise to remove excess of *potassium permangnate* followed by 3.0 ml of conc. *nitric acid* and titrate with *0.1N ammonium thiocyanate solutions* using *ferric alum* as indicator.

Each ml. of 0.1N NH_4SCN solution is equivalent to 0.01003 g Mercury.

5.2.8. - Determination of Silica (SiO_2)

Weigh 0.5 g (in case of high silica) or 1.0 g (low silica) finely powdered and dried sample in a platinum crucible (W_1). Add 4-5 g *anhydrous sodium carbonate* into the crucible. Mix thoroughly and cover the crucible with lid, if necessary. Place the crucible in muffle furnace. Allow the temperature to rise gradually to reach 900-950^0 and keep on this temp. for about ½ hour to complete the fusion. Take out the crucible and allow cool at room temperature. Extract the cooled mass in 25-30 ml dil *hydrochloric acid* in 250 ml beaker. Heat on hot plate/burner to dissolve the contents. Wash the crucible with distilled water. Keep the beaker on water bath and allow dry the mass. Dehydrate back and powder the mass. Take out the beaker and allow cooling at room temperature. Add 25-30 ml *hydrochloric acid* dilute to 100 ml distilled water. Boil the content and allow cool. Filter through Whatman no 40. filter paper. Wash the residue with hot water 6-8 times. Place the residue along with filter paper in platinum crucible. Ignite at 900-950^0 for 2-3 min. Allow to cool and weigh as SiO_2.

5.2.9. - Estimation of Sodium and Potassium by Flame Photometer:

Preparation of Standard solutions

Weigh 2.542 g of AR *sodium chloride* and dissolve in *purified water* and make upto 1000 ml in a volumetric flask. Dilute 1 ml of the stock solution to 100 ml. This gives standard of 1mg of sodium per 100 ml (10 ppm). Prepare 20, 30, 40 and 50 ppm standard solution.

Weigh 1.9115g of AR *potassium chloride* and dissolve in *purified water* and make up to 1000 ml in a volumetric flask. Dilute 1ml of the stock solution to 100ml. This gives standard of 1mg of sodium per 100 ml (10 ppm). Prepare 20, 30, 40 and 50 ppm standard solution.

Preparation of Sample solution

Weigh 10 g of sample in a preweighed silica dish and heat in a muffle furnace for 1hr at 600º. Cool and dissolve the ash in purified water and make up to 100ml in a volumetric flask.

Switch on the instrument first and then the pump. Keep distilled water for aspiration and allow it to stand for 15 min (warming time). Open the glass cylinder and ignite the flame. Adjust the instrument to zero.

Introduce the maximum concentration solution and adjust it to 100. Again introduce the purified water so that instrument shows zero. Then introduce the standard solution in ascending concentration. Note down the reading each time. Introduce the purified water for aspiration in between the standard solutions. Introduce the sample solution and if it is within the range take the reading. If it exceeds limit 100 then dilute the solution till the reading is within the range. Plot the curve with concentration in ppm against reading obtained. Find out the concentration of the sample solution. Take two or three readings and find out the average. Find out the concentration of sodium and potassium.

5.2.10. - Determination of Sodium Chloride:

Dissolve about 2-3g accurately weighed drug in 25 ml of *purified water* and left for 30 minutes, filter. Wash the filter paper completely with *purified water* and the filtrate is made 100 ml in volumetric flask, make the solution homogeneous, titrate 25 ml of this solution with 0.1 *N silver nitrate solution* using *potassium chromate* as indicator. The end point shows the light brick red colour.

Each ml. of 0.1 *N* Ag NO_3 solution is equivalent to 0.005845 g of NaCl.

5.2.11. - Determination of Sulphur:

Solution:

Carbon tetrachloride saturated with *Bromine*
Barium chloride – 10 per cent solution in water.

Procedure:

Take 0.5 – 1 g powdered sample in 250 ml beaker. Add 10 ml *carbon tetrachloride* saturated with bromine. Keep in cold condition in fume chamber over night. Add 10 – 15 ml conc. *nitric acid*. Digest on water bath. Add 10 ml conc. *hydrochloric acid*, digest it to expel nitrate fumes till syrupy mass. Cool and extract with *hydrochloric acid*, make volume to 100 ml. Boil and filter through Whatman No 40. filter paper. Wash the residue with hot water. Filter through Whatman 41 No. paper in 600 ml beaker. Acidify the filtrate with *hydrochloric acid*. Add 20 ml of 10 per cent *Barium chloride* solution. Stir the solution and digest on burner. Allow to settle $BaSO_4$ precipitate over night. Filter the precipitate through Whatman No. 42 filter paper. Wash the precipitate with water. Ignite the precipitate in muffle furnace in pre weighed platinum crucible up to 850^0. Allow to cool and weigh.

Each g of weight of precipitate is equivalent to 0.13734 g of Sulphur.

5.2.12. - Qualitative Reactions of Some Radicals:

Sodium

Sodium compounds, moistened with hydrochloric acid and introduced on a platinum wire into the flame of a Bunsen burner, give a yellow colour to the flame.

Solutions of sodium salts yield, with solution of uranyl zinc acetate, a yellow crystalline precipitate.

Potassium

Potassium compounds moistened with hydrochloric acid and introduced on platinum wire into the flame of a Bunsen burner, give a violde colour to the flame.

Moderately strong solutions of potassium salts, which have been previously ignited to remove ammonium salts, give a white, crystalline precipitate with perchloric acid.

Solutions of potassium salts, which have been previously ignited to free them from ammonium salts and from which iodine has been removed, give a yellow precipitate with solution os sodium cobaltinitrte and acetic acid.

Magnesium

Solution of magnesium salts yield a white precipitate with solution of ammonium carbonate, especially on boiling, but yield no precipitate in the presence of solution of ammonium chloride.

Solution of magnesium salts yield a white crystalline precipitate with solution of sodium phosphate in the presence of ammonium salts and dilute ammonia solution.

Solution of magnesium salts yield with solution of sodium hydroxide a white precipitate insoluble in excess of the reagent, but soluble in solution of ammonium chloride.

Carbonates and Bicarbonates

Carbonates and bicarbonates effervesce with dilute acids, liberating carbon doxide; the gas is colourless and produces a wihte precipitate in solution of calcium hydroxide.
Solutions of carbonates produce a brownish-red precipitate with solution of mercuric chloride; Solutions of bicarbonates produce a white precipitate.

Solutions of carbonates yield, with solution of silver nitrate, a with precipitate which becomes yellow on the addition of an excess of the reagent and brown on boiling the mixture. The precipitate is soluble in dilute ammonia solution and in dilute nitric acid.

Solutions of carbonates produce, at room temperature, a white precipitate with solution of magnesium sulphate. Solutions of bicarbonates yield no precipitate with the reagent at room temperature, but on boiling the mixture a white precipitate is formed.

Solutions of bicarbonates, on boiling, liberate carbon dioxide which produces a white precipitate in solution of calcium hydroxide.

Sulphates

Solutions of sulphates yield, with solution of barium chloride, a white precipitate insoluble in hydrochloric acid.

Solutions of sulphates yield, with solution of lead acetate, a white precipitate soluble in solution of ammonium acetate and in solution of sodium hydroxide.

Chlorides

Chlorides, heated with manganese dioxide and sulphuric acid, yield chlorine, recognisable by its odour and by giving a blue colour with potassium iodide and solution of starch.

Calcium

Solutions of calcium salts yield, with solution of ammonium carbonate, a white precipitate which after boiling and cooling the mixture, is insoluble in solution of ammonium chloride.

APPENDIX-6

AYURVEDIC DEFINITIONS AND METHODS

6.1. - Kalpanā Paribhā¾ā:

1	Kalka	Caraka sa¼hitā Sūtra sthāna, 4/7
2.	Kvātha / Ka¾āya	Śār¬gadhara sa¼hitā - II - 9/3
3.	Cūr´a	Śār¬gadhara sa¼hitā - II - 6/1
4.	Puºapāka Svarasa	Śār¬gadhara sa¼hitā - II - 1/21-23
5.	Svarasa	Śār¬gadhara sa¼hitā - II - 1/2
6.	Hima Ka¾āya	Śār¬gadhara sa¼hitā - II - 4/1

6.1.1. - Kalka: *Kalka* is the fine paste of macerated fresh plant material.

(*Paribhā¾ā Prabandha*)

6.1.2. - Kvātha / Ka¾āya: *Kvātha* or *Ka¾āya* is the filtered liquid obtained by boiling coarse powder of drug(s) in proportion of 4, 8 or 16 [*M¨du Dravya* - 4, *Madhyama Dravya* - 8 and *Ka¬hina Dravya* - 16 respectively] times of water and reduced to one-fourth.

(*Śār¬gadhara sa¼hitā* - II - 9/3)

6.1.3. - Cūr´a: The fine sieved powder of well dried drug(s) is called *Cūr´a.*

(*Śār¬gadhara sa¼hitā* - II - 6/1)

6.1.4. - Puºapāka Svarasa: It is a kind of procedure, where juice of fresh green herb will be obtained by the process of *Puºapāka*. Bundle the *Kalka* of green plant material in leaves of *Kāśmarī, Vaºa, Jambu* etc., and cover with clay in layers of about 2 cm thickness. Dry and place amidst fire till becomes reddish. Open the bundle and strain the juice from *Kalka* through a *muslin cloth.*

(*Śār¬gadhara sa¼hitā* - II - 1/21-23)

6.1.5. - Svarasa: The liquid part of fresh macerated plant material obtained by pressing through a fresh, *muslin cloth* is called as *Svarasa.*

(Śār¬gadhara sa¼hitā - II - 1/2)

6.1.6. - Hima Ka¾āya:*Hima Ka¾āya* is the extractive obtained by straining of 48 g [1 part] of powdered drug(s) soaked in 288 ml [6 parts] of water overnight.

(Śār¬gadhara sa¼hitā - II - 4/1)

6.2. – Sāmānya paribhāsa:

1	Kajjalī	Rasatara¬gi´ī - 2/27
2.	Kā®jika	Paribhā¾ā prabandha
3.	K¾āra	
4.	Cūr´odaka	Rasatara¬gi´ī – 11
5.	Prak¾epa	
6.	Bhāvanā	Rasatara¬gi´ī - 2/49
7.	Śodhana	
8.	Mūrcchana	Bhai¾ajya ratnāvalī - Jvara

6.2.1. - Kajjalī: *Kajjalī* is the fine black colored powder obtained by triturating *Gandhaka* [Sulphur] and *Pārada* [Mercury] without adding any liquid.

[*Rasa tara¬gi´ī* - 2/27]

6.2.2. - Kā®jika: Sour liquid prepared with of rice grain etc. is called as *Kā®jika.* Take *¾a¾îka śālī* in an earthen vessel, add five parts of water and boil. Shift the preparation into another earthen vessel add three parts of water and seal the mouth of the vessel tightly. Place the vessel aside for two to three weeks of period at regulated temperature during which the liquid becomes sour.

[*Paribhā¾ā prabandha*]

6.2.3. - K¾āra: *K¾āra* is alkaline substance obtained from the ashes of different drugs. Cut the drug in to small pieces, dry and place in an earthen pot, burn to ashes. Allow the ash to cool down to room temperature, add 6 parts of water and mix well. Allow to settle down and decant the supernatant layers through a piece of clean cloth. Repeat the process of staining two or three times till a clear liquid is obtained. Heat the liquid over a moderate fire till the water evaporates completely, leaving a solid salty white substance at the bottom, which is known as *K¾āra.*

6.2.4. - Cūr´odaka:

i]	Cūr´a [Lime powder]	250 mg
ii]	Water	60 ml

Take 250 mg of lime powder in a stainless steel vessel, add 60 ml of water and keep aside for 9 h. Decant the supernatant layers through a filter paper.The filtrate is known as Cūr´odaka.

[Rasatara¬gi´ī - 11]

6.2.5. - Prak¾epa: Fine powder form of the drug(s), which is added to a *kalpa* such as *Leha, Āsava Āri¾ta* etc. before administration is known as *Prak¾epa*.

6.2.6. - Bhāvanā: *Bhāvanā* is the process by which powders of drugs are levigated to a soft mass with specified liquids and allowed to dry.

[*Rasatara¬gi´ī* - 2/49]

6.2.7. - Śodhana: *Śodhana* is the process which removes the impurities to some extent and helps in increasing the therapeutic values of the drugs.

1.	Godantī śodhana	Rasatara¬gi´ī - 11/239
2.	Gairika śodhana	Rasa ratna samuccaya - 3/49 Āyurveda prakāśa - 2/272
3.	Gandhaka śodhana	Rasām¨tam - 2/3
4.	Guggulu śodhana	
5.	¯a¬ka´a Śodhana	Āyurveda prakāśa -2/ 244
6.	Tuttha śodhana	Rasām¨tam 3/74
7.	Bhallātaka śodhana	Rasām¨tam Pariśi¾°a
8.	Manaªśilā śodhana	Rasa ratna samuccaya - 3/93
9.	Vatsanābha śodhana	Rasām¨tam Pariśi¾°a
10.	Śilājatu śodhana	Rasatara¬gi´ī - 22/69-78
11.	Haratāla śodhana	Rasa ratna samuccaya - 3/93
12.	Hi¬gu Śodhana	Rasām¨tam
13.	Vijayā śodhana	Rasām¨tam Pariśi¾°a 8/147
14.	Kāśīśa śodhana	Rasām¨tam Adhyaya 3/158
15.	Pārada sāmānya śodhana	Rasatara¬gi´ī - 5/27-30
16.	A¾°a sa¬skāra of Pārada	

6.2.7.1. - Godantī Śodhana:

i]	Godantī		1 Part
ii]	Nimbu Svarasa	Fr.	Q.S.
	or		
	Dro´apu¾pī Svarasa	Pl.	Q.S.

Bundle small pieces of *Godantī* in a cloth, suspend in *Nimbu* or *Dro´apuspī svarasa* in a *Dolā yantra*, and boil for 3 h.

[*Rasatara¬gi´ī* - 11/239]

6.2.7.2. - Gairika Śodhana:

i]	Gairika	1 Part
ii]	Godugdha	Q.S.

Fine powder of *Gairika* is to be levigated with Cow's milk.

[*Rasaratna samuccaya* - 3/49]

or

i]	Gairika	1 Part
ii]	Gogh¨ta	Q.S.

Fry the fine powder of *Gairika* in little amount of *Gh¨ta.*

[*Āyurveda prakāśa* - 2/272]

6.2.7.3. - Gandhaka Śodhana:

i]	Gandhaka		1 Part
ii]	Godugdha		Q.S.
	or		
	Bh¨¬garāja svarasa	Pl.	Q.S.

Melt small pieces of *Gandhaka* in an iron pan smeared with *Gh¨ta* and pour in to a pot containing *Godugdha* or *Bh¨¬garāja svarasa*. Collect after cooling. Repeat the process for seven times. At the end of the seventh process, wash and dry the material.

[*Rasām¨tam* - 2/3]

6.2.7.4. - Guggulu Śodhana:

Remove manually the big pieces of sandstone, glass, wood etc. if any from the *Guggulu*. Cut *Guggulu* into small pieces, bundle in a cloth and immerse in *Dolā yantra* containing any one of the following liquids.

Gomūtra
Godugdha
Triphalā ka¾āya
Vāsā ka¾āya / svarasa or
Nirgu´²i svarasa with Haridrā cūr´a

Boil till the whole amount of *Guggulu* passes into the liquid through the cloth. Discard the residue present in the bundle if any.
Filter the liquid through *muslin cloth* and heat the mixture till a semi solid mass is obtained. Dry in sun and store until further use.

6.2.7.5. - ¯a¬ka´a Śodhana: Take small pieces of *¯a´ka´a* in an iron pan, fry till complete dehydration.

[*Āyurveda prakāśa* - 2/244]

6.2.7.6. - Tuttha Śodhana:

i]	Tuttha		1 Part
ii]	Raktacandana kvātha	Ht. Wd.	Q.S.
iii]	Ma®ji¾°hā kvātha	Rt.	Q.S.
iv]	Triphalā kvathā	P.	Q.S.

Prepare fine powder of *Tuttha* and levigate with the individual liquid medias number (ii) to (iv) mentioned above seven times each.

[*Rasām¨tam* - 3/74]

6.2.7.7. - Bhallātaka Śodhana:

i]	Bhallātaka	Fr.	1 Part
ii]	Gomūtra		Q.S.
iii]	Godugdha		Q.S.
iv]	I¾°ika cūr´a		Q.S.
v]	Water		Q.S.

Method of Preparation:-Take Bhallātaka, remove the attached thalamus and soak in *Gomūtra* for 7 days. Replace *Gomūtra* every 24 h with fresh *Gomūtra*. After 7 days, rinse the *Bhallātaka* twice with water, to wash off the *Gomūtra*. Soak *Bhallātaka* in *Godugdha* for 7 days, replacing *Godugdha* every 24 h with fresh *Godugdha*. After 7 days, rinse the *Bhallātaka* 2 or 3 times with water to wash off the *Godugdha*. Put the *Bhallātaka* in a thick jute bag containing coarse brick powder and rub carefully, with a view to reduce the oil content in *Bhallātaka*. Wash the processed seed with water and dry.

[*Rasām¨tam- Pariśi¾°a*]

6.2.7.8. - Manaªśilā Śodhana:

i]	Manaªśilā		1 Part
ii]	Agastya patra svarasa	Lf.	Q.S.
	Or		
	Ś¨¬gavera [Ārdraka] svarasa	Rz.	Q.S.

Prepare fine powder of *Manaªśilā* and levigate with any one of the above specified liquid media for seven times.

[*Rasa ratna samuccaya* - 3/93]

6.2.7.9. - Vatsanābha Śodhana:

i]	Vi¾a [Vatsanābha]	Rt.Tr.	1 Part
ii]	Gomūtra		Q.S.

Take small pieces of *Vatsanābha*, bundle in clean muslin cloth, and soak in *Gomūtra* for three days, replacing the later every day. Wash and dry to obtain *Śodhita Vatsanābha*.

[*Rasām¨tam- Parisi¾°a*]

6.2.7.10. - Śilājatu Śodhana:

i]	Śilājatu		2 Parts
ii]	Hot water		4 Parts
iii]	Triphalā Kvātha	P.	1 Part

Take powder of *Śilājatu,* add specified amounts of hot water and *Triphalā Kvātha* so as to disengage the soluble matter. Allow to settle down and decant the supernatant layers.
Repeat the process till a clear liquid is obtained.
Concentrate the decanted material to thick paste over moderate heat.
Dry in sun rays and preserve for further purpose.

[*Rasatara¬gi ´ī* - 22/69-78]

6.2.7.11. - Haritāla Śodhana:

i]	Haritāla		1 Part
ii]	Kū¾mā´²a Toya	Fr.	Q.S.
	or		
	Tila K¾āra Jala	Pl.	Q.S.
	or		
	Cūr´odaka		Q.S.

Take small pieces of *Haratāla,* bundle in clean muslin cloth, suspend in a *Dolā yantra* containing any one of the above liquid media. Boil for three hours, dry in sun rays and preserve for further purpose.

[*Rasa ratna samuccaya* - 3/70]

6.2.7.12. - Hi¬gu Śodhana:

i]	Rāmaºha [Hi¬gu]	Exd.	1 Part
ii]	Ājya [Gh¨ta]		Q.S.

Prepare fine powder of *Hi¬gu* and fry it in sufficient amounts of *Gh¨ta,* till it becomes crisp.

[*Rasatara¬gi ´ī,* 24/578]

6.2.7.13. - Vijayā Śodhana:

i]	Vijayā	1 Part
ii]	Jala	Q.S. for

prak¾ālana

Put Vijayā in a muslin bag and wash in water till free from terbdity and dry.

[*Rasamtra, Parisista 8/147*]

6.2.7.14. - Kāśīśa Śodhana:

i]	Kāśīśa	1 Part
ii]	Bh¨nga nīra (bh¨ngarāja)	Q.S. for bhāvanā

Bhāvanā is given with *Bh¨ngarāja rasa*, 3 times.

[*Rasām¨ta, Adhyāya 3/158*]

6.2.7.15. - Pārada Sāmānya Śodhana:

i]	Pārada [Mercury]	2 Parts
ii]	Sudhāraja [Lime powder]	2 Parts
iii]	Rasona [Laśuna]	2 Parts
iv]	Saindhava lava´a [Rock Salt]	1 Part

Take equal parts of *Pārada* and *Sudhāraja*, triturate for three days, and filter carefully through a clean cloth.
Add dehusked *Rasona* and *Saindhava lava´a* to the *Pārada*, triturate till the paste of *Rasona* becomes black.
Wash with warm water and separate the *Pārada* with caution.

[*Rasatara¯gi´ī* - 5/ 27-30]

6.2.7.16. - A¾ºasa¼skāra of Pārada

A¾ºasa¼skāra of *Pārada* have been prescribed in Ayurvedic classics for purification and to increase the therapeutic activities.

The *A¾ºasa¼skāra* are:

i] Svedana

ii] Mardana

iii] Mūrcchana

iv] Utthāpana

v] Pātana [Ūrdhva, Adhaª and Tiryak]

vi] Rodhana / Bodhana

vii] Niyāmana

viii] Dīpana / Sandīpana

6.2.7.16.a. - Svedana:

[*Rasah¨dayatantra* - 2/3]

i]	Pārada [Mercury]		1 Part
ii]	Āsurī [Rājikā]	Sd.	1/16th Part
iii]	Pa°u [Saindhava lava´a]		1/16th Part
iv]	Śu´°hī	Rz.	1/16th Part
v]	Marica	Fr.	1/16th Part
vi]	Pippalī	Fr	1/16th Part
vii]	Citraka	Rt.	1/16th Part
viii]	Ārdraka	Rz.	1/16th Part
ix]	Mūlaka	Rt. Tr.	1/16th Part
x]	Kā®jika		Q.S.

Method:

Take the ingredients numbered [ii] to [ix] in to wet grinder and grind with sufficient quantity of water to prepare *kalka* (homogeneous blend). Take leaf of *Bhūrja* [*Betula utilis*] or *Kadalī* [*Musa paradisiaca*], place it over four folded cloth, smear with the prepared *Kalka*, and gently place *Pārada* over it. Place the remaining part of *kalka* if any, over the *Pārada.* Suspend the *po°alī* in a *Dolā yantra* containing *Kā®jika*. Boil for three days. Remove *Pārada* and *kalka,* wash carefully with warm water and collect *Pārada.*

6.2.7.16.b. - Mardana:

[*Rasah¨dayatantra* - 2/4]

i]	Pārada [Mercury]	1 Part
ii]	Gu²a	1/16th Part
iii]	Dagdhor´a	1/16th Part
iv]	Lava´a [Saindhava lava´a]	1/16th Part
v]	Mandira dhūma	1/16th Part
vi]	I¾°ika cūr´a	1/16th Part
vii]	Āsurī [Rājikā]	1/16th Part
viii]	Kā®jika	Q.S.

Method:

Take the ingredients numbered [i] to [vii] in to *Khalva*yantra, add with required amounts of *Kā®jika* and levigate for three days. Remove *Pārada* and *Kalka*, wash carefully with warm water and collect *Pārada.*

6.2.7.16.c. - Mūrcchana:

[*Rasah¨dayatantra* - 2/6]

i]	Pārada [Mercury]		1 Part
ii]	G¨hakanyā [Kumārī]	Lf.	1/16th Part
iii]	Harītakī	P.	1/16th Part
iv]	Bibhītaka	P.	1/16th Part
v]	Āmalakī	P.	1/16th Part
vi]	Citraka	Rt.	1/16th Part

Method:

Take the ingredients numbered [iii] to [vi], dry, powder and pass through sieve number 85. Add ingredient number [ii] and grind with sufficient quantity of water to prepare *Kalka*. Add *Pārada* to the *Kalka* and triturate for three days.

6.2.7.16.d. - Ūtthāpana:

[*Rasah¨dayatantra* - 2/7]

i]	Pārada [Mercury]	1 Part
ii]	Kā®jika	Q.S.

Method:

Collect the *Pārada* at the end of *Mūrcchana* process and subject it to *Ūtthāpana*, and wash with *Kā®jika* and collect the *Pārada* carefully.

6.2.7.16.e. - Pātana:

The process of *Pātana* is again of three types, viz. *Ūrdhvapātana, Adha ªpātana* and *Tiryakpātana.*

Ūrdhvapātana:

[*Āyurveda prakāśa* - 1/68-71]

i]	Pārada [Mercury]	3 Parts
ii]	Ravi [Tāmra]	1 Part
iii]	Jambīra [Nimbu] rasa	Q.S.

Method:

Take *Pārada* and *Tāmra* in the specified ratio and levigate with *Jambīra svarasa* to prepare thick paste. Apply the paste over the lower pot of *±amarū yantra* and apply heat for 12 h. Collect the *Pārada* settled at the upper pot gently.

Adhaªpātana: [*Āyurveda prakāśa* - 1/75-77]

i]	Pārada [Mercury]		1 Part
ii]	Harītakī	P.	1/16th Part
iii]	Bibhītaka	P.	1/16th Part
iv]	Āmalakī	P.	1/16th Part
v]	Śigru	St. Bk.	1/16th Part
vi]	Citraka	Rt.	1/16th Part
vii]	Saindhava lava´a		1/16th Part
viii]	Āsurī [Rājikā]	Sd.	1/16th Part
ix]	Nimbu rasa		Q.S.

Method: Take the ingredients numbered [ii] to [vi], dry, powder and pass through sieve number 85. Add the powders to *Pārada* and levigate by adding ingredients numbered [vii] to [ix] to prepare fine paste. Apply the paste in the *Adhaªpātana yantra*, subject to heat and collect *Pārada.*

Tiryakpātana: [*Āyurveda prakāśa* - 1/79-81]

i]	Pārada [Mercury]	3 Parts
ii]	Ravi [Tamra]	1 Part
iii]	Jambīra [Nimbu] rasa	Q.S.

Method: Take *Pārada* obtained at the end of *Adhaªpātana* process, add with *Tāmra* and levigate with *Jambīra svarasa* to prepare thick paste. Apply the paste in the *Tiryakpātana yantra*, subject to heat and collect *Pārada.*

6.2.7.16.f. - Rodhana / Bodhana: [*Rasendracū²āma´i* - 4/88]

I]	Pārada [Mercury]	3 Parts
ii]	Saindhava lava´a jala	Q.S.

Method: Place the *Pārada* in a pot containing *Saindhava lava´a jala* and seal the mouth of the pot tightly. Place the pot undisturbed for three days. Decant the water on the fourth day to collect the *Pārada.*

6.2.7.14.g. - Niyāmana: [*Rasah¨dayatantra* - 2/10]

i]	Pārada [Mercury]		1 Part
ii]	Pha´i [Nāgavallī]	Lf.	1/16th Part
iii]	Laśuna	Bl.	1/16th Part
iv]	Ambujā		1/16th Part
v]	Karkº°i		1/16th Part
vi]	Mārkava [Bh¨¬garāja]	Pl.	1/16th Part
vii]	Ci®cikā [Ci®cā]	Lf.	1/16th Part
viii]	Kā®jī		Q.S.

Method: Prepare *Kalka* of the ingredients numbered [ii] to [vii], add with *Pārada* and prepare a *po˚alī*. Suspend the *po˚alī* in a *Dolā yantra* containing *Kā®jika* and boil. Remove *Pārada* and *Kalka,* wash carefully with warm water and collect *Pārada.*

6.2.7.16. h. - Dīpana / Sandīpana: [*Rasah ïdayatantra* - 2/11]

i]	Pārada [Mercury]		1 Part
ii]	Bhū [Sphaˆikā]		1/16th Part
iii]	Khaga [Kāśīśa]		1/16th Part
iv]	¯a¬ka´a		1/16th Part
v]	Marica	Fr.	1/16th Part
vi]	Lava´a [Saindhava lava´a]		1/16th Part
vii]	Āsurī [Rājikā]	Sd.	1/16th Part
viii]	Śigru		1/16th Part
ix]	Kā®jika		Q.S.

Method: Prepare *Kalka* of the ingredients numbered [ii] to [viii], add with *Pārada* and prepare a *po˚alī*. Suspend the *po˚alī* in a *Dolā yantra* containing *Kānjika* and boil for three days. Remove *Pārada* and *kalka,* wash carefully with warm water and collect *Pārada.*

6.2.8. - Mūrchanā: *Mūrcchana* is the process which removes Ā*ma do¾a* of *Taila / Gh ïta* and provides good color and fragrance. *Mūrcchana* process is to be followed before any *Sneha* preparation.

[*Bhai¾ajya ratnāvalī*]

Mūrcchana

Era´²a taila Mūrcchana	Bhai¾ajya ratnāvalī - Jvara
Gh ïta Mūrcchana	Bhai¾ajya ratnāvalī - Jvara
Taila Mūrcchana	Bhai¾ajya ratnāvalī - Jvara

6.2.8.1. - Mūrcchana of Era´²a Taila **(***Bhai¾ajya ratnāvalī, Jvarādhikāra*.)

Ingredients:

1.	Ma®ji¾°hā API	*Rubia cordifolia*	P.	12 g
2.	Mustā API	*Cyperus rotundus*	Rz.	12 g
3.	Dhānyaka API	*Coriandrum sativum*	Sd.	12 g
4.	Āmalakī API	*Emblica officinalis*	P.	12 g
5.	Harītakī API	*Terminalia chebula*	P.	12 g
6.	Bibhītaka API	*Terminalia belerica*	P.	12 g
7.	Agnimantha API	*Clerodendron phlomidis* (Official substitute)	Rt.	12 g
8.	Hrīverā API	*Coleus vettiveroides*	Rt.	12 g
9.	Kharjūra API	*Phoenix sylvestris*	Fr.	12 g

10.	Va°a API	*Ficus religiosa*	Lf. Bud.	12 g
11.	Haridrā API	*Curcuma longa*	Rz.	12 g
12.	Dāruharidrā API	*Berberis aristata*	St.	12 g.
13.	Nalikā (Tvak API)	*Cinnamomum tamala*	St. Bk.	12 g.
14.	Śu´°hī API	*Zingiber officinale*		12 g.
15.	Ketakī API	*Pandanus odoratissimus*	Rt.	12 g.
16.	Dadhi API	Curd		1.536 l
17.	Kā®jika API			1.536 l
18.	Era´²a taila API	*Ricinus communis*	Oil	768 ml

Method of preparation: Take the ingredients (*Kalka dravyas*) numbered 1 to 15 in the composition, dry, powder and pass through sieve number 85. Transfer the powdered ingredients to wet grinder, grind with sufficient quantity of water to prepare *Kalka* (homogeneous blend). Take *Era´²a taila* in a stainless steel vessel and heat it mildly. Add increments of *Kalka*. Add *Dadhi* and Kā®jika in the specified ratio and stir thoroughly. Continue heating till the mixture becomes moisture free. Filter while hot through a *muslin cloth* and allow to cool.

6.2.8.2. - Mūrcchana of Gh¨ta

(*Bhaisajya ratnāvalī, Jvarādhikāra*.)

Ingredients:

1.	Harītakī API	*Terminalia chebula*	P.	48 g
2.	Dhātrī (Āmalakī API)	*Emblica officinalis*	P.	48 g
3.	Bibhītaka API	*Terminalia belerica*	P.	48 g
4.	Mustā API	*Cyperus rotundus*	Rz.	48 g
5.	Haridrā API	*Curcuma longa*	Rz.	48 g
6.	Mātulu¬ga API	*Citrus medica*	Ft.	48 g
7.	Gh¨ta API	*Clarified butter of cow's milk*		768 g
8.	Jala API	Water		3.072 l

Method of Preparation:

Take all ingredients of pharmacopoeial quality

Wash, clean, dry the ingredients numbered 1 to 5 of the formulation composition powder separately and pass through sieve number 85 (*Kalka dravyas).*

Wash, clean the *Mātulu¬ga* and separate the juicy flesh from its rind. Grind and filter through *muslin cloth* to obtain *Svarasa*.

Transfer the *Kalka dravyas* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend.

Take *Gh¨ta* in a stainless steel vessel and heat mildly.

Add increments of *Kalka*. Stir thoroughly while adding Svarasa and water.

Heat for 3 h with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Stop heating and allow to stand overnight.

Start the heating next day and observe the boiling mixture for subsidence of froth *(phena śānti)* and constantly check the *Kalka* for formation of *varti (madhyama pāka lak¾a´a).*

Expose the *varti* to flame and confirm the absence of crackling sound indicating absence of moisture. Stop heating when the *Kalka* forms a *varti* and the froth subsides. Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
Pack it in tightly closed glass containers to protect from light and moisture.

Standards:

Description*:* A yellow-coloured, soft, low melting medicated fat, unctuous to touch with odour of haridra and haldi like taste.

Physico-chemical parameters:

Refractive index at 40^0:	1.439,	Appendix 3.1
Weight per ml at 40^0:	0.967,	Appendix 3.2
Saponification value:	229,	Appendix 3.10
Iodine value:	100,	Appendix 3.11
Acid value:	Not more than 0.33,	Appendix 3.12
Peroxide value:	Not more than 1.35,	Appendix 3.13
Congealing point:	28^0 to 18^0 ,	Appendix 3.4.2

Other requirements:

Mineral oil:	Absent,	Appendix 3.15
Microbial Limits:		Appendix 2.4
Aflotoxins:		Appendix 2.7

Storage: Pack it in tightly closed containers to protect from light and moisture.

6.2.8.3. - Mūrcchana of Taila **(***Bhai¾ajya ratnāvalī, Jvarādhikāra*.)

Ingredients:

1.	Ma®ji¾°hā API	*Rubia cordifolia*	Rt.	96 g
2.	Harītakī API	*Terminalia chebula*	P.	24 g
3.	Bibhītaka API	*Terminalia belerica*	P.	24 g
4.	Āmalakī API	*Emblica officinalis*	P.	24 g
5.	Hrīverā API	*Coleus vettiveroides*	Rt.	24 g
6.	Haridrā API	*Curcuma longa*	Rz.	24 g
7.	Jaladhara (Mustā API)	*Cyperus rotundus*	Rz.	24 g
8.	Lodhra API	*Symplocos racemosa*	St. Bk.	24 g
9.	Sūcīpu¾pa (Ketakī API)	*Pandanus odoratissimus*	Rt.	24 g
10.	Va°ā¬kura (Nyagrodha API)	*Ficus bengalensis*	Lt. Bd.	24 g
11.	Nalikā (Tvak API)	*Cinnamomum tamala*	St. Bk.	24 g
12.	Taila (Tila API)	*Sesamum indicum*	Oil	1.536 l
13.	Jala API	Water		6.144 l

Method of preparation: Take the ingredients (*Kalka dravyas*) numbered 1 to 11 in the composition, dry, powder and pass through sieve number 85. Transfer the powdered ingredients to wet grinder and grind with sufficient quantity of water to prepare *Kalka*

(homogeneous blend). Take *Tila Taila* in a stainless steel vessel and heat it mildly. Add increments of *Kalka***.** Stir thoroughly while adding water in the ratio of 1:4. Start heating and constantly check the *Kalka* for formation of *varti* (*madhyama pāka lak¾a´a*) and observe the boiling mixture for appearance of froth. Stop heating when the *Kalka* forms a *varti* and the froth emerges. Filter while hot through a *muslin cloth* and allow to cool.

6.3. - Yantra Paribhā¾ā:

1	Khalva yantra	*Rasatara¬gi´ī* - 4/53
2.	Tiryak pātana yantra	*Āyurveda prakāśa* - 1/79
3.	±amaru yantra	*Rasatara¬gi´ī* - 4/41
4.	Dolā yantra	*Rasaratna samuccaya* - 9/3-4

6.3.1. - Khalva yantra: *Khalva yantra* is an instrument made up of good quality of stone in different sizes and shapes, useful for trituration and levigation processes. It resembles with mortar and pestle.

[*Rasatara¬gi´ī* - 4/53]

6.3.2. - Tiryak pātana yantra: *Tiryak pātanā yantra* is an instrument prepared for distillation of *Pārada* with the delivery tank weld approximately at an angle of 45^0.

[Ā*yurveda prakāśa* - 1/79]

6.3.3. - ±amarū yantra: *±amarūyantra* is a contravenes of shape resembling *±amarū* for sublimation prepared by sealing two pots with their mouths one telescoping the other sealing joint securely.

[*Rasatara¬gi´ī* - 4/41]

6.3.4. - Dolā Yantra: *Dolā yantra* consists of a pot half filled with specified liquid with a horizontal rod placed on the rim from which the bundle of material to be treated will be immersed and heated.

[*Rasaratna samuccaya* - 9/3-4]

APPENDIX-7
K½¡RASŪTRA

7.1. - Methods of Physical Test

7.1.1. - Length: Length is the distance from end to end of the thread, and measured as follows: Fix a standard meter scale on a table. Place the thread with one cut end exactly coinciding with a division on the scale. Applying just enough tension to keep the thread straight, place the other cut end on the scale, and note the division on the scale with which it coincides. Read the length and record it to a mm on the meter scale, (which should be marked in mm). Repeat the test on four more threads belonging to the same batch. The average is taken as the length of the thread.

7.1.2. - Weight: Record the weight of each thread used in the test for Length, on a balance of sensitivity 0.1 mg. (0.0001 g) The average is the weight of the thread.

7.1.3. - Diameter: Determine the diameter on a measuring instrument of the dial gauge type, with a sensitivity of 0.0025 mm. The table of the dial gauge is about 5 cm in diameter, with a pressor foot of about 12.5 mm. The total load applied by the foot when in use shall be 200 g ± 15 g.
Take the thread to be measured from its tube and expose it to room temperature for about half an hour. Hold the thread across the gauge table with just the tension required to keep it straight, and allow the pressor foot to touch it. Record the reading on the dial gauge as the thickness of the thread at that point. Three readings are to be taken for each thread, one at mid point, and two at equidistance on either side of the midpoint. No point should be within 3 cm of either end of the thread.

The test is repeated with four more threads of the same batch. The average is taken as the diameter of the thread.

7.1.4. - Tensile strength: This is expressed as the breaking load in kg when tested as given below.

The thread under test is tied to a hook suspended from a stand. A weighing pan of 250 g is attached to the other end of the thread, and a weight of 2 kg is placed on the pan. Weights are added to the pan in increments of 50 g, allowing five seconds between such additions. At the time the thread breaks, the total weights in the pan and weight of the pan itself is recorded as the breaking load of the thread. If the breakage occurs within 1 cm from either ends, the test should be repeated on a fresh thread. The average of five tests is recorded as the breaking load of one batch.

7.2. - Methods of Chemical Test

7.2.1. - Loss on drying: Take 5 K¾āras¦tra and weigh accurately. Place in the form of a coil, in a tared petri dish; keep at 105^0 in an oven for 3h. Cool in a desiccator, weigh to constant weight and calculate loss on drying.

7.2.2. - Water soluble extractive: Take 5 K¾āras¦tra and weigh accurately. Macerate the test material with water (1: 40 w/v) for 5 minutes at room temperature, reflux for 5 minutes on steam bath, cool to room temperature and filter into a graduated tube. Make up the original volume with water. Evaporate a known volume and dry to a constant weight at 100 -105^0.

7.2.3. - n- Hexane soluble extractive: Carry out as given above using n-*hexane* instead of water.

7.2.4. - *p*H (Alkalinity): Take about 0.1 g of coated material of K¾āras¦tra and add 10 ml of carbon dioxide free water. Vortex the mixture for 1 minute, set aside for 15 minutes, vortex again for 1 minute and filter. Determine the pH of clear supernatant using digital pH meter.

7.2.5. - Sodium and Potassium:

Prepare separate stock solution of *sodium / potassium* (500 mEq) by dissolving 2.9230 g *sodium chloride* / 3.7280 g *potassium chloride* in 100 ml triple distilled water. Prepare separate working standard solutions containing 0.5, 1.0, 2.0, 4.0 and 5.0 mEq of *sodium/potassium* from the respective standard stock solutions. Using flame photometer with appropriate filters, calibrate the standard solutions and prepare separate calibration plots respectively for *sodium/potassium*.

Take 0.1 g coated material of K¾āras¦tra add 15 ml of triple distilled water in 50 ml of volumetric flask and shake vigorously and make the volume upto the mark. Filter the solution and choosing *sodium* and *potassium* filter, calculate the content of the *sodium/potassium* respectively in the coated material of K¾āras¦tra by interpolation from the calibration plot.

7.2.6. - Total alkalies: Estimate the total alkalies as carbonate in the coated material of K¾āras¦tra by titrating a known volume of the aqueous solution prepared for determination of pH, with N/25 *hydrochloric acid* using pH meter to an end point pH of 3.6. Calculate percentage of total alkali as carbonate using the titer value.

7.2.7. – Turmeric: Moisten 0.2 g of coated material of K¾āras¦tra and 0.05 g Turmeric, each separately, with 0.5 ml % v /v hydrochloric acid for 5 minutes. Extract each separately with 4 x 5 ml *acetone* by vortexing for 30 seconds, at 0,5th and 10th minutes. Pool the respective extracts, filter and make up the volume to 25 ml using *acetone*. Read the absorbance of the each extract after suitable dilution, at 418 nm against *acetone* Blank. Calculate the percentage of Turmeric in the coated material of K¾āras¦tra using the absorbance of Reference Turmeric.

7.2.8. - Curcumin

Moisten 0.2 g of coated material of K¾āras¦tra with 0.5 ml % v/v *hydrochloric acid* for 5 minutes. Extract the mixture with 4 x 5 ml *acetone* by vortexing for 30 seconds, each at 0, 5th and 10th minute. Pool the extracts, filter and make up the volume to 25 ml using *acetone*. Take 10 ml of the solution, evaporate at room temperature to about 0.1 ml.

Apply quantitatively 0.1 ml of sample solution, 15 µl (1 mg/ml) solution of Reference Curcumin in *acetone* and 50 µl of *acetone* as Blank on a chromatoplate. Develop the Plate in *chloroform*: *methanol* (49:1). Mark the yellow coloured Curcumin zone in reference, test sample and blank . Separate the spots and extract each with 5 x 4 ml *methanol* and make up the volume to 25 ml in each case. Read the absorbance of *methanol* solution of coated material of K¾āras¦tra and Curcumin after suitable dilution against blank at 418 nm. Calculate the percentage of Curcumin in the sample with respect to the Reference Curcumin.

7.2.9. - Sulphated Ash

Heat silica crucible to redness for 10 minute, allow to cool in a desiccator and weigh.
Take 3 K¾āras¦tras, in the crucible and weigh accurately. Ignite gently at first, until the substance is thoroughly charred. Cool, moisten the residue with 1 ml of conc. *Sulphuric acid*, heat gently until white fumes are no longer evolved and ignite at 800^0 until all black particles have disappeared (conduct the ignition in a place protected from air currents). Allow the crucible to cool, add a few drops of conc. *sulphuric acid* and heat.
Ignite as before, allow to cool and weigh to constant weight. Calculate the percentage of Sulphated ash.

7.2.10. - Euphol

Extract 0.2 g of coated material of K¾āras¦tra with 5 x 5 ml n-*hexane* by vortexing for 30 seconds, each at 0, 5^{th} ,10^{th} ,15^{th} and 20^{th} minute. Pool the extracts, filter and recover the solvent under reduced pressure and redissolve the residue in 1 ml *chloroform*: *methanol* (3:2). Apply quantitatively 100 µl of the above solution, 100 µl (5 mg /ml) solution of Reference *Euphol* in n-*hexane* and 100 µl of n-*hexane* as Blank on a chromatogram plate. Develop the plate in *chloroform*: n-*hexane* (4:1). Mark the *Euphol* zones in sample, Reference *Euphol* and Blank by visualizing in iodine chamber. Remove the iodine by vaporizing in an oven at 50^0 for 20 minutes. Separate the zones individually, extract each with 5 x 4 ml n-*hexane* and make up the volume to 25 ml in each case. Take 2 ml from each extract separately in a test tube and dry on a boiling water bath. Cool the residue to the room temperature and add 4 ml of *acetic anhydride* to each and cool further in an ice bath for 15 minutes. Add 0.05ml cold conc. *sulphuric acid* carefully to each tube and mix thoroughly and set aside in a dark cupboard for exactly 1.5 hours and read the absorbance at 281 nm against Blank. Calculate the percentage of *Euphol* in the coated material of K¾āras¦tra with respect to the Reference *Euphol*.

APPENDIX-8

WEIGHTS AND MEASURES

8.1. - METRIC EQUIVALENTS OF CLASSICAL WEIGHTS AND MEASURES
Weights and measures described in Ayurvedic classics and their metric equivalents adopted by the Ayurvedic Pharmacopoeia Committee

The following table of metric equivalents of weights and measures, linear measures and measurement of time used in the Ayurvedic classics have been approved by the Ayurvedic Pharmacopoeia committee in consultation with Indian Standards Institution.

I. WEIGHTS AND MEASURES

Classical Unit		Metric Equivalent
1 Ratti or Gu®j¢		= 125 mg
8 Ratti or Gu®j¢s	=1 M¢¾a	= 1 g
12 M¢¾as	=1 Kar¾a (Tola)	= 12 g
2 Kar¾as (Tolas)	=1 ¹ukti	= 24 g
2 ¹uktis (4 Kar¾as or Tolas)	=1 Palam	= 48 g
2 Palams	=1 Prasrti	= 96 g
2 Pras¨tis	=1 Ku²ava	= 192 g
2 Ku²avas	=1 M¢nika	= 384 g
2 M¢nikas	=1 Prastha	= 768 g
4 Prasthas	=1 ¡²haka	= 3 kg 73 g
4 ¡²hakas	=1 D¨o´a	= 12kg 228 g
2 D¨o´as	=1 ¹¦rpa	= 24kg 576 g
2 ¹¦rpas	=1 D¨o´i (Vahi)	= 49kg 152 g
4 D¨o´is	=1 Kh¢ri	= 196kg 608g
1 Palam		= 48 g
100 Palams	=1 Tula	= 4 kg 800 g
20 Tulas	=1 Bh¢ra	= 96 kg

In case of liquids, the metric equivalents would be the corresponding litre and milliliter.

II. LINEAR MEASURES

Classical Unit	Inches	Metric Equivalents
1. Yavodara	1/8 of ¾"	0.24 cm
2. A¬gula	¾"	1.95 cm
3. Bitahasti	9"	22.86 cm
4. Aratni	10 ½"	41.91 cm
5. Hasta	18"	45.72 cm
6. N¨pahasta (R¢jahasta)	22"	55.88 cm
7. Vyama	72"	182.88 cm

III. MEASUREMENT OF TIME

Unit		Equivalent(in hours,minutes & in seconds)
2 K¾a¬a	=1 Lava	
2 Lavas	=1 Nime¾a	
3 Nime¾as	=1 Ka¾°ha	= 4.66 seconds
1 Ghati		= 24 Minutes
30 Kas°has	=1 Kal¢	= 2 Minutes 20 seconds
20 Kal¢ + 3 Ka¾°has	=1 Muh¦rta	= 48 Minutes
30 Muh¦rtas	=1 Ahor¢tra	= 24 Hrs.
15 Ahor¢tras	=1 Pak¾a	= 15 Days
2 Pak¾as	=1 M¢sa	= 30 Days/ One Month
2 M¢sa	=1 §tu	= 60 Days/ Two Months
3 §tus	=1 Ayana	= 6 Months
2 Ayanas	=1 Samvatsara	= 12 Months/ One Year
5 Samvatsara	=1Yuga	= 5 Years
1 Ahor¢tra of Devas		= 1 Year
1 Ahor¢tra of Pitaras		= 1 Month

8.2. - METRIC SYSTEM :

Measure of Mass (Weights)

1 Kilogram (Kg) – is the mass of the International Prototype Kilogram.
1 Gramme (g) – the 1000^{th} part of 1 Kilogram.
1Milligram (mg) – the 1000^{th} part of 1 gramme.
1 Microgram (µg) – the 1000^{th} part of 1 milligram.

Measures of capacity (Volumes)

1 Litre (1) is the volume occupied at its temperature of maximum density by a quantity of water having a mass of 1 Kilogram.
1 Millilitre (ml) the 1000^{th} part of 1 litre.

The accepted relation between the litre and the cubic centimetre is 1 litre –1000.027 cubic centimeters.

Relation of capacity of Weight (Metric)

One litre of water at 20^0 weighs 997.18 grams when weighed in air of density 0.0012 gram per millilitre against brass weights of density 84 grams per millilitre.

Measures of Length

1 Metre (m) is the length of the International Prototype Metre at 0.
1 Centimetre (cm) – the 100^{th} part of 1 metre.
1 Millimetre (mm) – the 1000^{th} part of 1 metre.
1 Micron (µ) – the 1000^{th} part of 1 millimetre
1 Milliimicron (mµ) – the 1000^{th} part of micron.

APPENDIX - 9
Classical Ayurvedic References

1 : 1 ABHAY¡RI½¯A (अभयारिष्ट) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, Ar°org¢dhik¢ra ; 105-110)

अभयायास्तुलामेकां मृद्वीकाऽर्द्धतुलां तथा ।
विड्गस्य दशपलं मधूककुसमस्य च ।। 105 ।।
चतुर्द्रोणे जले पक्त्वा द्रोणमेवावशेषयेत् ।
शीतीभूते रसे तस्मिन् पूते गुडतुलां क्षिपेत् ।। 106 ।।
श्वदंष्ट्रां त्रिवृतां धान्यं धातकीमिन्द्रवारुणीम् ।
चव्यं मधुरिकां शुण्ठीं दन्तीं मोचरसं तथा ।। 107 ।।
पलयुग्ममितं सर्वं पात्रे महति मृण्मये ।
क्षिप्त्वा संरुध्य तत्पात्रं मासमात्रं निधापयेत् ।। 108 ।।
ततो जातरसं ज्ञात्वा परिस्राव्य रसं नयेत् ।
बलं कोष्ठञ्च वह्निञ्च वीक्ष्य मात्रां प्रयोजयेत् ।। 109 ।।
अर्शांसि नाशयेच्छीघ्रं तथाष्टावुदराणि च ।
वर्चोमूत्रविबन्धघ्नो वह्निं सन्दीपयेत् परम् ।। 110 ।।

(भैषज्यरत्नावली, अर्शोरोगाधिकार ; 105-110)

1 : 2 AM§T¡RI½¯A (अमृतारिष्ट) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, Jvar¢dhik¢ra ; 690-693)

अमृतायाः पलशतं दशमूल्यास्तथैव च ।
पादावशिष्टं पक्त्वा च चतुर्द्रोणे जले भिषक् ।। 690 ।।
गुडस्य त्रितुलाः सिद्धे क्वाथे शीते क्षिपेत्पुनः ।
अजाज्याः षोडशपलं द्विपलं रक्तपुष्पकम् ।। 691 ।।
सप्तच्छदं तथा व्योषं नागकेशरमब्दकम् ।
कट्वीप्रतिविषे वत्सबीजञ्च पलसम्मितम् ।। 692 ।।
सर्वमेकीकृतं भाण्डे निदध्यान्मासमात्रकम् ।
अमृतारिष्ट इत्येष प्रोक्तो ज्वरकुलान्तकृत् ।। 693 ।।

(भैषज्यरत्नावली, ज्वराधिकार ; 690-693)

1 : 4 ARAVIND¡SAVA (अरविन्दासव) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, B¢larog¢dhika ; 185-189)

अरविन्दमुशीरञ्च काश्मरीं नीलमुत्पलम् ।
मञ्जिष्ठैला बलामांसीरम्बुदं शारिवां शिवाम् ।। 185 ।।
बिभीतकवचाधात्रीः शटीं श्यामां सनीलिनीम् ।
पटोलं पर्पटं पार्थं मधूकं मधुकं मुराम् ।। 186 ।।
पलमानेन संगृह्य द्राक्षायाः पलविंशतिम् ।
धातकीं षोडशपलां जलद्रोणद्वये क्षिपेत् ।। 187 ।।
शर्करायास्तुलां तत्र तुलार्द्धं माक्षिकस्य च ।
मासं संस्थापयेद् भाण्डे मृत्तिकापरिनिर्मिते ।। 188 ।।
बालानां सर्वरोगघ्नो बलपुष्ट्यग्निवर्धनः ।
अरविन्दासवः प्रोक्त आयुष्यो ग्रहदोषहृत् ।। 189 ।।

(भैषज्यरत्नावली, बालरोगाधिकार ; 185-189)

1 : 5 A¹OK¡Rl½¯A (अशोकारिष्ट) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, Str¤rog¢dhik¢ra ; 114-117)

अशोकस्य तुलामेकाञ्चतुर्द्रोणे जले पचेत् ।
पादशेषे रसे पूते शीते पलशतद्वयम् ।। 114 ।।
दद्यात् गुडस्य धातक्याः पलषोडशिकं मतम् ।
अजाजीं मुस्तकं शुण्ठीं दार्व्युत्पलफलत्रिकम् ।। 115 ।।
आम्रास्थि जीरकं वासां चन्दनञ्च विनिक्षिपेत् ।
चूर्णयित्वा पलांशेन ततो भाण्डे निधापयेत् ।। 116 ।।
मासादूर्ध्वञ्च पीत्वैनमसृग्दररुजां जयेत् ।
ज्वरञ्च रक्तपित्तार्शोमन्दाग्नित्वमरोचकम् ।। 117 ।।
मेहशोथारुचिहरस्त्वशोकारिष्टसंज्ञितः ।।

(भैषज्यरत्नावली, स्त्रीरोगाधिकार ; 114-117)

1 : 6 A¹VAGANDH¡DYARl½¯A (अश्वगन्धाद्यरिष्ट) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, M¦rcch¢dhik¢ra ; 13-19)

तुलाद्र्धं चाश्वगन्धाया मुसल्याः पलविंशतिः ।
मञ्जिष्ठाया हरीतक्या रजन्योर्मधुकस्य च ।। 13 ।।
रास्नाविदारीपार्थानां मुस्तकत्रिवृतोरपि ।
भागान् दशपलान् दद्यादनन्ताश्यामयोस्तथा ।। 14 ।।

चन्दनद्वितयस्यापि वचायाश्चित्रकस्य च ।
भागानष्टपलान् क्षुण्णानष्टद्रोणेऽम्भसः पचेत् ।। 15 ।।
द्रोणशेषे कषायेऽस्मिन् पूते शीते प्रदापयेत् ।
धातक्याः षोडशपलं माक्षिकस्य तुलात्रयम् ।। 16 ।।
व्योषं तु द्विपलं ग्राह्यं त्रिजातकचतुष्पलम् ।
चतुष्पलं प्रिय[3]~गोश्च द्विपलं नागकेशरम् ।। 17 ।।
मासादूर्ध्वं पिबेदेनं कर्षैपीपरिमाणतः ।
मूर्च्छामपस्मृतिं शोषमुन्मादमपि दारुणम् ।। 18 ।।
काश्यमशर्सि मन्दत्वमग्नेर्वातभवान् गदान् ।
अश्वगन्धाद्यरिष्टोऽयं पीतो हन्यादसंशयम् ।। 19 ।।
(भैषज्यरत्नावली, मूर्च्छाधिकार ; 13-19)

1 : 3 BABB¥L¡Rl½¯A (बब्बूलारिष्ट) (AFI, Part-II)

([1]¢r¬gadharasa¼hit¢, Madhyamakha´[2]a, Adhy¢ya 10 ; 66-68$^{1}/_{2}$)

तुलाद्वयं तु बब्बूल्याश्चतुर्द्रोणे जले पचेत् ।
द्रोणशेषे रसे शीते गुडस्य च तुलां क्षिपेत् ।। 66 ।।
धातकीं षोडशपलां कृष्णां च द्विपलां तथा ।
जातीफलानि क[3]~कोलमेलात्वक्पत्रकेशरम् ।। 67 ।।
लवङ्गं मरिचं चैव पलिकान्युपकल्पयेत् ।
मासं भाण्डे स्थितस्त्वेष बब्बूलारिष्टको जयेत् ।। 68 ।।
क्षयं कुष्ठमतीसारं प्रमेहश्वासकासकम् ।
(शार्ङ्गधरसंहिता, मध्यमखण्ड, अध्याय 10 ; 66-68$^{1}/_{2}$)

1 : 24 BAL¡Rl½¯A (बलारिष्ट) (AFI, Part-I)

(Bhai¼ajyaratn¢val◌ा, V¢tavy¢dhyadhik¢ra ; 569-572)
बलाश्वगन्धयोर्ग्राह्यं पृथक् पलशतं शुभम् ।
चतुर्द्रोणे जले पक्त्वा द्रोणमेवावशेषयेत् ।। 569 ।।
शीते तस्मिन् रसे पूते क्षिपेद् गुडतुलात्रयम् ।
धातकीं षोडशपलां पयस्यां द्विपलांशिकाम् ।। 570 ।।
पञ्चाङ्गुलपलद्वन्द्वं रास्नामेलां प्रसारणीम् ।
देवपुष्पमुशीरञ्च श्वदंष्ट्राञ्च पलांशिकाम् ।। 571 ।।
मासं भाण्डे स्थितस्त्वेष बलारिष्टो महाफलः ।
हन्त्युग्रान् वातजान् रोगान् बलपुष्ट्यग्निवर्धनः ।। 572 ।।
(भैषज्यरत्नावली, वातव्याध्यधिकार ; 569-572)

1 : 18 DA¹AM¥L¡Rl½¯A (दशमूलारिष्ट) (AFI, Part-I)

(¹¢r¬gadharasa¼hit¢, Madhyamakha´²a, Adhy¢ya ; 10 ; 78-92)

दशमूलानि कुर्वीत भागैः पञ्चपलैः पृथक् ।। 78 ।।
पञ्चविंशत्पलं कुर्याच्चित्रकं पौष्करं तथा ।
कुर्याद्विंशत्पलं लोध्रं गुडूची तत्समा भवेत् ।। 79 ।।
पलैः षोडशभिर्धात्री रविसंख्यैर्दुरालभा ।
खदिरो बीजसारश्च पथ्या चेति पृथक्पलैः ।। 80 ।।
अष्टभिर्गणितैः कुष्ठं मञ्जिष्ठा देवदारु च ।
विड्गं मधुकं भार्गी कपित्थोऽक्षः पुनर्नवा ।। 81 ।।
चव्यं मांसी प्रियंगुश्च सारिवा कृष्णजीरकम् ।
त्रिवृता रेणुकं रास्ना पिप्पली क्रमुकः शठी ।। 82 ।।
हरिद्रा शतपुष्पा च पद्मकं नागकेशरम् ।
मुस्तमिन्द्रयवः शृङ्गी जीवकर्षभकौ तथा ।। 83 ।।
मेदा चान्या महामेदा काकोल्यौ ऋद्धिवृद्धिके ।
कुर्यात्पृथग्द्विपलिकान्पचेदष्टगुणे जले ।। 84 ।।
चतुर्थांशं श्रृतं नीत्वा मृद्भाण्डे सन्निधापयेत् ।
ततः षष्टिपलां द्राक्षां पचेन्नीरे चतुर्गुणे ।। 85 ।।
त्रिपादशेषं शीतं च पूर्वक्वाथे श्रृतं क्षिपेत् ।
द्वात्रिंशत्पलिकं क्षौद्रं दद्याद्गुडचतुःशतम् ।। 86 ।।
त्रिंशत्पलिकं धातक्याः कंकोलं जलचन्दनम् ।
जातीफलं लवङ्गं च त्वगेलापत्रकेशरम् ।। 87 ।।
पिप्पली चेति सञ्चूर्ण्य भागैर्द्विपलिकैः पृथक् ।
शाणमात्रां च कस्तूरीं सर्वमेकत्र निक्षिपेत् ।। 88 ।।
भूमौ निखातयेद्भाण्डं ततो जातरसं पिबेत् ।
कतकस्य फलं क्षिप्त्वा रसं निर्मलतां नयेत् ।। 89 ।।
ग्रहणीमरुचिं श्वासं कासं गुल्मं भगन्दरम् ।
वातव्याधिं क्षयं छर्दिं पाण्डुरोगं च कामलाम् ।। 90 ।।
कुष्ठान्यर्शांसि मेहांश्च मन्दाग्निमुदराणि च ।
शर्करामश्मरीं मूत्रकृच्छ्रं धातुक्षयं जयेत् ।। 91 ।।
कृशानां पुष्टिजननो वन्ध्यानां गर्भदः परः ।
अरिष्टो दशमूलाख्यस्तेजःशुक्रबलप्रदः ।। 92 ।।
(शा्र्गधरसंहिता, मध्यमखण्ड, अध्याय 10 ; 78-92)

1 : 20 DR¡K½¡Rl½¯A (द्राक्षारिष्ट) (AFI, Part-I)

(¹¢r¬gadharasa¼hit¢, Madhyamakha´²a, Adhy¢ya 10 ; 69-72$^{1}/_{2}$)

द्राक्षातुलाऽर्द्धं द्विद्रोणे जलस्य विपचेत्सुधीः ।। 69 ।।
पादशेषे कषाये च पूते शीते विनिक्षिपेत् ।
गुडस्य द्वितुलां तत्र त्वगेलापत्रकेशरम् ।। 70 ।।
प्रियंगुर्मरिचं कृष्णा विडङ्गं चेति चूर्णयेत् ।
पृथक्पलोन्मितैर्भागैस्ततो भाण्डे निधापयेत् ।। 71 ।।
समन्ततो घट्टयित्वा पिबेज्जातरसं ततः ।
उरःक्षतं क्षयं हन्ति कासश्वासगलामयान् ।। 72 ।।
द्राक्षारिष्टाह्वयः प्रोक्तो बलकृन्मलशोधनः ।
(शा्र्गधरसंहिता, मध्यमखण्ड, अध्याय 10 ; 69-72$^{1}/_{2}$)

1 : 1 DR¡K½¡SAVA (द्राक्षासव) (AFI, Part-II)

(Bhai¼ajyaratn¢val◌, Ar°org¢dhik¢ra ; 1-5)

द्राक्षापलशतं दत्त्वा चतुर्द्रोणेऽम्भसः पचेत् ।
द्रोणशेषे रसे तस्मिन् पूते शीते प्रदापयेत् ।। 1 ।।
शर्करायास्तुलां दत्त्वा तत्तुल्यं मधुनस्तथा ।
पलानि सप्त धातक्याः स्थापयेदाज्यभाजने ।। 2 ।।
जातीलवङ्गकक्कोललवलीफलचन्दनैः ।
कृष्णात्रिगन्धसंयुक्तैर्भागैरर्द्धपलांशकैः ।। 3 ।।
त्रिसप्ताहाद् भवेत् पेयं तस्य मात्रा यथाबलम् ।
नाम्ना द्राक्षासवो ह्येष नाशयेद् गुदकीलकान् ।। 4 ।।
शोषारोचकहृत्पाण्डुरक्तपित्तभगन्दरान् ।
गुल्मोदरकृमिग्रन्थिक्षतशोषज्वरान्तकृत् ।
वातपित्तप्रशमनः शस्तश्च बलवर्णकृत् ।। 5 ।।
(भैषज्यरत्नावली, अर्शोरोगाधिकार ; 1-5)

1 : 16 J¸RAK¡DYARl½¯A (जीरकाद्यरिष्ट) (AFI, Part-I)

(Bhai¼ajyaratn¢val◌, Str◌rog¢dhik¢ra ; 492-495)

जीरकस्य तुलाद्वन्द्वं चतुर्द्रोणजले पचेत् ।
द्रोणशेषे क्षिपेत्तत्र तुलात्रयमितं गुडम् ।। 492 ।।
धातकीं षोडशपलां शुण्ठीञ्च द्विपलोन्मिताम् ।
जातीफलं मुस्तकञ्च चातुर्जातं यमानिकाम् ।। 493 ।।

कक्कोलं देवपुष्पञ्च पलमानेन निक्षिपेत् ।
मासं संस्थाप्य भाण्डे च मृत्तिकापरिनिर्मिते ।। 494 ।।
ततः कल्कान् विनिर्हृत्य पाययेत् कर्षमात्रया ।
अरिष्टो जीरकाख्योऽयं निहन्यात् सूतिकामयान् ।
ग्रहणीमतिसारञ्च तथा वह्नेश्च वैकृतम् ।। 495 ।।
(भैषज्यरत्नावली, स्त्रीरोगाधिकार ; 492-495)

1 : 9 KANAK¡SAVA (कनकासव) (AFI, Part-I)

(Bhai¾ajyaratn¢val¯, Hikk¢°v¢s¢dhik¢ra ; 98-102)

स³~{kqद्य कनकं शाखामूलपत्रफलैः सह ।
ततश्चतुष्पलं ग्राह्यं वृषमूलत्वचस्तथा ।। 98 ।।
मधूकं मागधी व्याघ्री केशरं विश्वभेषजम् ।
भाङ्गीं तालीशपत्रञ्च सञ्चूर्ण्यैषां पलद्वयम् ।। 99 ।।
स³~गृह्य धातकीप्रस्थं द्राक्षायाः पलविंशतिम् ।
जलद्रोणद्वयं दत्त्वा शर्करायास्तुलां तथा ।। 100 ।।
क्षौद्रस्यार्धतुलाञ्चापि सर्वं सम्मिश्र्य यत्नतः ।
भाण्डे निक्षिप्य चावृत्य निदध्यान्मासमात्रकम् ।। 101 ।।
निहन्ति निखिलान् श्वासान् कासं यक्ष्माणमेव च ।
क्षतक्षीणं ज्वरं जीर्णं रक्तपित्तमुरःक्षतम् ।। 102 ।।
(भैषज्यरत्नावली, हिक्काश्वासाधिकार ; 98-102)

1 : 14 KHADIR¡RI½¯A (खदिरारिष्ट) (AFI, Part-I)

(¹¢r¬gadharasa¼hit¢, Madhyamakha´²a, Adhy¢ya ; 10 ; 60-65)

खदिरस्य तुलाऽर्द्धं तु देवदारु च तत्समम् ।
बाकुची द्वादशपला दार्वी स्यात्पलविंशतिः ।। 60 ।।
त्रिफला विंशतिपला ह्यष्टद्रोणेऽम्भसः पचेत् ।
कषाये द्रोणशेषे च पूते शीते विनिक्षिपेत् ।। 61 ।।
तुलाद्वयं माक्षिकस्य तुलैका शर्करा मता ।
धातक्या विंशतिपलं कंकोलं नागकेशरम् ।। 62 ।।
जातीफलं लवङ्गैलात्वक्पत्राणि पृथक् पृथक् ।
पलोन्मितानि कृष्णाया दद्यात्पलचतुष्टयम् ।। 63 ।।
घृतभाण्डे विनिक्षिप्य मासादूर्ध्वं पिबेन्नरः ।
महाकुष्ठानि हृद्रोगं पाण्डुरोगार्बुदे तथा ।। 64 ।।
गुल्मं ग्रन्थि कृमीन्कासं श्वासं प्लीहोदरं जयेत् ।
एष वै खदिरारिष्टः सर्वकुष्ठनिवारणः ।। 65 ।।
(शा र्गधरसंहिता, मध्यमखण्ड, अध्याय 10 ; 60-65)

1 : 13 KUM¡RY¡SAVA (B) कुमार्यासव (ख) (AFI, Part-I)
(Yogaratn¢kara, Gulmacikits¢ page 527)

कुमार्याश्च रसद्रोणे गुडं पलशतं तथा ।
तुलाf3~घ्रसंख्यां विजयां क्वाथयेत्तज्जलार्मणे ।। 1 ।।
चतुर्थांशावशेषे तु पूते तस्मिन्निधापयेत् ।
मधुनश्चाऽऽढकं दत्त्वा धातक्या द्विपलाष्टकम् ।। 2 ।।
स्निग्धभाण्डे विनिक्षिप्य कल्कं चैव प्रदापयेत् ।
जातीफलं लवङ्गं च कंकोलं च कबाबकम् ।। 3 ।।
जटिलाचव्यचित्रं च जातिपत्री सकर्कटम् ।
अक्षं पुष्करमूलं च प्रत्येकं च पलं पलम् ।। 4 ।।
मृतं शुल्वं तथा लोहं शुक्तिमात्रं प्रदापयेत् ।
भूम्यां वा धान्यराशौ वा स्थापयेद्दिनविंशतिम् ।। 5 ।।
तमुद्धृत्य पिबेन्मात्रां यथा चाग्निबलाबलम् ।
पञ्चकासं तथा श्वासं क्षयरोगं च दारुणम् ।। 6 ।।
उदराणि तथाऽष्टौ च षडशर्सि च नाशयेत् ।
वातव्याधिमपस्मारमन्यान् रोगान् सुदारुणान् ।। 7 ।।
(योगरत्नाकर, गुल्मचिकित्सा ; पृष्ठ 527)

1 : 11 KU¯AJ¡Rl½¯A (कुटजारिष्ट) (AFI, Part-I)
(Bhai¾ajyaratn¢val¨, At¨s¢r¢dhik¢ra ; 97-99)

तुलां कुटजमूलस्य मृद्वीकार्द्धतुलां तथा ।
मधूकपुष्पकाश्मर्योर्भागान् दशपलोन्मितान् ।। 97 ।।
चतुर्द्रोणेऽम्भसः पक्त्वा द्रोणञ्चैवावशेषितम् ।
धातक्या विंशतिपलं गुडस्य च तुलां क्षिपेत् ।। 98 ।।
मासमात्रं स्थितो भाण्डे कुटजारिष्टसंज्ञितः ।
ज्वरान् प्रशमयेत् सर्वान् कुर्यात्तीक्ष्णं धनञ्जयम् ।
दुर्वारां ग्रहणीं हन्ति रक्तातीसारमुल्बणम् ।। 99 ।।
(भैषज्यरत्नावली, अतीसाराधिकार; 97-99)

1 : 32 LOH¡SAVA (लोहासव) (AFI, Part-I)

(¹¢r¬gadharasa¼hit¢, Madhyamakha´²a, Adhy¢ya 10 ; 34-38)

लोहचूर्णं त्रिकटुकं त्रिफलां च यवानिकाम् ।
विड्गं मुस्तकं चित्रं चतु:संख्यापलं पृथक् ।। 34 ।।
धातकीकुसुमानां तु प्रक्षिपेत् पलविंशतिम् ।
चूर्णीकृत्य तत: क्षौद्रं चतु:षष्टिपलं क्षिपेत् ।। 35 ।।
दद्याद्गुडतुलां तत्र जलद्रोणद्वयं तथा ।
घृतभाण्डे विनिक्षिप्य निदध्यान्मासमात्रकम् ।। 36 ।।
लोहासवममुं मर्त्य: पिबेद्वह्निकरं परम् ।
पाण्डुश्वयथुगुल्मानि जठराण्यर्शसां रुजम् ।। 37 ।।
कुष्ठं प्लीहामयं कण्डूं कासं श्वासं भगन्दरम् ।
अरोचकं च ग्रहणीं हृद्रोगं च विनाशयेत् ।। 38 ।।
(शार्ङ्गधरसंहिता, मध्यमखण्ड, अध्याय 10 ; 34-38)

1 : 26 MUSTAK¡RI½¯A (मुस्तकारिष्ट) (AFI, Part-I)

(Bhai¾ajyaratn¢val¡, Agnim¢dy¢dirog¢dhik¢ra ; 108-111)

मुस्तकस्य तुलाद्वन्द्वं चतुर्द्रोणेऽम्बुन: पचेत् ।
पादशेषे रसे तस्मिन् क्षिपेद् गुडतुलात्रयम् ।। 108 ।।
धातकीं षोडशपलां यमानीं विश्वभेषजम् ।
मरिचं देवपुष्पञ्च मेथीं वह्निञ्च जीरकम् ।। 109 ।।
पलयुग्ममितं क्षिप्त्वा रुद्धभाण्डे निधापयेत् ।
संस्थाप्य मासमात्रन्तु तत: संस्रावयेद् भिषक् ।। 110 ।।
अजीर्णमग्निमान्द्यञ्च विसूचीमपि दारुणाम् ।
ग्रहणीं विविधां हन्ति नात्र कार्या विचारणा ।। 111 ।।
(भैषज्यरत्नावली, अग्निमान्द्यादिरोगाधिकार ; 108-111)

1 : 21 P¡RTH¡DYARI½¯A (पार्थाद्यरिष्ट) (AFI, Part-I)

(*Synonym* - Arjun¢ri¾°a) (पर्याय- अर्जुनारिष्ट)

(Bhai¾ajyaratn¢val¡, H¨drog¢dhik¢ra ; 73-75)
पार्थत्वचस्तुलामेकां मृद्वीकार्द्धतुलां तथा ।
भागं मधूकपुष्पस्य पलविंशतिसम्मितम् ।। 73 ।।
चतुर्द्रोणेऽम्भस: पक्त्वा द्रोणमेवावशेषयेत् ।
धातक्या विंशतिपलं गुडस्य च तुलां क्षिपेत् ।। 74 ।।

मासमात्रं स्थितो भाण्डे भवेत्पार्थाद्यरिष्टकः ।
हृत्फुफ्फुसगदान् सर्वान् हन्त्ययं बलवीर्यकृत् ।। 75 ।।
(भैषज्यरत्नावली, हृद्रोगाधिकार; 73-75)

1 : 22 PIPPALY¡DY¡SAVA (पिप्पल्याद्यासव) (AFI, Part-I)

(¹¢r¬gadharasa¼hit¢, Madhyamakha´²a, Adhy¢ya 10 ; 28-33)

पिप्पली मरिचं चव्यं हरिद्रा चित्रको घनः ।। 28 ।।
विड्गं क्रमुको लोध्रः पाठा धात्र्येलवालुकम् ।
उशीरं चन्दनं कुष्ठं लवङ्गं तगरं तथा ।। 29 ।।
मांसी त्वगेलापत्रं च प्रियङ्गुर्नागकेशरम् ।
एषामर्धपलान्भागान्सूक्ष्मचूर्णीकृताञ्छुभान् 30 ।।
जलद्रोणद्वये क्षिप्त्वा दद्याद्गुडतुलात्रयम् ।
पलानि दश धातक्या द्राक्षा षष्टिपला भवेत् ।। 31 ।।
एतान्येकत्र संयोज्य मृद्भाण्डे च विनिक्षिपेत् ।
ज्ञात्वाऽऽगतरसं सर्वं पाययेदग्न्यपेक्षया ।। 32 ।।
क्षयं गुल्मोदरं कार्श्यं ग्रहणीं पाण्डुतां गदम् ।
अर्शांसि नाशयेच्छीघ्रं पिप्पल्याद्यासवस्त्वयम् ।। 33 ।।
(शार्ङ्गधरसंहिता, मध्यमखण्ड, अध्याय 10 ; 28-33)

1 : 2 PUNARNAVADY¡RI½¯A (पुनर्नवाद्यरिष्ट) (AFI, Part-II)

(Bhai¾ajyaratn¢val◌ि, ¹otharog¢dhik¢ra ; 192-196)

पुनर्नवे द्वे बले सपाठे वासा गुडूची सहचित्रकेण ।
निदिग्धिका च त्रिपलानि पक्त्वा द्रोणार्द्धशेषे सलिले ततस्तु ।। 192 ।।
पूत्वा रसं द्वे च गुडात्पुराणात् तुले मधुप्रस्थयुतं सुशीतम् ।
मासं निदध्याद् घृतभाजनस्थं पर्णे यवानां परतश्च मासात् ।। 193 ।।
चूर्णीकृतैरर्द्धपलांशिकैस्तं हेमत्वगेलामरिचाम्बुपत्रैः ।
गन्धान्वितं क्षौद्रघृतप्रदिग्धं जीर्णे पिबेद् व्याधिबलं समीक्ष्य ।। 194 ।।
हृत्पाण्डुरोगं श्वयथुं प्रवृद्धं प्लीहभ्रमारोचकमेहगुल्मान् ।
भगन्दरं षड् जठराणि कासं श्वासं ग्रहण्यामयकुष्ठकण्डूः ।। 195 ।।
शाखानिलं बद्धपुरीषताञ्च हिक्कां किलासञ्च हलीमकञ्च ।
क्षिप्रं जयेद् वर्णबलायुरोगस्तेजोन्वितो मांसरसान्नभोजी ।। 196 ।।
(भैषज्यरत्नावली, शोथरोगाधिकार ; 192-196)

1 : 23 PUNARNAV¡SAVA (पुनर्नवासव) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, ¹otharog¢dhik¢ra ; 197-201)

त्रिकटुं त्रिफलां दार्वीं श्वदंष्ट्रां बृहतीद्वयम् ।
वासामेरण्डमूलञ्च कटुकां गजपिप्पलीम् 197 ।।
शोथघ्नीं पिचुमर्द्दञ्च गुडूचीं शुष्कमूलकम् ।
दुरालभां पटोलं च पलांशेन विचूर्णयेत् ।। 198 ।।
धातकीं षोडशपलां द्राक्षायाः पलविंशतिम् ।
तुलामानां सितां दत्त्वा माक्षिकार्द्धतुलां तथा ।। 199 ।।
जलद्रोणद्वयं क्षिप्त्वा मासं भाण्डे निधापयेत् ।
पुनर्नवासवो ह्येष शोथोदरविनाशनः ।। 200 ।।
प्लीहानमम्लपित्तञ्च यकृद्गुल्मज्वरादिकान्
कृच्छ्रसाध्यामयान् सर्वान् नाशयेन्नात्र संशयः ।। 201 ।।
(भैषज्यरत्नावली, शोथरोगाधिकार ; 197-201)

1 : 31 ROHITAK¡RI½¯A (रोहीतकारिष्ट) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, Pl¤hayak¨drog¢dhik¢ra ; 84-87.)

रोहीतकतुलामेकाञ्चतुर्द्रोणे जले पचेत् ।
पादशेषे रसे पूते शीते पलशतद्वयम् ।। 84 ।।
दद्याद् गुडस्य धातक्याः पलषोडशिका मता ।
पञ्pdीलं त्रिजातं च त्रिफलाञ्च विनिक्षिपेत् ।। 85 ।।
चूर्णयित्वा पलांशेन ततो भाण्डे निधापयेत् ।
मासादूर्ध्वं च पिबतां गुदजा यान्ति संक्षयम् ।। 86 ।।
ग्रहणीपाण्डुहृद्रोगप्लीहगुल्मोदराणि च ।
कुष्ठशोफारुचिहरो रोहीतारिष्टसंज्ञकः ।। 87 ।।
(भैषज्यरत्नावली, प्लीहयकृद्रोगाधिकार ; 84-87.)

1 : 37 S¡RIV¡DY¡SAVA (सारिवाद्यासव) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, Pramehapi²ak¢dhik¢ra ; 22-27)

शारिवां मुस्तकं लोध्रं न्यग्रोधं पिप्पलं शटीम् ।
अनन्तां पद्मकं बालं पाठां धात्रीं गुडूचिकाम् ।। 22 ।।
उशीरं चन्दनद्वन्द्वं यमानीं कटुरोहिणीम् ।
पत्रमेलाद्वयं कुष्ठं स्वर्णपत्रीं हरीतकीम् ।। 23 ।।
एषां चतुष्पलान् भागान् सूक्ष्मचूर्णीकृतान् शुभान् ।
जलद्रोणद्वये क्षिप्त्वा दद्याद् गुडतुलात्रयम् ।। 24 ।।

पलानि दश धातक्या द्राक्षां षष्ठिपलां तथा ।
मासं संस्थापयेद् भाण्डे संवृते मृण्मये शुभे ।। 25 ।।
शारिवाद्यासवस्यास्य पानान्मेहाश्च विंशतिः ।
शराविकादयः सर्वाः पिडकास्तत्कृताश्च याः ।। 26 ।।
औपदंशिकरोगाश्च वातरक्तं भगन्दरम् ।
सर्व एते शमं यान्ति व्याधयो नात्र संशयः ।। 27 ।।
(भैषज्यरत्नावली, प्रमेहपिडकाधिकार ; 22-27)

1 : 8 U¹£R¡SAVA (उशीरासव) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, Raktapitt¢dhik¢ra ; 137-141)

उशीरं बालकं पद्मं काश्मर्यं नीलमुत्पलम् ।
प्रिय³~गुं पद्मकं लोध्रं मञ्जिष्ठां धन्वयासकम् ।। 137 ।।
पाठां किराततिक्तञ्च न्यग्रोधोदुम्बरं शटीम् ।
पर्पटं पुण्डरीकं च पटोलं काञ्चनारकम् ।। 138 ।।
जम्बूशाल्मलिनिर्यासं प्रत्येकं पलसम्मितम् ।
सर्वं सुचूर्णितं कृत्वा द्राक्षायाः पलविंशतिम् ।। 139 ।।
धातकीं षोडशपलां जलद्रोणद्वये क्षिपेत् ।
शर्करायास्तुलां दत्त्वा क्षौद्रस्यार्द्धतुलां तथा ।। 140 ।।
मासं संस्थापयेद् भाण्डे मांसीमरिचधूपिते ।
उशीरासव इत्येष रक्तपित्तविनाशनः ।
पाण्डुकुष्ठप्रमेहार्शःकृमिशोथहरस्तथा ।। 141 ।।
(भैषज्यरत्नावली, रक्तपित्ताधिकार ; 137-141)

3 : 14 DA¹AM¥LA HAR£TAK£ (दशमूल¯हरीतकी) (AFI, Part-I)

(A¾°¢¬gah¨daya, Cikits¢sth¢na, Adhy¢ya 17 ; 14-16)

दशमूलकषायस्य कंसे पथ्याशतं पचेत् ।। 14 ।।
दत्वा गुडतुलां तस्मिन् लेहे दद्याद्विचूर्णितम् ।
त्रिजातकं त्रिकटुकं किञ्चिच्च यवशूकजम् ।। 15 ।।
प्रस्थार्धं च हिमे क्षौद्रात्तन्निहन्त्युपयोजितम् ।।
प्रवृद्धशोफज्वरमेहगुल्मकाश्र्यामवाताम्लकरक्तपित्तम् ।
वैवर्ण्यमूत्रानिलशुक्रदोषश्वासारुचिप्लीहगरोदरं च ।। 16 ।।
(अष्टाङ्गहृदय चिकित्सास्थान, अध्याय 17 ; 14-16)

3 : 15 DR¡K½¡VALEHA (द्राक्षावलेह) (AFI, Part-I)

(A¾°¢¬gah¨daya, Cikits¢sth¢na, Adhy¢ya 16 ; 29-31.)

द्राक्षाप्रस्थं कणाप्रस्थं शार्करार्धतुलां तथा ।। 29 ।।
द्विपलं मधुकं शुण्ठीं त्वक्क्षीरीं च विचूर्णिताम् ।
धात्रीफलरसद्रोणे तत्क्षिप्त्वा लेहवत्पचेत् ।। 30 ।।
शीतान्मधुप्रस्थयुताद् लिह्यात्पाणितलं ततः ।
हलीमकं पाण्डुरोगं कामलां च नियच्छति ।। 31 ।।
(अष्टाङ्गहृदय चिकित्सास्थान, अध्याय 16 ; 29-31.)

3 : 3 EL¡DYA MODAKA(एलाद्य मोदक) (AFI, Part-I)

(Bhai¾ajyaratn¢val, Mad¢tyay¢dhik¢ra ; 17-20.)

एलां मधूकमग्निञ्च रजन्यौ द्वे फलत्रयम् ।
रक्तशालिं कणां द्राक्षां खर्जूरञ्च तिलं यवान् ।। 17 ।।
विदारीं गोक्षुर बीजं त्रिवृताञ्च शतावरीम् ।
सञ्चूर्ण्य मोदकं कुर्यात् सितया द्विप्रमाणया ।। 18 ।।
धारोष्णेनापि पयसा मुद्गयूषेण वा समम् ।
पिबेदक्षप्रमाणन्तु प्रातर्नत्वाम्बिकां गदी ।। 19 ।।
मद्यपानसमुत्थानां विकारा निखिला अपि ।
सेवनादस्य नश्यन्ति व्याधयोऽन्ये च दारुणाः ।। 20 ।।
(भैषज्यरत्नावली, मदात्ययाधिकार ; 17-20.)

3 : 19 MADHUSNUHī RAS¡YANA (मधुस्नुही रसायन) (AFI, Part-I)

(Sahasrayoga, Lehaprakara´a ; 41.)

त्रिकटुत्रिफलात्रिजातजातीफलपत्राग्निवरालधान्यकानि ।
यवानीविडङ्गचव्यकुष्ठत्रिवृद्ग्रन्थिकवाजिन्धयुतानि ।। 1 ।।
सभाङ्गीतेजोवतिकेसराणिनिष्कद्वयोन्मानविचूर्णितानि ।
संशुद्धगन्धोपलमाहिषाक्षमधुस्नुहीनां च चतुष्पलानि ।। 2 ।।
द्विषट्पलोन्मानघृते विपक्वे सिता पलद्वादशकं क्षिपेच्च ।
ततोन्मथित्वा तु खजेन तस्मिन्सुपाकमायाति ततोऽवतार्य ।। 3 ।।
पूर्वोक्तचूर्णानि विकीर्य शीतेगन्धोपलस्यापि रजांसि दत्त्वा ।। 4 ।।
संयोज्य सम्यक्च सुशीतलेऽस्मिन् प्रस्थं प्रदद्यान्मधुनः सुपात्रे ।
विन्यस्य गुप्तं तु रसायनं तत् प्रातर्लिहेत्कर्षायुतं हिताशी ।
कुष्ठं किलासं पिटकान्प्रमेहान् भगंदराशोंऽर्बुदगण्डमालाः ।। 5 ।।

निहन्ति कण्ड्वामयावातरक्तपित्तोद्भवान्गुह्यभवान्व्रणांश्च ।
रसायनोऽयं मुनिना कृतश्च मधुस्नुहीनामक एष मुख्यः ।। 6 ।।
(सहस्रयोग, लेहप्रकरण ; 41.)

7 : 27 BH¡SKARALAVA³A C¥R³A (भास्करलवण चूर्ण) (AFI, Part-I)

(*Synonym* : Lava´abh¢skara C¦r´a)(पर्यायः लवणभास्कर चूर्ण)
(¹¢r¬gadharasa¼hit¢, Madhyamakha´²a, Adhy¢ya 6 ; 138-144)

सामुद्रलवणं कार्यमष्टकर्षमितं बुधैः ।
पञ्चसौवर्चलं ग्राह्यं बिडं सैन्धवधान्यकात् ।। 138 ।।
पिप्पली पिप्पलीमूलं कृष्णजीरकपत्रकम् ।
नागकेशरतालीसमम्लवेतसकं तथा ।। 139 ।।
द्विकर्षमात्राण्येतानि प्रत्येकं कारयेद् बुधः ।
मरिचं जीरकं विश्वमेकैकं कर्षमात्रकम् ।। 140 ।।
दाडिमं स्याच्चतुष्कर्ष त्वगेले चार्द्धकार्षिके ।
एतच्चूर्णीकृतं सर्वं लवणं भास्कराभिधम् ।। 141 ।।
शाणप्रमाणं देयं तु मस्तुतक्रसुरासवैः ।
वातश्लेष्मभवं गुल्मं प्लीहानमुदरं क्षयम् ।। 142 ।।
अर्शांसि ग्रहणीं कुष्ठं विबिन्धं च भगन्दरम् ।
शोफं शूलं श्वासकासावामवातञ्च हृद्रुजम् ।। 143 ।।
मन्दाग्निं नाशयेदेतद् दीपनं पाचनं परम् ।
सर्वलोकहितार्थाय भास्करेणोदितं पुरा ।। 144 ।।
(शाङ्र्गधरसंहिता, मध्यमखण्ड, अध्याय 6 ; 138-144.)

7 : 8 GOM¥TRA HAR¢TAK¦ (गोमूत्र–हरीतकी) (AFI, Part-I)

(A¾°¢¬gah¨daya, Uttarasth¢na, Adhy¢ya 22 ; 102.)

गोमूत्रक्वथनविलीनविग्रहाणां
पथ्यानां जलमिश्रिकुष्ठभावितानाम् ।
अत्तारं नरमणवोऽप वक्त्ररोगाः
श्रोतारं नरमिव न स्पृशन्त्यनर्थाः ।। 102 ।।
(अष्टाङ्गहृदय उत्तरास्थान, अध्याय 22 ; 102.)

7 :12J¡T£PHAL¡DYA C¥R³A (जातीफलाद्य चूर्ण) (AFI, Part-I)

(¹¢r¬gadharasa¼hit¢, Madhyamakha´²a, Adhy¢ya 6 ; 70-74)

जातीफललवङ्गैलापत्रत्वङ्नागकेशरैः ।। 70 ।।
कर्पूरचन्दनतिलैस्त्वक्क्षीरीतगरामलैः ।
तालीसपिप्पलीपथ्यास्थूलजीरकचित्रकैः ।। 71 ।।
शुण्ठीविडङ्गमरिचैः समभागविचूर्णितैः ।
यावन्त्येतानि सर्वाणि कुर्याद्भङ्गां च तावतीम् ।। 72 ।।
सर्वचूर्णसमा देया शर्करा च भिषग्वरैः ।
कर्षमात्रं ततः खादेन्मधुना प्लावितं सुधीः ।। 73 ।।
अस्य प्रभावाद् ग्रहणीकासश्वासारुचिक्षयाः ।
वातश्लेष्मप्रतिश्यायाः प्रशमं यान्ति वेगतः ।। 74 ।।
(शाङ्र्गधरसंहिता, मध्यमखण्ड, अध्याय 6 ; 70-74.)

7 : 18 N¡RASI»HA C¥R³A (नारसिंह चूर्ण) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, V¢j¤kara´¢dhik¢ra ; 30-37.)

शतावरीरजः प्रस्थं प्रस्थं गोक्षुरकस्य च ।
वराह्या विंशतिपलं गुडूच्याः पञ्चविंशतिः ।। 30 ।।
भल्लातकानां द्वात्रिंशच्चित्रकस्य दशैव तु ।
तिलानां शोधितानाञ्च प्रस्थं दद्यात् सुचूर्णितम् ।। 31 ।।
त्र्यूषणस्य पलान्यष्टौ शर्करायाश्च सप्ततिः ।।
माक्षिकं शर्करार्द्धेन माक्षिकार्द्धेन वै घृतम् ।। 32 ।।
शतावरीसमं देयं विदारीकन्दजं रजः ।
एतदेकीकृतं चूर्णं स्निग्धे भाण्डे निधापयेत् ।। 33 ।।
शाणार्द्धमुपयुञ्जीत यथेष्टञ्चास्य भोजनम् ।
मासैकमुपयोगेन जरां हन्ति रुजामपि ।। 34 ।।
वलीपलितखालित्यमेहपाण्ड्वाढ्यपीनसान् ।
हन्त्यष्टादशकुष्ठानि तथाष्टावुदराणि च ।। 35 ।।
भगन्दरं मूत्रकृच्छ्रं गृध्रसीञ्च हलीमकम् ।
क्षयञ्चैव महाव्याधिं पञ्चकासान् सुदारुणान् ।। 36 ।।
अशीतिं वातजान् रोगांश्चत्वारिंशच्च पैत्तिकान् ।
विंशतिं श्लैष्मिकांश्चापि संसृष्टान् सन्निपातिकान् ।।
सर्वानशेर्षागदान् हन्ति वृक्षमिन्द्राशनिर्यथा ।। 37 ।।
(भैषज्यरत्नावली, वाजीकरणाधिकार ; 30-37.)

6 : 19 D¡±IM¡DI GH§TA(दाडिमादि घृत) (AFI, Part-I)

(A¾°¢¬gah¨daya, Cikits¢sth¢na, Adhy¢ya 16 ; 2-4.)

दाडिमात्कुडवो धान्यात्कुडवार्ध पलं पलम् ।
चित्रकाच्छृंगवेराच्च पिप्पल्यर्धपलं च तैः ।। 2 ।।
कल्कितैर्विंशतिपलं घृतस्य सलिलाढके ।
सिद्धं ह्रत्पाण्डुगुल्मार्शःप्लीहवातकफार्तिनुत् ।। 3 ।।
दीपनं श्वासकासघ्नं मूढवातानुलोमनम् ।
दुःखप्रसविनीनां च वन्ध्यानां च प्रशस्यते ।। 4 ।।
(अष्टाङ्गहृदय चिकित्सास्थान, अध्याय 16 ; 2-4.)

6 : 5 INDUK¡NTA GH§TA(इन्दुकान्त घृत) (AFI, Part-I)

(Sahasrayoga, Gh¨taprakara´a ; 5.)

पूतीकदारुदशमूलकषायसिद्धं ।
सक्षीरषट्पलयुतं घृतमिन्दुकान्तम् ।।
(सहस्रयोग, घृतप्रकरण ; 5.)

6 : 35 MAH¡ TRIPHAL¡DYA GH§TA (महात्रिफलाद्य घृत)(AFI, Part-I)

(Bhai¾ajyaratn¢val◌ा, Netrarog¢dhik¢ra ; 173-180.)

त्रिफलायाः रसप्रस्थं प्रस्थं भृंगरसस्य च ।
वृषस्य च रसप्रस्थं शतावर्याश्च तत्समम् ।। 173 ।।
अजाक्षीरं गुडूच्याश्च आमलक्या रसं तथा ।
प्रस्थं प्रस्थं समाहृत्य सर्वैरैभिर्घृतं पचेत् ।। 174 ।।
कल्कैः कणा सिता द्राक्षा त्रिफला नीलमुत्पलम् ।
मधुकं क्षीरकाकोली मधुपर्णी निदिग्धिका ।। 175 ।।
तत् साधुसिद्धं विज्ञाय शुभे भाण्डे निधापयेत् ।
ऊद्र्ध्वपानमधः पानं मध्ये पानञ्च शस्यते ।। 176 ।।
यावन्तो नेत्ररोगास्तान् पानादेवापकर्षति ।
नक्तान्ध्ये तिमिरे काचे नीलिकापटलार्बुदे ।। 177 ।।
अभिष्यन्देऽधिमन्थे च पक्ष्मकोपे सुदारुणे ।
नेत्ररोगेषु सर्वेषु वातपित्तकफेषु च ।। 178 ।।
अदृष्टिं मन्ददृष्टिञ्च कफवातप्रदूषिताम् ।
स्रवतो वातपित्ताभ्यां सकण्ड्वासन्नदूरदृक् ।। 179 ।।
गृध्रदृष्टिकरं सद्यो बलवर्णाग्निवर्द्धनम् ।

सर्वं नेत्रामयं हन्यात् त्रिफलाद्यं महद् घृतम् ।। 180 ।।
(भैषज्यरत्नावली, नेत्ररोगाधिकार ; 173-180.)

6 : 13 TIKTAKA GH§TA (तिक्तक घृत) (AFI, Part-I)

(A¾°¢¬gah¨daya, Cikits¢sth¢na, Adhy¢ya 19 ; 2-7.)

पटोलनिम्बकटुकां दार्वीपाठादुरालभाः ।। 2 ।।
पर्पटं त्रायमाणां च पलांशं पाचयेदपाम् ।
द्व्याढकेऽष्टांशशेषेण तेन कर्षोन्मितैस्तथा ।। 3 ।।
त्रायन्तीमुस्तभूनिम्बकलिङ्गकणचन्दनैः ।
सर्पिषो द्वादशपलं पचेत्तत्तिक्तकं जयेत् ।। 4 ।।
पित्तकुष्ठपरीसर्पपिटिकादाहतृड्भ्रमान् ।
कण्डूपाण्ड्वामयान् गण्डान् दुष्टनाडी व्रणापचीः ।। 5 ।।
विस्फोटविद्रधीगुल्मशोफोन्मादमदानपि ।
हृद्रोगतिमिरव्यङ्गग्रहणीश्वित्रकामलाः ।। 6 ।।
भगन्दरमपस्मारमुदरं प्रदरं गरम् ।
अर्शोऽस्रपित्तमन्यांश्च सुकृच्छ्रान् पित्तजान् गदान् ।। 7 ।।
(अष्टाङ्गहृदय चिकित्सास्थान, अध्याय 19 ; 2-7.)

5 : 3 GOK½UR¡DI GUGGULU (गोक्षुरादि गुग्गुलु) (AFI, Part-I)

(¹¢r¬gadharasa¼hit¢, Madhyamakha´²a, Adhy¢ya 7 ; 84-87.)

अष्टाविंशतिसंख्यानि पलान्यानीय गोक्षुरात् ।
विपचेत्षड्गुणे नीरे क्वाथो ग्राह्योऽर्धशेषितः ।। 84 ।।
ततः पुनः पचेत्तत्र पुरं सप्तपलं क्षिपेत् ।
गुडपाकसमाकारं ज्ञात्वा तत्र विनिक्षिपेत् ।। 85 ।।
त्रिकटु त्रिफला मुस्तं चूर्णितं पलसप्तकम् ।
ततः पिण्डीकृतस्याऽस्य गुटिका मुखयोजिता ।। 86 ।।
हन्यात्प्रमेहं कृच्छ्रं च प्रदरं मूत्रघातकम् ।
वातास्रं वातरोगांश्च शुक्रदोषं तथाश्मरीम् ।। 87 ।।
(शाङ्र्गधरसंहिता, मध्यमखण्ड, अध्याय 7 ; 84-87.)

5 : 1 K¡¿CAN¡RA GUGGULU (काञ्चनार गुग्गुलु) (AFI, Part-I)

(¹¢r¬gadharasa¼hit¢, Madhyamakha´²a, Adhy¢ya 7 ; 95-100.)

काञ्चनारत्वचो ग्राह्यं पलानां दशकं बुधैः ।। 95 ।।
त्रिफला षट्पला कार्या त्रिकटु स्यात्पलत्रयम् ।
पलैकं वरुणं कुर्यादेलात्वक्पत्रकं तथा ।। 96 ।।
एकैकं कर्षमात्रं स्यात्सर्वाण्येकत्र चूर्णयेत् ।
यावच्चूर्णमिदं सर्वं तावन्मात्रस्तु गुग्गुलुः ।। 97 ।।
संकुट्य सर्वमेकत्र पिण्डं कृत्वा च धारयेत् ।
गुटिकाः शाणिकाः कार्याः प्रातर्ग्राह्या यथोचितम् ।। 98 ।।
गण्डमालां जयत्युग्रामपचीमर्बुदानि च ।
ग्रन्थीन्व्रणांश्च गुल्मांश्च कुष्ठानि च भगन्दरम् ।। 99 ।।
प्रदेयश्चानुपानार्थं क्वाथो मुण्डितकाभवः ।
क्वाथः खदिरसारस्य पथ्याक्वाथोऽथ कोष्णकम् ।। 100 ।।
(शाङ्र्गधरसंहिता, मध्यमखण्ड, अध्याय 7 ; 95-100.)

5 : 8 L¡K½¡ GUGGULU (लाक्षा गुग्गुलु) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, Bhagn¢dhik¢ra ; 12-13.)

लाक्षास्थिसंहृत्ककुभाश्वगन्धाश्चूर्णीकृता नागबला पुरश्च ।
संभग्नमुक्तास्थिरुजं निहन्याद³~गानि कुर्यात्कुलिशोपमानि ।। 12 ।।
अत्रान्यतोपिदृष्टत्वात्तुल्यश्चूर्णेन गुग्गुलुः ।। 13 ।।
(भैषज्यरत्नावली, भग्नाधिकार ; 12-13.)

5 : 1 PA«C¡M§TA LAUHA GUGGULU
(पंचामृत लौह गुग्गुलु)(AFI, Part-II)

(Bhai¾ajyaratn¢val¤, Masti¾karog¢dhik¢ra ; 52-55.)

रसगन्धकताराभ्रमाक्षिकाणां पलं पलम् ।
लौहस्य द्विपलं चापि गुग्गुलोः पलसप्तकम् ।। 52 ।।
मर्दयेदायसे पात्रे दण्डेनाप्यायसेन च ।
कटुतैलसमायोगाद्यामद्वयमतन्द्रितः ।। 53 ।।
गुञ्जात्रयप्रयोगेण गदा मस्तिष्कसम्भवाः ।
स्नायुजा वातजाश्चापि विनश्यन्ति न संशयः ।। 54 ।।
नासौ संजायते देहे मनुष्याणां कदाचन ।
यं पंचामृतलौहाख्यौ गुग्गुलुर्न हरेद्गदम् ।। 55 ।।

6 : 27 PA«CATIKTA GUGGULU GH§TA
(पञ्चतिक्त गुग्गुलु घृत)(AFI, Part-I)

(***Synonym*** : (Nimbadi gh¨ta) (पर्याय: निम्बादि घृत)

(A¾°¢¬gah¨daya, Cikits¢sth¢na, Adhy¢ya 21 ; 57-60)

निम्बामृतावृषपटोलनिदिग्धिकानां
भागान् पृथग्दश पलान् विपचेद्घटेऽपाम् ।
अष्टांशशेषितरसेन पुनश्च तेन्
प्रस्थं घृतस्य विपचेत्पिचुभागकल्कै: ।। 57 ।।
पाठां विडङ्गसुरदारुगजोपकुल्या-
द्विक्षारनागरनिशामिशिचव्यकुष्ठै: ।
तेजोवतीमरिचवत्सकदीप्यकाग्नि-
रोहिण्यरुष्करवचाकणमूलयुक्तै: ।। 59 ।।
मञ्जिष्ठयाऽतिविषया विषया यवान्या
संशुद्धगुग्गुलुपलैरपि पञ्चसंख्यै: ।
तत्सेवितं प्रधमति प्रबलं समीरं
सन्ध्यस्थिमज्जगतमप्यथ कुष्ठमीदृक् ।। 59 ।।
नाडीव्रणार्बुदभगन्दरगण्डमाला-
जत्रूर्ध्वसर्वगदगुल्मगुदोत्थमेहान् ।
यक्ष्माऽरुचिश्वसनपीनसकासशोफ-
हृत्पाण्डुरोगमदविद्रधिवातरक्तम् ।। 60 ।।

(अष्टाङ्गहृदय चिकित्सास्थान, अध्याय 21 ; 57-60.)

5 : 2 PUNARNAV*ƒ* GUGGULU (पुनर्नवा गुग्गुलु) **(AFI, Part-II)**

(Bh¢ratabhai¾ajya-Ratn¢kara T¨tyabh¢ga ; 4012)

पुनर्नवामूलशतं विशुद्धं, रुबूकमूलञ्च तथा प्रयोज्यम् ।
दत्त्वा पलं षोडशकञ्च शुण्ठ्या संकुट्य सम्यग्विपचेद् घटेऽपाम् ।। 1 ।।
पलानि चाष्टादश कौशिकस्य तेनाष्टशेषेण पुन: पचेत्तु ।। 2 ।।
निकुम्भचूर्णस्य पलं गुडूच्या: पलद्वयञ्च द्विपलं प्रतीह ।
फलत्रयं त्र्यूषणचित्रकाणि सिन्धूत्थभल्लातविड्गकानि ।। 3 ।।
कर्षं तथा माक्षिकधातुचूर्णं पुनर्नवाया: पलमेव चूर्णम् ।
चूर्णानि दत्त्वा ह्यवतार्य शीते खादेन्नरो माषत्रयप्रमाणम् ।। 4 ।।
वातासृजं वृद्धिगदञ्च सप्त जयत्यवश्यं त्वथ गृध्रसीञ्च ।
ज3~घोरुपृष्ठत्रिकबस्तिजञ्च तथामवातं प्रबलञ्च शीघ्रम् ।। 5 ।।

(भारतभैषज्यरत्नाकर, तृतीयभाग ; 4012)

5 :11 SAPTAVI»¹ATIKA GUGGULU
(सप्तविंशतिक गुग्गुलु) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, Bhagandar¢dhik¢ra ; 16-21.)

त्रिकटुत्रिफलामुस्तविडङ्गामृतचित्रकम् ।
शट्येला पिप्पलीमूलं हपुषा सुरदारु च ।। 16 ।।
तुम्बुरु पुष्करं चव्यं विशाला रजनीद्वयम् ।
विडसौवर्चले क्षारौ सैन्धवं गजपिप्पली ।। 17 ।।
यावन्त्येतानि चूर्णानि तावद्द्विगुणगुग्गुलुः ।
कोलप्रमाणां गुडिकां भक्षयेन्मधुना सह ।। 18 ।।
कासं श्वासं तथा शोथमर्शांसि च भगन्दरम् ।
हृच्छूलं पार्श्वशूलञ्च कुक्षिबस्तिगुदे रुजम् ।। 19 ।।
अश्मरीं मूत्रकृच्छञ्च अन्त्रवृद्धिं तथा कृमीन् ।
चिरज्वरोपसृष्टानां क्षयोपहतचेतसाम् ।। 20 ।।
आनाहञ्च तथोन्मादं कुष्ठानि चोदराणि च ।
नाडीदुष्टव्रणान सर्वान् प्रमेहं श्लीपदं तथा ।
सप्तविंशतिको हन्ति सर्वरोगनिषूदनः ।। 21 ।।
(भैषज्यरत्नावली, भगन्दराधिकार ; 16-21.)

5 : 12 Sl»HAN¡DA GUGGULU (सिंहनाद गुग्गुलु) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, ¡mav¢t¢dhik¢ra ; 130-135.)

पलत्रयं कषायस्य त्रिफलायाः सुचूर्णितम् ।
सौगन्धिकपलञ्चैकं कौशिकस्य पलन्तथा ।। 130 ।।
कुडवं चित्रतैलस्य सर्वमादाय यत्नतः ।
पाचयेत्पाकविद्वैद्यः पात्रे लौहमये दृढे ।। 131 ।।
हन्ति वातं तथा पित्तं श्लेष्माणं खञ्जपङ्गुताम् ।
श्वासं सुदुर्जयं हन्ति कासं पञ्चविधन्तथा ।। 132 ।।
कुष्ठानि वातरक्तानि गुल्मशूलोदराणि च ।
आमवातं जयेदेतदपि वैद्यविवर्ज्जितम् ।। 133 ।।
एतदभ्यासयोगेन जरापलितनाशनम् ।
सर्पिस्तैलवसोपेतमश्नीयाच्छालिषष्टिकम् ।। 134 ।।
सिंहनाद इति ख्यातो रोगवारणदर्पहा ।
वह्निवृद्धिकरः पुंसां भाषितो दण्डपाणिना ।। 135 ।।
(भैषज्यरत्नावली, आमवातावाधिकार ; 130-135.)

5 :4 TRAYODA¹¡«GA GUGGULU (त्रयोदशांग गुग्गुलु) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, Vatavy¢dhyadhik¢ra ; 89-92.)

आभाश्वगन्धा हवुषा गुडूची शतावरी गोक्षुरवृद्धदारकम् ।
रास्ना शताह्वा सशटी यमानी सनागरा चेति समैश्च चूर्णम् ।। 89 ।।
तुल्यं भवेत्कौशिकमत्र मध्ये देयं तथा सर्पिरथार्द्धभागम् ।
कोलार्धमात्रन्तु ततः प्रयोगान् कृत्वानुपानं सुरयाथ यूषैः ।। 90 ।।
मद्येन वा कोष्णजलेन वाथ क्षीरेण वा मांसरसेन वापि ।
कटिग्रहे गृध्रसिबाहुपृष्ठे हनुग्रहे जानुनि पादयुग्मे ।। 91 ।।
सन्धिस्थिते चास्थिगते च वाते मज्जाश्रिते स्नायुगते च दुष्टे ।
रोगान् जयेद्वातकफानुविद्धान् वातेरितान् हृद्ग्रहयोनिदोषान् ।।
भग्नास्थिविद्धेषु च खञ्जवाते त्रयोदशाङ्गं प्रवदन्ति सन्तः ।। 92 ।।
(भैषज्यरत्नावली, वातव्याध्यधिकार ; 89-92.)

5 : 5 TRIPHAL¡ GUGGULU (त्रिफलागुग्गुलु) (AFI, Part-I)

(¹¢r¬gadharasa¼hit¢, Madhyamakha´²a, Adhy¢ya 7 ; 82-83)

त्रिपलं त्रिफलाचूर्णं कृष्णाचूर्णं पलोन्मितम् ।
गुग्गुलुं पाञ्चपलिकं क्षोदयेत्सर्वमेकतः ।। 82 ।।
ततस्तु गुटिकां कृत्वा प्रयुञ्ज्याद्वह्न्यपेक्षया ।
भगन्दरं गुल्मशोथावर्शांसि च विनाशयेत् ।। 83 ।।
(शाङ्र्गधरसंहिता, मध्यमखण्ड, अध्याय 7 ; 82-83)

5 : 10 V¡T¡RI GUGGULU (वातारि गुग्गुलु) (AFI, Part-I)

(Bhai¾ajyaratn¢val¤, Amav¢t¢dhik¢ra ; 87-89.)

वातारितैलसंयुक्तं गन्धकं पुरसंयुतम् ।
फलत्रययुतं कृत्वा पिट्टयित्वा चिरं रुजि ।। 87 ।।
भक्षयेत्प्रत्यहं प्रातरुष्णतोयानुपानतः ।
दिने दिने प्रयोक्तव्यं माससमेकं निरन्तरम् ।। 88 ।।
सामवातं कटीशूलं गृध्रसी खञ्जपङ्गुताम् ।
वातरक्तं सशोथञ्च सदाहं क्रोष्टुशीर्षकम् ।
शमयेद्बहुशो दृष्टमपि वैद्यविवर्जितम् ।। 89 ।।
(भैषज्यरत्नावली, आमवाताधिकार ; 87-89.)

5 : 9 VYO½¡DI GUGGULU (व्योषादि गुग्गुलु) (AFI, Part-I)

(A¾°¢¬gah¨daya, Cikits¢sth¢na, Adhy¢ya 21 ; 49.)

व्योषाग्निमुस्तत्रिफलाविडङ्गैर्गुग्गुलुं समम् ।। 49 ।।

(अष्टाङ्गहृदय चिकित्सा स्थान, अध्याय 21 ; 49.)

5 : 7 YOGAR*f*JA GUGGULU (योगराज गुग्गुलु) (AFI, Part-I)

(Bhai¾ajyaratn¢val◌, ¡mavat¢dhik¢ra ; 90-95.)

चित्रकं पिप्पलीमूलं यमानी कारवी तथा ।
विडङ्गान्यजमोदा च जीरकं सुरदारु च ।। 90 ।।
चव्येला सैन्धवं कुष्ठं रास्नागोक्षुरधान्यकम् ।
त्रिफलां मुस्तकं व्योषं त्वगुशीरं यवाग्रजम् ।। 91 ।।
तालीशपत्रं पत्रञ्च श्लक्ष्णचूर्णानि कारयेत् ।
यावन्त्येतानि चूर्णानि तावन्मात्रन्तु गग्गुलुम् ।। 92 ।।
सम्मर्द्य सर्पिषा गाढं स्निग्धे भाण्डे निधापयेत् ।
अतो मात्रां प्रयुञ्जीत यथेष्टाहारवानपि ।। 93 ।।
योगराज इति ख्यातो योगोऽयममृतोपमः ।
आमवाताढ्यवातादीन् कृमिदुष्टव्रणानि च ।। 94 ।।
प्लीहगुल्मोदरानाहदुर्नामानि विनाशयेत् ।
अग्निञ्च कुरुते दीप्तं तेजो वृद्धिं बलं तथा ।
वातरोगान् जयत्येष सन्धिमज्जगतानपि ।। 95 ।।

(भैषज्यरत्नावली, आमवाताधिकार ; 90-95.)

8 : 12 ¹AMB¥K¡DYA TAILA (शम्बूकाद्य तैल((AFI, Part-I)

(Bhai¾ajyaratn¢val◌, Kar´arog¢dhik¢ra ; 40.)

शम्बूकस्य च मांसेन कटुतैलं विपाचितम् ।
तस्य पूरणमात्रेण कर्णनाडी प्रशाम्यति ।। 40 ।।

(भैषज्यरत्नावली, कर्णरोगाधिकार ; 40.)

K½¡RA SŪTRA (क्षार सूत्र()

(चक्रदत्त, अर्शश्चिकित्सा, 148)

भावितं रजनीचूर्णैः स्नुहीक्षीरैः पुनः पुनः ।
बन्धनात् सुदृढं सूत्रं भिनत्त्यर्शोभगन्दरम् ।। 148 ।।

कृशदुर्बलभीरूणां नाडी मर्माश्रिता च या ।
क्षारसूत्रेण तां छिन्द्यान्नतु शस्त्रेण बुद्धिमान् ।। 26 ।।
एषण्या गतिमन्विष्य क्षारसूत्रानुसारिणीम् ।
सूचीं निदध्याद् गत्यन्ते तथोन्नम्याशु निर्हरेत् ।। 27 ।।
सूत्रस्यान्तं समानीय गाढं बन्धं समाचरेत् ।
ततः क्षारबलं वीक्ष्य सूत्रमन्यत् प्रवेशयेत् ।। 28 ।।
क्षाराक्तं मतिमान् वैद्यो यावन्न छिद्यते गतिः ।
भगन्दरेऽप्येष विधिः कार्यो वैद्येन जानता ।। 29 ।।
अर्बुदादिषु चोत्क्षिप्य मूले सूत्रं निधापयेत् ।
सूचीभिर्यववक्त्राभिराचितं वा समन्ततः ।
मूले सूत्रेण बध्नीयाच्छिन्ने चोपचरेद् व्रणम् ।। 30 ।।
(सुश्रुतसंहिता, चिकित्सास्थान, अध्याय 17 ; 26-30)

APPENDIX-10

LIST OF SINGLE DRUGS USED IN FORMULATIONS

10.1 List of Single Drugs of Animal origin used in Formulations with equivalent English Names:

Aj¢k¾ra	Goat milk
Dadhi (Godadhi)	Cows milk
Gh¨ta (Gogh¨ta)	Clarified butter from cow's milk
Gom¦tra	Cow's urine
K¾audra (Madhu)	Honey
L¢k¾¢	Laccifer lacca
M¢k¾ika (Madhu)	Honey
Samb¦ka	Pilo globosa
Sarpi (Gogh¨ta)	Clarified butter from cow's milk

10.2 List of Single Drugs of Mineral/Metal origin used in Formulations with equivalent English Names:

Abhraka Bhasma	Mica
Gandhaka	Sulphur
Loha C¦r´a	Megnatite
M¨ta Loha	Megnatite
M¨ta °ulva.	Copper
M¢k¾ika dh¢tu C¦r´a.	Chalcopyrite
M¢k¾ika	Chalcopyrite
Rajata	Silver
Rasa (śuddha P¢rada)	Mercury
S¢mudra Lava´a	Sea salt
Saindhava Lava´a	Rock salt
Sarjik¾¢ra	Fuller earth
Sauvarcala Lava´a	Black salt
Sindh¦ttha (Saindhava Lava´a)	Rock salt
Vi²a Lava´a	Black salt

10.3 List of Single Drugs of Plant origin used in Formulations, with Latin Nomenclature:

Name of the Drug	Botanical Name
Agaru	*Aquilaria agallocha* Roxb.
Agnimantha	*Clerodendrum phlomidis* Linn.
Ājamodā	*Apium leptophyllum* (Pers.) F.V.M. ex Benth.
Āmalakī	*Phyllanthus embilca* (*Emblica officinalis* Gaertn.)
Apāmārga	*Achyranthes aspera* Linn.
Ārdraka	*Zingiber officinale* Rosc.
Arka	*Calotropis procera* (Ait.) R. Br.
Asana	*Pterocarpus marsupium* Roxb.
Aśvagandhā	*Withania somnifera* Dunal.
Ativisā	*Aconitum heterophyllum* Wall. Ex Royle
Balā	*Sida cordifolia* Linn.
Bākucī	*Psoralea corylifolia* Linn.
Bhallātaka	*Semecarpus anacardium* Linn.
Bh¨¬garāja	*Eclipta alba* Hassk
Bibhītaka	*Terminalia bellirica* Roxb.
Bilva	*Aegle marmelos* Corr.
Brāhmī	*Bacopa monnieri* (Linn.) Wettst.
B¨hatī	*Solanum indicum* Linn.
Bhūmyāmalkī	*Phyllanthus amarus* Schun. & Th.
Cakramarda	*Cassia tora* Linn.
Cavya	*Piper retrofractum* Vahl.
Ci®ca	*Tamarindus indica* Linn.
Citraka	*Plumbago zeylanica* Linn.
Darabh	*Imperata cylindrica* (L.) Beauv
Dā²ima	*Punica granatum* Linn.
Dantī	*Baliospermum montanum* Muell-Arg.

Dāruharidrā	*Berberis aristata* DC
Devadāru	*Cedrus deodara* (Roxb.) Loud.
Dhānyaka	*Coriandrum sativum* Linn.
Drāk¾ā	*Vitis vinifera* Linn.
Elāvāluka	*Prunus* avium Linn.
Era´²a	*Ricinus communis* Linn.
Gambhārī	*Gmelina arborea* Linn.
Gok¾ura	*Tribulus terrestris* Linn.
Gu²ūcī	*Tinospora cordifolia* (Willd.) Miers.
Guggulu	*Commiphora wightii* (Arn.) Bhand.
Haridrā	*Curcuma longa* Linn.
Harītakī	*Terminalia chebula* Retz.
Hi¼srā	*Capparis spinosa* Linn.
Hi¬gu	*Ferula foetida* Regel.
Hrīvera	*Coleus vettiveroides* K.C. Jacob
Ik¾u	*Saccharum officinarum* Linn.
Īśvarī	*Aristolochia indica* Linn.
Indravāru´ī	*Citrullus colocynthis* Schrad.
Jambu	*Syzygium cuminii* (Linn.) Skeels
Jatāmā¼sī	*Nardostachys jatamansi* DC.
Jātī	*Jasminum officinale* Linn.
Jātiphala	*Myristica fragrans* Houtt.
Jivantī	*Leptadenia* reticulata Weight & Arn.
Jīvaka	*Malaxis acuminata* D.Don
Kākanāśikā	*Martynia annua* L.
Kākolī	*Lilium polyphyllum* D.Don
Kamala	*Nelumbo nucifera* Gaertn.
Ka¬kola	*Piper cubeba* Linn. f.
Ka´°akārī	*Solanum surattense* Burm.f.
Kara®ja	*Pongamia pinnata* (Linn.)

Karka°aś¨¬gī	*Pistacia lentiscus* Linn.
Kāsa	*Saccharum spontaneum* Linn.
Ka°phala	*Myrica esculenta* Buch._Ham. Ex D.Don
Ka°ukā	*Picrorhiza kurroa* Royle ex Benth.
Khadira	*Acacia catechu* (Linn. f.) Willd.
Kola	*Zizyphus jujuba* Lam.
K¨¾´ ajīraka	*Carum carvi* Linn.
K¨¾´ asārivā	*Cryptolepis buchanani* Roem. & Schult.
K¾īravidārī	*Ipomoea digitata* Linn.
Kula®jana	*Alpinia galanga* Willd.
Kulattha	*Vigna unguiculata* (Linn.) Walp.
Kunduru	*Boswellia serrata* Roxb.
Ku¬kuma(Vāhlīka)	*Crocus sativws* L.
Kū¾mā´²a	*Benincasa hispida* (Thunb.) Cogn.
Ku¾°ha	*Saussurea lappa* C.B. Clarke
Laśuna	*Allium sativum* Linn.
Lava¬ga	*Syzygium aromaticum* (Linn.) Merr. & L.M. Perry
Marica	*Piper nigrum* Linn.
Matsyāk¾ī	*Alternanthera sessilis* (Linn.) R.Br.
Medā	*Polygonatum cirrhifolium* Royal
Mocarasa (Śālmalī)	*Salmalia malabarica* (DC) Schott & Endl.
Mūlaka	*Raphanus sativus* Linn.
Ma®ji¾°hā	*Rubia cordifolia* Linn.
Mustā	*Cyperus rotundus* Linn.
Nāgakeśara	*Mesua ferrea* Linn.
Nimba	*Azadirachta indica* A.Juss.
Padmaka	*Prunus cerasoides* D.Don
Palāśa	*Butea monosperma* (Lam.) Kuntze
Pā°olā	*Trichosanthes dioica* Roxb.
Pā¾ā´a Bheda	*Bergenia ciliata* (Haw.) Sternb.

Pā°alā	*Stereospermum suaveolens* DC.
Pā°hā	*Cissampelos pareira* Linn.
Pippalī	*Piper longum* Linn.
Priyāla	*Buchanania lanzan* Spreng.
Priya¬gu	*Callicarpa macrophylla* Vahl.
P¨śnipar´ī	*Uraria picta* Desv.
Pūga	*Areca catechu* Linn.
Punarnavā (Rakta)	*Boerhaavia diffusa* Linn.
Pu¾kara	*Inula racemosa* Hook.f.
Raktacandana	*Pterocarpus santalinus* Linn.
§¾abhaka	*Malaxis muscifera* (Lindley) Kuntze.
§ddhī	*Habenaria intermedia* D.Don
Śaileya	*Parmelia perlata* (Huds.) Ach.
Śālaparnī	*Desmodium gangeticum* DC.
Śāli	*Oryza sativa* Linn.
Sama¬ga (Lajjālu)	*Mimosa pudica* L.
Sa¬khapu¾pī	*Convolvulus pluricaulis* Choisy
Saptalā	*Euphorbia dracunculoides* Lam.
Sarala	*Pinus roxburghii* Sargent.
Sar¾apa	*Brassica campestris* Linn.
Śatāvarī	*Asparagus recemosus* Willd.
Śatī	*Hedychium spicatum* Ham. Ex Smith
Śigru	*Moringa oleifera* Lam.
Ś¨¬gā°aka	*Trapa natans* Linn.
Śthūlailā	*Amomum subulatum* Roxb.
Śūk¾mailā	*Elettaria cardamomum* (Linn.) Maton
Śu´°hī	*Zingiber officinale* Roxb.
Śūra´a	*Amorphophallus campanulatus* (Roxb.) Blume
Śveta sārivā	*Hemidesmus indicus* (Linn.) R.Br.
Śvetacandana	*Santalum album* Linn.

Śvetajīraka	*Cuminum cyminum* Linn.
Śyonāka	*Oroxylum indicum* vent.
Tagara	*Valeriana wallichii* DC.
Tālīsa	*Abies webbiana* Lindl.
Tila	*Sesamum indicum* Linn.
Triv¨t	*Operculina turpethum* (Linn.) Silva Manso
Tugāk¾īrī	*Bambusa bambos* Druce.
Tvak	*Cinnamomum zeylanicum* Blume
Tvakapatra	*Cinnamomum tamala* (Buch.-Ham) Nees & Eberm.
Uśīra	*Vetiveria zizanioides* (Linn.) Nash
Utpala	*Nymphaea stellata* Willd.
Vacā	*Acorus calamus* Linn.
Vāsā	*Adhatoda vasica* Nees
Vi²a¬ga	*Embelia ribes* Burm.f.
Vidārī	*Pueraria tuberosa* DC.
Ya¾°ī	*Glycyrrhiza glabra* Linn.
Yava	*Hordeum vulgare* Linn.
Yavānī	*Trachyspermum ammi* (Linn.) Sprague ex Turril

APPENDIX-11

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