THE AYURVEDIC PHARMACOPOEIA OF INDIA

THE AYURVEDIC PHARMACOPOEIA OF INDIA

PART - II (FORMULATIONS)
VOLUME - III

First Edition

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
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FOREWORD

Standardization of drugs and pharmaceuticals by setting Pharmacopoeial standards of Ayurveda, Siddha & Unani (ASU) medicines is a priority area identified by the Department of AYUSH. The Ayurvedic Pharmacopoeia Committee (APC) is continuously working towards this goal in collaboration with eminent research and Ayurvedic institutions in the country. After publishing the Pharmacopoeial standards of 549 single drugs going in various formulations, the APC has also published two volumes API (Part-II) containing 101 formulations. In this series, the third volume of Ayurvedic Pharmacopoia of India Part-II containing 51 formulations is being published by Department of AYUSH. This volume contains Pharmacopoeial standards of commonly used Ayurvedic formulations in various Ayurvedic hospitals, dispensaries and also by the practitioners of the system.

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

There is no doubt that this publication on multiple ingredient Compound Formulations will provide the required technical knowledge to manufacturers, regulators, scientists, teachers, researchers and students in this field. I place on record my appreciation for the continuous efforts made by the members of the Ayurvedic Pharmacopoeia Committee (APC), Scientists working in various Laboratories, Prof. S.S. Handa, Chairman, APC, Dr. S.K. Sharma, Adviser (Ayurveda), Department of AYUSH, Dr. Ramesh Babu, Director General, Central Council for Research in Ayurveda and Siddha (CCRAS) and his team, Director, Pharmacopoeial Laboratory of Indian Medicine (PLIM), Ghaziabad and his team in particular for helping to bring out this volume.

(S. Jalaja)

New Delhi
August 12, 2010

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LEGAL NOTICES

In India there are laws dealing with drugs that are the subject of official monographs. The 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. III, is the book of standards for Compound Formulations included therein and the standards prescribed in the Ayurvedic Pharmacopoeia of India, Part-II, (Formulations) Vol. III, would be official. If considered necessary these standards can be amended and the Chairman of the Ayurvedic Pharmacopoeia Committee is authorized to issue such amendments. Whenever such amendments are issued, the Ayurvedic Pharmacopoeia of India, Part-II (Formulations), Vol. III, 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-III. Wherever the abbreviation "API, Pt.-II, Vol.-III" is used, it stands for the same and for the Supplements or Amendments thereto.

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

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 (Appendix - 9.3). Where *Water* is used as an ingredient it should meet the requirements for *Jala* (Potable Water) covered by its monograph in the Ayurvedic Pharmacopoeia of India-Part-I, Vol.-VI.

Monograph for each Formulation includes its 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, provided that the *same ratio* is maintained as stated in the monographs, with the ingredients complying with its compendial requirements, and also ensuring that the final product complies with all of the requirements stated in the Formulation Composition for the specific compound formulation,

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.

Wherever an 'Official Substitute', is provided for in the composition of a Formulation, it implies a deviation from the original Formulation, using the nomenclature of the 'Official Substitute'.

Wherever a Formulation Composition specifies a drug that is officially 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 formulation of a permitted preservative. In such circumstances the label should state the name and the concentration of the preservative and the appropriate storage conditions.

The direction 'freshly prepared' or 'fresh' given in a formulation implies that the ingredient(s) processed with a juice, decoction, extract etc. should be prepared and added in the required manner to the formulation within 24 hours after their preparation.

Monograph: Each monograph begins with a Definition in an introductory paragraph followed by the Formulation Composition giving the scientific names of the drugs used along with a brief account of the Method of Preparation. For drugs of plant origin, the part used has also been specified.

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 detected by means of the prescribed tests in the Appendix-2 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. Under Formulation Composition, each ingredient for which a monograph has been given in the A.P.I., the pharmacopoeial claim is indicated by the letters API; where the ingredient has currently no monograph or it is under process, the letter API is given within brackets.

Added Substances: A Formulation contains no added substances/excipients, except when specifically permitted in the individual monograph. Unless otherwise specified in the individual monograph, or elsewhere in the General Notices, such added substances/excipients shall be 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 added substances shall comply with the quality indicated for it, 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 it may help in the evaluation of an article. However substantial departure from 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 an 'odour' is said to be present, it is examined by smelling the drug directly after opening the container. If 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', as a characteristic for that Formulation.

The taste of a drug is examined by taking a small quantity of drug by the tip of a moist glass rod and allowing it to remain on the tongue. ***This does not apply in the case of poisonous ingredients.***

Powders: Many ingredients in the Formulations are subjected to comminuting by hand or machine during the process of manufacture and mixed together. It is desirable that such powders maintain certain average particle size for ease of handling and effective processing.

There are also compound formulations where the dosage form itself is a powder and particle size is a standard for the finished product. It is essential in such cases that both the distribution and average particle size are monitored to be consistent and measurable during processing, so that the finished product complies with the specified standard.

To provide for such situations, the fineness of a powder, whether it is used in the processing or is itself a final product, is given in terms of sieve sizes, using the BIS sieves as standard. The sieve sizes follow the latest revision of the BIS. For the convenience of users, the equivalents or nearest equivalent numbers according to the earlier BIS have also been given.

The fineness of powder, where it is itself a dosage form, is expressed in terms of percentage of fractions passing through specified sieves. For other procedures a mesh size appropriate for the purpose is suggested.

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 identification of individual ingredients where these do not exceed ten in number and are added '*in situ*' to the formulation. 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. Where any ingredient is to be subjected to a *Śodhana*, this shall be carried out as specified in the monograph or in the text referred to therein.

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 the others are given in Appendices, with a suitable reference in the monograph to the specific Appendix.

An analyst is not precluded from employing an alternate method in any instance if one is satisfied that the method, which one 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 an assay or any test procedure, *not less* than the specified number of dosage units or quantities should be taken for analysis. Proportionately larger or smaller quantities than the specified weights and volumes may be taken for substances under assay or test substances, Reference Standards or Standard Preparations, 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 a manner as to provide at least equivalent accuracy.

One of the solid dosage forms in which Ayurvedic drugs are traditionally presented is the *Vaṭī* or *Guṭikā*. Monographs for *Vaṭī/Guṭikā* are included, along with their method of preparation using a hand operated machine. Standards appearing in these monographs also relate to this dosage form.

However, manufactures are not precluded from using the same Formulation Composition given in the monograph to produce *tablets* in place of *Vaṭīs* employing suitable machinery. In case a manufacturer prefers to manufacture compressed tablets instead of *Vaṭī/Guṭikā*, the necessary alterations in term of adjuvants, size, weight etc., shall be made by him/her, and records for the same maintained for mandatory use. The labeling of such products shall also indicate the excipients/adjuvants used.

The onus is also on the manufactures in such cases to provide dosage form tests like average weight, uniformity of weight, disintegration time etc.

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 the individual monographs and wherever limit is not given in the monograph, they must comply with the limits given in the respective Appendices. The methods for determination of these parameters are given in the 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 gel G 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 measurements 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.

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 the metric system, which are approximate conversions from classical weights mentioned in Ayurvedic texts. A conversion table is appended giving classical weights with their metric equivalents (Appendix 7). Doses mentioned in the A.P.I. 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 provides a 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 intended purpose in a convenient manner.

It provides the required degree of protection to the contents from 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 container.

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 an 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 contamination and from loss of contents 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, and from loss or deterioration of contents 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 reveal evidence of tampering, if any.

Multiple Unit Container- A multiple unit container is a 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.

Labeling: 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
Refractive index	–	–	R.I or η
volume	–	–	vol
weight	–	–	wt
weight in weight	–	–	w/w
weight in volume	–	–	w/v
volume in volume	–	–	v/v
quantity sufficient	–	–	QS
Diameter	–	–	dia.
Dilute	–	–	dil.

Concentrated	–	–	con.
Dry	–	–	Dr.
Specific Gravity	–	–	Sp. gr.

ABBREVIATIONS FOR PARTS OF PLANTS

Aerial part(s)	–	–	A. Pt.
Aerial root(s)	–	–	A. Rt.
Androecium	–	–	Adr.
Aril	–	–	Ar.
Bud	–	–	Bd.
Bulb	–	–	Bl.
Endosperm (Bīja majjā)	–	–	Enm.
Extract	–	–	Ext.
Exudate	–	–	Exd.
Flower	–	–	Fl.
Fruit	–	–	Fr.
Fruit rind	–	–	Fr. R.
Heart wood	–	–	Ht. Wd.
Inflorescence	–	–	Ifl.
Kernel	–	–	Kr.
Latex	–	–	Lt.
Leaf	–	–	Lf.
Leaf rachis	–	–	Lf. R.
Oleo-resin	–	–	O.R.
Pericarp	–	–	P.
Plant (whole)	–	–	Pl.
Resinous encrustation	–	–	Res. Enc.
Rhizome(s)	–	–	Rz.
Ripe fruit Pulp	–	–	Rp. Fr. Pp.
Root bark	–	–	Rt. Bk.
Root stock	–	–	Rt. Stck.
Root tuber	–	–	Rt. Tr.
Root(s)	–	–	Rt.
Seed(s)	–	–	Sd.
Siliceous Concretion	–	–	S.C.
Stamen(s)	–	–	Stmn.

Stem	–	–	St.
Stem bark	–	–	St. Bk.
Stem tuber	–	–	St. Tr.
Style	–	–	Stl.
Stigma	–	–	Stg.
Sublimed Extract	–	–	Subl. Ext.
Subterranean root	–	–	Sub. Rt.
Wood Extract	–	–	Wd. Ext.

INDO-ROMANIC EQUIVALENTS FOR DEVANĀGARĪ ALPHABETS

अ	A	a	ड	ḌA	ḍa
आ	Ā	ā	ढ	ḌHA	ḍha
इ	I	i	ण	ṆA	ṇa
ई	Ī	ī	त	TA	ta
उ	U	u	थ	THA	tha
ऊ	Ū	ū	द	DA	da
ऋ	Ṛ	ṛ	ध	DHA	dha
ए	E	e	न	NA	na
ऐ	AI	ai	प	PA	pa
ओ	O	o	फ	PHA	pha
औ	AU	au	ब	BA	ba
ं	Ṃ	ṃ	भ	BHA	bha
ः	Ḥ	ḥ	म	MA	ma
क	KA	ka	य	YA	ya
ख	KHA	kha	र	RA	ra
ग	GA	ga	ल	LA	la
घ	GHA	gha	व	VA	va
ङ	ṄA	ṅa	श	ŚA	śa
च	CA	ca	ष	ṢA	ṣa
छ	CHA	cha	स	SA	sa
ज	JA	ja	ह	HA	ha
झ	JHA	jha	ळ	ḶA	ḷa
ञ	ÑA	ña	क्ष	KṢA	kṣa
ट	ṬA	ṭa	त्र	TRA	tra
ठ	ṬHA	ṭha	ज्ञ	JÑA	jña

PREFACE

In the Ayurvedic Formulary of India Part I and Part II there are 636 Formulations. Out of these nearly 65 per cent are solid dosage forms (*Cūrṇa, Vaṭī, Guṭikā* etc.), about 20 per cent are liquid preparations (*Āsava, Ariṣṭa, Taila* etc.) and about 15 per cent are semisolids (*Avaleha, Ghṛta, Lepa* etc.). Each of the Formulations contains a number of ingredients, a few even going upto 75. It is observed that nearly 70 per cent each of the liquid and semisolid preparations contain over ten ingredients. Since the spectrum of tests which can be applied to liquids and semisolids for pharmacopoeial monographs are more limited than that available for solids, these preparations are particularly difficult to deal with. Considering the total of 636 Formulations about 50 per cent 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 achieve. 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, only a few generalized quality parameters are adopted. Not all Ayurvedic drug manufacturers may be having in-house standard methods of preparation (SOPs) and their own quality parameters for finished Compound Formulations. Therefore there is no consistency in the SOPs and quality parameters among them. This results in a lot of variability in the quality of the same classical Ayurvedic formulation produced by the same recommended classical procedures, but by different manufacturers even among their different batches. An effort has been made now to optimize and 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 drugs) so far six volumes have been published viz. Vol I (80 monographs), Vol II (78 monographs), Vol III (100 Monographs), Vol IV (68 monographs), Vol V (92 monographs) and Vol VI (101 monographs) for single drugs of plant origin, and Vol VII (21 monographs) for Minerals and Metals, which go into one or more compound formulations included in the Ayurvedic Formulary of India, Part-I and Part-II. The two volumes of the Ayurvedic Pharmacopoeia of India, Part-II published in 2007 and 2008 respectively contain official standards for 101 compound formulations, selected from Ayurvedic Formulary of India, Part-I and Part-II.

In continuation of the work on the quality standards of classical Ayurvedic compound formulations, the present Vol-III of the Ayurvedic Pharmacopoeia of India, Part-II contains official standards for compound formulations included in the Ayurvedic Formulary of India, Part-I, Part-II and Part-III (under preparation).

The title of the monograph for each Compound Formulation is given in *Saṃskṛta* 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) and physico-chemical parameters. Other 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 for it in the Ayurvedic Pharmacopoeia of India. In a few cases, where pharmacopoeial standards for individual ingredient were not available, collaborating institutes developed standards for such an ingredient before using it in the Formulation. Monographs of the Compound Formulations provide Assay methods for and range of limits of, any one chemical constituent or group of chemical constituents, wherever possible.

The General Notices 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 Pharmacopoeia Committee hopes that the publication of Ayurvedic Pharmacopoeia of India, Part-II (Formulations) Vol-III, containing quality standards and method of preparation of the Compound Formulations would serve to assist in the implementation of the Drugs and Cosmetic Act and Rules thereunder. It is also expected that such implementation would generate a feedback, which is necessary for updating the prescribed standards.

The Ayurvedic Pharmacopoeia Committee urges the Government of India to recommend the adoption of these monographs published in the Ayurvedic Pharmacopoeia of India, Part-II (formulations) – Vol III 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-III 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, VII and the Ayurvedic Pharmacopoeia of India, Part-II (formulations), Vol-I, II 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 Pharmacopoeia Committee duly acknowledges the contributions made by the staff of the participating institutions associated with the APC project work for developing quality standards of Ayurvedic Compound Formulations.

The Committee expresses gratitude to the Secretary, Department of AYUSH. Ms. S. Jalaja and Joint Secretary Shri B. Anand for providing financial and administrative support. The Committee also sincerely thank Dr. MM Padhi, Deputy Director [Tech.]; Dr. Pramila Pant, Assistant Director [Chem.]; Dr. Bishnupriya Dhar, Assistant Director [P'cognosy]; Dr. B.S. Sharma, Research Officer [Ay.]; Dr. Chhote Lal, Dr. AKS Bhadoria and Dr. MN Rangne; Dr. K. Sandhya Rani, S.R.F. [Ayu.]; Dr. Nikhil Jirankalgikar S.R.F. [Ayu.]; Mr. Chinmay Rath S.R.F. [Bot.]; Ms. Kuljeet Kaur S.R.F. [Pharmacy] Ms. Talat Anjum Research Officer [Bot.] and other associated officers, for their constant efforts in bringing out this volume. Thanks are also due to Dr. Rajeev Kumar Sharma, Senior Scientific Officer, Dr. Jayaprkash, Research Officer, Sh. Ravindra Singh, Assistant Director [Chem.]; Sh. N.S. Mehra, Research Officer, C. Arunachalam, Research Assistant; PLIM, Ghaziabad. The Committee also acknowledges Mr. Ashish, Ms. Deepti and Ms. Meenakshi, D.E.O., for typing and arranging the technical data as required.

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 manufacturers 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. Pendse, Honorary Director, Indian Drug Research Association, 955-Sadashiv Peth, Lakshmi Road, Poona-2	*Member*
10.	Dr. M.V. Venkataraghavan, Chellakoti, Nungabakkum, Madras-34	*Member*
11.	Ayurvedacharya 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, Surat	*Member*

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), Dr. P.D. Sethi (2001), Ms. Savita Satakopan (2005-06) and Prof. S.S. Handa (2006-09) 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.5-5/CCRAS-2006/TECH./APC/HQRS dated 19th March, 2009 consisting of following members.

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

OFFICIAL MEMBERS

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

2.	Dr. D.R. Lohar, M.Sc.; Ph.D. Director, Pharmacopoeial Laboratory for Indian Medicine, Central Govt. Offices Complex, Kamla Nehru Nagar, Ghaziabad – 201 002.	Member (Ex-officio)
3.	Managing Director, Indian Medicines Pharmaceutical Corporation Ltd., Mohan, Via – Ram Nagar, Distt.- Almora, Uttranchal.	Member (Ex-officio)
4.	Drugs Controller General (India), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi – 110 011.	Member (Ex-officio)

NON-OFFICIAL MEMBERS

Phytochemistry & Chemistry Sub-Committee

1.	Dr. P.D. Sethi, M. Pharm., Ph.D., (Former Director, Central Indian Pharmacopoeial Laboratory) B-140, Shivalik Enclave, New Delhi – 110 017.	Chairman
2.	Prof. V.K. Kapoor, M. Pharm., Ph.D. (Former Dean and Chairman, University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh) 1473, Pushpac Complex, 49B, Chandigarh - 160 047.	Member
3.	Dr. Jayaraman Arunachalam, Head, national Centre for Compositional Characterization of Materials-Bhaba Atomic Research Centre (BARC), DAE/Govt. of India, ECIL, Hyderabad – 500 062	Member
4.	Dr. (Miss.) A. Saraswati, Director (Institute), CSMDRIA&S, Arinagar Anna Govt. Hospital Campus Arumbakkam, Chennai – 600 062	Member
5.	Dr. D. Vijaya Kumar, Scientist E-I, Reaction Engineering Laboratory, Indian Institute of Chemical Technology (CSIR), Hyderabad – 500 007	Member

Pharmacognosy Sub-Committee

1.	Ms. S. Satakopan, M.Sc. (Senior Scientific Officer (Retd.), Government of Gujarat, Gujarat State Food and Drug Control Administration, Vadodara) 7/4, Padmam Flats, Seventh Street, Nanganallur, Chennai – 600 061.	Chairman
2.	Dr. (Mrs.) Shanta Mehrotra, Ph.D., Emeritus Scientist, National Botanical Research Institute, Rana Pratap Marg, P.B. No.-436, Lucknow – 226 001 (U.P.).	Member
3.	Dr. M.A. Iyengar, Ph.D, Former Prof. & Head of Pharmacognosy , Manipal College of Pharmaceutical Sciences Res-14, HIG, HUDCO, Manipal – 576 104.	Member
4.	Dr. Indira Balachandran, Centre for Medicinal Plants Research, Aryavaidyasala, Kottakal, Malappuram, Kerala -6776 503	Member

Formulary Sub-Committee

(Rasa Shastra / Bhaishajya Kalpana – Ayurvedic Pharmacy)

1.	Prof. S.K. Dixit, A.B.M.S.; D.Ay.M; Ph.D. (Former Head, Deptt. of Rasa Shastra, BHU), B-3/402, Shivala, Varanasi 221 005 (UP.).	Chairman
2.	Dr. B.L. Gaur, Ph.D.; Vice-Chancellor, Jodhpur Ayurvedic University, Jodhpur, Rajasthan	Member
3.	Dr. S. S. Savrikar, M.D. Ph.D. (Ay.) (Former Vice-chancellor, GAU Jamnagar) Head, Dept. of Rasashastra, RA Podar Ayurved Medical College, Worli, Mumbai	Member
4.	Dr. P. Madhavankutty Varrier, Aryavaidyasala, Kottakal, Malappuram, Kerala -6776 503	Member

Ayurveda Sub-Committee

(Single Drugs of Plants, Minerals, Metals, Animal origin)

1.	Prof. V.K. Joshi, M.D. (Ay.), Ph.D. Deptt. of Dravyaguna, Institute of Medical Sciences, Banaras Hindu University (BHU), Varanasi – 221 005 (U.P.).	Chairman
2.	Dr. K. Raghunathan, Former Deputy Director, CCRAS H. No. 664, Sector-28, Faridabad - 121 008	Member
3.	Dr. M.R. Uniyal, (Former Director, CRIA, CCRAS), Advisor, Medicinal Plants, Govt. of Uttarakhand, E 141, Nehru Colony, Dharampur, Dehradun	Member
4.	Dr. M. C. Sharma, Director, NIA Jaipur	Member

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 for functioning.

4. The functions of the Committee shall be as follows:

(i) To prepare Ayurvedic Pharmacopoeia of India of single drugs and compound formulations.

(ii) To prescribe 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 draft SOPs 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.

1. University Institute of Pharmaceutical Sciences, Punjab University, Chandigrah-160014

2. Ram Narayan Ruia College, Matunga, Mumbai

3. Captain Srinivasa Murty Drug Research Institute Ayurveda (CSMDRIA), Aringner Anna Government Hospital Campus, Arumbakkam, Chennai-600016

4. Indian Institute of Chemical Technology (CSIR), Hyderabad-500007

5. B.V. Patel, Pharmaceutical Education, and Research Development (PERD) Centre, Thaltej, Ahmedabad-380054

6. Indian Institute of Integrative Medicine (Formerly RRL), Jammu

7. National Botanical Research Institute (Council of Scientific & Industrial Research), Rana Pratap Marg, P.B. No. 436, Lucknow-226001

8. Institute of Minerals and Materials Technology (Formerly RRL) CSIR, Bhubaneswar

9. Institute of Post Graduate Teaching & Research in Ayurveda, Gujrat Ayurveda University, Jamnagar

MONOGRAPHS

CONTENTS

ARKA

General Descripition:

Arka is a liquid preparation obtained by distillation of certain liquids or drugs soaked in water using the *Arkayantra* or any convenient modern distillation apparatus.

General Method of Preparation:

The drugs are cleaned and coarsely powdered. Some quantity of water is added to the drugs for soaking and kept over-night. The following morning it is poured into the *Arkayantra* and the remaining water is added and boiled. The vapour is condensed and collected in a receiver. In the beginning, the vapour consists of only steam and may not contain the essential principles of the drugs. It should therefore be discarded. The last portion also may not contain therapeutically essential substance and should be discarded. The aliquots collected in between contain the active ingredients and may be mixed together to ensure uniformity of the *Arka*.

Characteristics:

Arka is a suspension of the distillate in water having slight turbidity and colour according to the nature of the drugs used and smell of the predominant drug.

BRĀHMYARKA

(AFI Part III, 2:11)

Definition:

Brāhmyarka is a liquid preparation obtained by hydro-distillation of the entire plant of *Bacopa monnieri*.

Formulation Composition:

1	Brāhmī API	*Bacopa monnieri*	Pl.	1.0 kg
2	Jala API for soaking and for preparation of Arka	Potable Water	–	30.0 l

Method of preparation:

- Take Brāhmī of pharmacopoeial quality.
- Wash, dry and powder the ingredient and pass through 355 μm IS Sieve (sieve number 44) to obtain coarse powder.
  Place 1.0 kg of *Brāhmī* powder in a round bottom standard joint flask of 50 l capacity. Add 30.0 l of *Jala*.
- Attach the proper distillation assembly, double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts and continue the distillation to collect about 20.0 l of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Brāhmyarka is a turbid pale yellow liquid with a faint odour and slightly astringent taste.

Identification:

Thin layer chromatography:

Dissolve 0.1 ml of the oil obtained by hydro-distillation of the *Arka* in 1 ml of toluene or in any suitable solvent. In a separate setup extract *Brāhmī* oil from *Brāhmī* API. Apply 2 μl each of the solutions on TLC plate separately and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate* (97: 3) as mobile phase. After development, allow the plate to dry in air and spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. and examine under ultraviolet light at 254 nm. Both the chromatograms show major spots at R_f 0.17 (purple brown), 0.35 (red brown) and 0.63 (saffron red).

Gas chromatography:

Carry out the gas chromatography using a 30 m fused silica capillary column walls coated with BP-10 maintained at 150^0 for 2 min. programmed at the rate of 7^0/min to 200^0, again 15^0/17 min.

to 260^0 and detector at 300^0 with a flow rate of carrier gas 1.5 ml/ min. with injection port temperature 280^0.

Inject separately 0.1µl of oil obtained by hydro-distillation of the crude drug as well as of *Arka* and programme the column as given in preceding paragraph.

Both the chromatograms show major peaks at R_t 14.12, 20.42 and 14.23, 21.78.

Physico-chemical parameters:

Specific gravity (20^0):	0.998 to 1.0,	Appendix 3.2

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Buddhimandatā (mental retardation), Smṛtibhrama (impaired memory)

Dose:

10 to 20 ml per day in divided doses

GULĀBĀRKA

(AFI Part III, 2:6)

Definition:

Gulābārka is a liquid preparation obtained by hydro-distillation of dried petals of *Rosa damascena*.

Formulation Composition

1	Gulāba (API)	*Rosa damascena*	Dry petals	1.0 kg
2	Jala API for soaking and for Preparation of Arka	Potable Water	–	12.5 l

Method of preparation:

- Take Gulāba petals of pharmacopoeial quality and wash.
- Place 1.0 kg of *Gulāba* petals in a round bottom standard joint flask of 30 l capacity. Add 12.5 l of *Jala*.
- Attach the proper distillation assembly with distillation and receiving heads, double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts and continue the distillation to collect about 10.0 l of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Gulābārka is a hazy liquid with pleasing fragrance of rose flower, sweetish to slightly bitter in taste.

Identification:

Thin layer chromatography:

Dissolve 0.1 ml of the oil obtained by hydro-distillation of the *Arka* under assay in 1 ml of *toluene*. Dissolve separately 0.1 ml each of *cirtonellol*, *geraniol* and *phenyl ethanol* in 1 ml each of *toluene*. Apply 2 µl each of the solution of the oil and reference solution on TLC plate and develop the plate to a distance of 8 cm using *ethyl acetate*: *hexane* (20: 80) as mobile phase. After development, allow the plate to dry in air and 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 0.42 (orange-red) corresponding to *geraniol* and 0.46 (pinkish-purple) corresponding to *cirtronellol* in visible light.

Gas chromatography:

Carry out the gas chromatography using a 30 m fused silica capillary column walls coated with FFAP maintained at 90^0 for 2 min. then programmed at the rate of 7^0/ min. to 220^0 and detector at 260^0 and with a flow rate of carrier gas 1.5 ml/min.

Inject separately 0.1 µl of oil obtained by hydro-distillation of drug under assay and, programme the column as given in preceding paragraph.

The chromatogram shows major peak at R_t 12.52 (corresponding to linalool), 16.64 (corresponding to *citronellol*), 17.34 (corresponding to *nerol*), 18.25 (corresponding to *geraniol*) and 19.68 (corresponding to *phenyl ethanol*).

Physico-chemical parameters:

Specific gravity (20^0): 1.0 Appendix 3.2

Assay:

Gulābārka contains 0.035 to 0.08 per cent v/v of essential oil, determined for a well stirred quantity of not less than 2.0 l. (Appendix 2.2.11).

Other requirements:

Microbial limits: Complies with Appendix 2.4

Aflatoxins: Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Dāha (burning sensation), Tṛṣṇā (thirst), Hṛllāsa (nausea), Netraroga (eye diseases)

Dose:

10 to 20 ml per day in divided doses

External use : 2-3 drops in each eye, 2/3 times a day

JAṬĀMĀṂSYARKA

(AFI Part 1, 2:3)

Definition:

Jaṭāmāṃsyarka is a liquid preparation obtained by hydro-distillation of rhizomes of *Nardostachys jatamansi*.

Formulation Composition:

1	Jaṭāmāṃsī API	*Nardostachys jatamansi*	Rz.	1.0 kg
2	Jala API for soaking and for preparation of Arka	Potable Water	–	25.0 l

Method of preparation:

- Take Jaṭāmaṃsī of pharmacopoeial quality.
- Wash, dry and powder the ingredient and pass through 355 μm IS Sieve (sieve number 44) to obtain coarse powder.
- Place 1.0 kg of *Jaṭāmaṃsī* powder in a round bottom standard joint flask of 50 l capacity. Add 25.0 l of *Jala*.
- Attach the proper distillation assembly with double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts and continue the distillation to collect about 18.0 l of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Jaṭāmāṃsyarka is a liquid having a slight turbidity with a spicy, slightly pungent and lingering bitter taste.

Identification:

Thin layer chromatography:

Dissolve 0.1 ml of the oil obtained by hydro-distillation of the *Arka* under assay in 1 ml of *toluene* or in any suitable solvent. In a separate setup extract *Jaṭāmaṃsī* oil from *Jaṭāmaṃsī* API. Apply 4 μl each of the oil solutions on TLC plate and develop the plate to a distance of 8 cm using *toluene* (double run) as mobile phase. After development, allow the plate to dry in air and spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. Both the chromatograms show major spots at R_f 0.25 (bluish purple), 0.33 (blue), 0.42 (pink), 0.69 and 0.79 (both pinkish purple) in visible light.

Gas chromatography:

Carry out the gas chromatography analysis procedure using a 30 m fused silica capillary column walls coated with FFAP maintained at 90^0 for 2 min, then programmed at the rate of 7^0/min to 220^0 and detector at 260^0 and with a flow rate of carrier gas 1.5 ml/ min.

Inject separately 0.1µl of oil obtained by hydro-distillation of the crude drug as well as of the oil of the *Arka* under assay and, after 2 min. increase the temperature of the column to 220^0 at a rate of 7^0/min.

Both the chromatograms show major peaks at R_t 20.26, 21.61, 22.51 (corresponding to patchouli alcohol), 23.01, 24.06 and 26.22.

Physico-chemical parameters:

Specific gravity (20^0):	0.995 to 1.0,	Appendix 3.2

Assay:

Jaṭāmāṃsyarka contains 0.04 to 0.06 per cent v/v of essential oil, determined for a well stirred quantity of not less than 2.0 l. (Appendix2.2.11).

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Agnimāndya (digestive impairment); Arocaka (tastelessness); Mukhadaurgandhya (halitosis); Unmāda (mania/psychosis); Apasmāra (epilepsy)

Dose:

10 to 20 ml per day in divided doses

KĀKAMĀCYARKA

(AFI Part III, 2:1)

Definition:

Kākamācyarka is a liquid preparation obtained by hydro-distillation of fruits of *Solanum nigrum*.

Formulation Composition:

1	Kākamācī API	*Solanum nigrum*	Fr.	1.0 kg
2	Jala API for soaking and for preparation of Arka	Potable Water	–	30.0 l

Method of preparation:

- Take Kākamācī of pharmacopoeial quality.
- Wash, dry and powder the ingredient and pass through 355 μm IS Sieve (sieve number 44) to obtain coarse powder.
- Place 1.0 kg of *Kākamācī* powder in a round bottom standard joint flask of 50 l capacity. Add 30.0 l of *Jala*.
- Attach the proper distillation assembly, double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts control and continue the distillation to collect about 20.0 1 of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Kākamācyarka is a light greenish liquid with slight turbidity, taste slightly bitter.

Identification:

Thin layer chromatography:

Dissolve 0.1 ml of the oil obtained by hydro-distillation of the *Arka* in 1 ml of *toluene*. In a separate setup extract *Kākamācī* oil from *Kākamācī* API and dissolve 0.1 ml of oil in 1 ml of *toluene* or in any suitable solvent. Apply 2 μl each of the solution of oils on TLC plate separately and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate* (97: 3) as mobile phase. After development, allow the plate to dry in air and spray the plate with *acetic anhydride sulphuric acid reagent* followed by heating at 105^0 for about 10 min. Both the chromatograms show major spots at R_f 0.17 (yellowish Grey) and 0.63 (sky blue) in visible light.

Gas chromatography:

Carry out Gas chromatography using a 30 m fused silica capillary column walls coated with BP-10 maintained at 150^0 for 2 min programmed at the rate of 7^0/min to 200^0 again 15^0/17 min to 260^0 and detector at 300^0 and with a flow rate of carrier gas 1.5 ml/ min with injection port temperature 260^0.

Inject separately 0.1μl each of the oil obtained by hydro-distillation of the crude drug as well as of the *Arka* and programme the column as given above.

Both the chromatograms show major peaks at R_t 22.01, 23.53 and 23.75.

Physico-chemical parameters:

Specific gravity (20^0):	0.998 to 1.0,	Appendix 3.2

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Hṛdroga (heart diseases); Yakṛdroga (liver disorders); Śotha (inflammation); Chardi (emesis); Netraroga (disorders of eye)

Dose:

10 to 20 ml per day in divided doses

MUṆḌĪTIKĀRKA

(AFI Part III, 2:12)

Definition:

Muṇḍīitikārka is a liquid preparation obtained by hydro-distillation of flowers of *Sphaeranthus indicus*.

Formulation Composition:

1	Muṇḍīitikā (API)	*Sphaeranthus indicus*	Fl.	1.0 kg
2	Jala API for soaking and for preparation of Arka	Potable Water	–	35.0 l

Method of preparation:

- Take Muṇḍīitikā of pharmacopoeial quality.
- Wash, dry and powder the ingredient and pass through 355 μm IS Sieve (sieve number 44) to obtain coarse powder.
- Place 1.0 g of *Muṇḍīitikā* powder in a round bottom standard joint flask of 50 l capacity. Add 35.0 l of *Jala*.
- Attach the proper distillation assembly with double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts and continue the distillation to collect about 20.0 l of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Muṇḍīitikārka is a slightly turbid dark brownish liquid.

Identification:

Thin layer chromatography:

Dissolve 0.1 ml of the oil obtained by hydro-distillation of *Arka* in 1 ml of toluene or in any suitable solvent, similarly dissolve separately 0.1 ml of *Muṇḍīitikā* oil obtained by hydro-distillation of *Muṇḍīitikā* API. Apply 2 μl each of the solutions of the oil on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate* (97: 3) as mobile phase. After development, allow the plate to dry in air and spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min and examine under ultraviolet light at 254 nm. Both the chromatograms show major spots at R_f 0.16 (orange-red), 0.35 (red- brown) and 0.63 (saffron-red).

Gas chromatography:

Carry out the gas chromatography using 30 m fused silica capillary column having walls coated with BP-10 maintained at 90^0 for 2 min. then programmed at the rate of 7^0/min to 220^0, injection port temperature 240^0 and detector at 260^0 and with a flow rate of carrier gas 1.5 ml/min.

Inject 0.1 µl of oil obtained by hydro-distillation of the *Arka* and programme the column as given in preceeding paragraph. The chromatogram shows peaks at R_t 42.15 (all mixed), 42.46 and 42.75.

Physico-chemical parameters:

Specific gravity (20^0):	0.998 to1.0,	Appendix 3.2

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Plīhārti (splenic disorders), Meha (increased frequency and turbidity of urine), Vātārti (disorders due to vitiation of vāta doṣa), Tvakroga (skin diseases), Aruṃṣikā (dandroff)

Dose:

10 to 20 ml per day in divided dose

NĪLOḌUPUṢPĀRKA

(AFI Part III, 2:8)

Definition:

Nīloḍupuṣpārka is a liquid preparation obtained by hydro-distillation of the entire plant of *Borago officinalis*.

Formulation Composition:

1	Nīloḍupuṣpa (API)	*Borago officinalis*	Pl.	1.0 kg
2	Jala API for soaking and for preparation of Arka	Potable Water	–	30.0 l

Method of preparation:

- Take Nīloḍupuṣpa of pharmacopoeial quality.
- Wash, dry and powder the ingredient and pass through 355 μm IS Sieve (sieve number 44) to obtain coarse powder.
- Place 1.0 kg of *Nīloḍupuṣpa* powder in a round bottom standard joint flask of 50 l capacity. Add 30.0 l of *Jala*.
- Attach the proper distillation assembly with distillation and receiving heads, double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts and continue the distillation to collect about 15.0 l of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Nīloḍupuṣpārka is a slightly turbid pale liquid with a slightly spicy and sour taste.

Identification:

Thin layer chromatography:

Dissolve 0.1 ml of the oil obtained by hydro-distillation of *Arka* in 1 ml of *toluene* and 0.1 ml of authentic *Nīloḍupuṣpa* oil in 1 ml of *toluene* in any suitable solvent. Apply 2 μl each of the oil solution on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate* (97: 3) as mobile phase. After development, allow the plate to dry in air and spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. and examine under ultraviolet light at 254 nm. It shows major spots at R_f 0.17 (orange-red), 0.35 (red-brown) and 0.63 (saffron-red).

Gas chromatography:

Carry out the gas chromatography using a 30 m fused silica capillary column coated with BP-10 maintained at 150^0 for 2 min. then programmed at the rate of 7^0/ min. to 200^0 and again 15^0/17

min. to 260^0 and detector at 300^0 keeping flow rate of carrier gas 1.5 ml/min. with injection port temperature 280^0.

Inject separately 0.1 µl of oil obtained by hydro-distillation of the *Arka* and programme the column as given in preceding paragraph. The chromatogram shows major peaks at R_t 11.94, 13.07, 13.83, 14.11 and 23.14.

Physico-chemical parameters:

Specific gravity (20^0): 0.998 to1.0, Appendix 3.2

Other requirements:

Microbial limits: Complies with Appendix 2.4

Aflatoxins: Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Kapharoga (diseases due to vitiation of kapha doṣa), Kāsa (cough), Śvāsa (dyspnoea/asthma), Kaṇṭḥaroga (throat diseases)

Dose:

10 to 20 ml per day in divided doses

PARPAṬĀRKA

(AFI Part III, 2:9)

Definition:

Parpaṭārka is a liquid preparation obtained by hydro-distillation of the entire plant of *Fumaria vaillantii*.

Formulation Composition:

1	Parpaṭa API	*Fumaria parviflora* (= *F. vaillantii*)	Pl.	1.0 kg
2	Jala API for soaking and for preparation of Arka	Potable Water	–	30.0 l

Method of preparation:

- Take Parpaṭa of pharmacopoeial quality.
- Wash, dry and powder the ingredient and pass through 355 μm IS Sieve (sieve number 44) to obtain coarse powder.
- Place 1.0 kg of *Parpaṭa* powder in a round bottom standard joint flask of 50 l capacity. Add 30.0 1 of *Jala*.
- Attach the proper distillation assembly with distillation and receiving heads, double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts and continue the distillation to collect about 20.0 l of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Parpaṭārka is a slightly turbid light yellow liquid with a sweet odour.

Identification:

Thin layer chromatography:

Dissolve 0.1 ml of the oil obtained by hydro-distillation of the *Arka* under assay in 1 ml of *toluene* or in any suitable solvent. In a separate setup extract *Parpaṭa* oil from *Parpaṭa* API and dissolve 0.1 ml of the oil in 1ml of *toluene* or in any suitable solvent. Apply 2 μl each of the solution on TLC plate and develop the plate to a distance of 8 cm using *toluene* as mobile phase. After development, allow the plate to dry in air and 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 0.17 (orange-red.), 0.35 (red-brown) and 0.63 (saffron-red) in visible light.

Gas chromatography:

Carry out the gas chromatography using a 30 m fused silica capillary column, walls coated with BP-10 maintained at 150^0 for 2 min then programmed at the rate of 7^0/ min. to 200^0, again 15^0/17 min. to 260^0 and detector at 300^0 and with a flow rate of carrier gas 1.5 ml/min. with injection port temperature 280^0.

Inject 0.1 µl of oil obtained by hydro-distillation of the *Arka* under assay and programme the column as given in preceding paragraph. The chromatogram shows major peak at R_t 14.14, 23.67.

Physico-chemical parameters:

Specific gravity (20^0):	0.998 to 1.0,	Appendix 3.2

Assay:

Parpaṭārka contains not less than 0.02 per cent v/v of essential oil, determined for a well stirred quantity of not less than 2.0 l. (Appendix2.2.11).

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Kaphajvara (fever due to kapha doṣa); Tṛṣṇā (thirst); Atisāra (diarrhoea); Dāha (burning sensation); Raktapitta (bleeding disorders); Bhrama (vertigo)

Dose:

10 to 20 ml per day in divided doses

PUDĪNĀRKA

(AFI Part II, 2:1)

Definition:

Pudīnārka is a liquid preparation obtained by hydro-distillation of aerial parts of *Mentha viridis*.

Formulation Composition:

1	Pudīnā API	*Mentha viridis*	A. Pt.	1.0 kg
2	Jala API for soaking and for preparation of Arka	Potable Water	–	30.0 l

Method of preparation:

- Take Pudīnā of pharmacopoeial quality.
- Wash, dry and powder the ingredient and pass through 355 μm IS Sieve (sieve number 44) to obtain coarse powder.
- Place 1.0 kg of *Pudīnā* powder in a round bottom standard joint flask of 50 l capacity. Add 30.0 l of *Jala*.
- Attach the proper distillation assembly with distillation and receiving heads, double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts and continue the distillation to collect about 15.0 l of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Pudīnārka is a slightly turbid liquid with a pleasant mint odour; slightly bitter to taste, producing a cooling sensation.

Identification:

Thin layer chromatography:

Dissolve 0.1 ml of the oil obtained by hydro-distillation of the *Arka* under assay and 0.1 g each of 1-*menthol*, *menthone* and *menthyl acetate* in 1 ml of *toluene* each. Apply 4 μl of the solution of oil and 2 μl each of reference solutions on TLC plate. Develop the plate to a distance of 8 cm using *methanol*: *toluene* (1: 19) as mobile phase. After development, allow the plate to dry in air and 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 0.15 (maroon purple corresponding to *menthol*), 0.30 (bluish purple, corresponding to *menthone*) and 0.45 (dark maroon purple, corresponding to *menthyl acetate*) in visible light.

Gas chromatography:

Carry out the gas chromatography using a 30 m fused silica capillary column, walls coated with FFAP maintained at 90^0 for 2 min then programmed at the rate of 7^0/ min to 220^0, and detector at 260^0 and with a flow rate of carrier gas 1.5 ml/min with injection port temperature 220^0.

Inject 0.1 µl of oil obtained by hydro-distillation of the *Arka* under assay and programme the column as given in preceding paragraph. The chromatogram shows major peaks at R_t 6.37 (corresponding to *limonene*), 10.81 (corresponding to *menthone*), 11.3 (corresponding to *iso-menthone*), 12.82 (corresponding to *menthyl acetate*) and 13.97 (corresponding to 1-*menthol*).

Physico-chemical parameters:

Specific gravity (32^0): 0.9831 to 1.0, Appendix 3.2

Assay:

Pudīnārka contains 0.14 to 0.18 per cent v/v of essential oil, determined for a well stirred quantity of not less than 2.0 l. (Appendix2.2.11).

Other requirements:

Microbial limits: Complies with Appendix 2.4

Aflatoxins: Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Chardi (vomiting); Ajīrṇa (indigestion); Udaraśūla (abdominal pain); Agnimāndya (digestive impairment)

Dose:

10 to 20 ml per day in divided doses

PUNARNAVĀRKA

(AFI Part III, 2:10)

Definition:

Punarnavārka is a liquid preparation obtained by hydro-distillation of roots of *Boerhaavia diffusa*.

Formulation Composition:

1	Punarnavā (Rakta Punarnavā API)	*Boerhaavia diffusa*	Rt.	1.0 kg
2	Jala API for soaking and for preparation of Arka	Potable Water	–	35.0 l

Method of preparation:

- Take Punarnavā of pharmacopoeial quality.
- Wash, dry and powder the ingredient and pass through 355 μm IS Sieve (sieve number 44) to obtain coarse powder.
- Place 1.0 kg of *Punarnavā* powder in a round bottom standard joint flask of 50 l capacity. Add 35.0 l of *Jala*.
- Attach the proper distillation assembly, double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts and continue the distillation to collect about 20.0 l of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Punarnavārka is a slightly milky turbid liquid.

Identification:

Thin layer chromatography:

Dissolve 0.1 ml of the oil obtained by hydro-distillation of the *Arka* in 1 ml of *toluene*. In a separate setup extract *Punarnavā* oil from *Punarnavā* API and dissolve 0.1 ml of oil in 1 ml of *toluene* or in any suitable solvent. Apply 2 μl each of the solution of oils on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate* (97: 3) as mobile phase. After development, allow the plate to dry in air and spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min and examine under ultraviolet light at 254 nm. Both the chromatograms show major spot at R_f 0.63 (saffron red).

Gas chromatography:

Carry out the gas chromatography using a 30 m fused silica capillary column walls coated with BP-10 maintained at 150^0 for 2 min programmed at the rate of 7^0/min to 200^0 again 15^0/17 min to 260^0 and detector at 300^0 and with a flow rate of carrier gas 1.5 ml/min with injection port temperature 260^0.

Inject 0.1µl of oil obtained by hydro-distillation of the crude drug as well as oil of *Arka* and programme the column as given in preceding paragraph.

The chromatograms show major peaks at R_t 13.93 and 22.89.

Physico-chemical parameters:

Specific gravity (20^0):	0.999 to 1.0,	Appendix 3.2

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Jalodara (ascites), Śotha (inflammation), Netraroga (disorders of eyes); Grāhī ; Raktapitta (bleeding disorders)

Dose:

10 to 20 ml per day in divided doses

External use: 2-3 drops in each eye, 2/3 times a day

ŚATĀHVĀRKA

(AFI Part III, 2:14)

Definition:

Śatāhvārka is a liquid preparation obtained by hydro-distillation of fruits of *Anethum sowa*.

Formulation Composition:

1	Śatāhvā API	*Anethum sowa*	Fr.	1.0 kg
2	Jala API for soaking and for preparation of Arka	Potable Water	–	12.0 l

Method of preparation:

- Take Śatāhvā of pharmacopoeial quality.
- Wash, dry and powder the ingredient and pass through 355 μm IS Sieve (sieve number 44) to obtain coarse powder.
- Place 1.0 kg of *Śatāhvā* powder in a round bottom standard joint flask of 30 l capacity. Add 12.0 l of *Jala*.
- Attach the proper distillation assembly with double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts and continue the distillation to collect about 7.0 l of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Śatāhvārka is a slightly turbid liquid with pleasing flavour of sowa fruits and a sweetish spicy, slightly bitter taste.

Identification:

Thin layer chromatography:

Dissolve 0.1 ml of the oil obtained by hydro-distillation of the *Arka* under assay in 1 ml of *toluene* or in any suitable solvent. Dissolve separately 0.1 g of *carvone* in 1 ml of *toluene*. Apply 2 μl each of the solution of oil and reference solution on TLC plate. Develop the plate to a distance of 8 cm using *toluene* (double run) as mobile phase. After development, allow the plate to dry in air and 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 0.10 (blue purple), 0.32 (pink corresponding to *carvone*), 0.46 (pinkish blue), 0.55 (dark coke coloured) in visible light.

Gas chromatography:

Carry out the gas chromatography using a 30 m fused silica capillary column walls coated with BP-10 maintained at 90^0 for 2 min then programmed at the rate of 7^0/min to 230^0 for 5 min and detector at 260^0 and with a flow rate of carrier gas 1.5 ml/ min.

Inject separately 0.1 µl each of oil obtained by hydro-distillation of drug under assay and, *carvone* reference standard and programme the column as given above.

The chromatogram shows major peaks at R_t 5.2, 8.7, 10.4 and 11.5 (corresponding to *carvone*).

Assay:

Śatāhvārka contains 0.20 to 0.50 per cent v/v of essential oil, determined for a well stirred quantity of not less than 2.0 l. (Appendix 2.2.11).

Physico-chemical parameters:

Specific gravity (20^0):	0.991 to 0.998,	Appendix 3.2

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Jvara (fever); Vāta Kaphaja roga (diseases due to vāta and kapha doṣa); Vraṇaśūla (pain due to wound): Akṣiroga (diseases of eye), Agnimāndya (digestive impairment), Atisāra (diarrhoea)

Dose:

10 to 20 ml per day in divided doses

VANYĀJAMODĀRKA

(AFI Part III, 2:15)

Definition:

Vanyājamodārka is a liquid preparation obtained by hydro-distillation of fruits of *Trachyspermum roxburghianum*.

Formulation Composition:

1	Vanyājamodā (API)	*Trachyspermum roxburghianum*	Fr.	1.0 kg
2	Jala API for soaking and for preparation of Arka	Potable Water	–	20.0 l

Method of preparation:

- Take the raw materials of pharmacopoeial quality.
- Wash, dry and powder the ingredient and pass through 355 μm IS Sieve (sieve number 44) to obtain coarse powder.
- Place 1.0 kg of Vanyājamodā powder in a round bottom standard joint flask of 30 l capacity. Add 20.0 l of *Jala*.
- Attach the proper distillation assembly with distillation and receiving heads, double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts and continue the distillation to collect about 15.0 l of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Vanyājamodārka is a cloudy milky turbid liquid having characteristic spicy odour with slightly pungent lingering bitter taste.

Identification:

Thin layer chromatography:

Dissolve 0.1 ml of the oil obtained by hydro-distillation of the *Arka* under assay in 1 ml of *toluene* or in any suitable solvent. Dissolve 0.1 mg of each of *β-cycloavandulal* and *seslin* in 1 ml of *toluene* separately. Apply 2 μl of the solution of the oil and reference solutions on TLC plate. Develop the plate to a distance of 8 cm using *ethyl acetate*: *hexane* (2: 8) as mobile phase. After development, allow the plate to dry in air and 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 (greenish-blue corresponding to *sesline*), 0.44 (peach coloured, corresponding to *β-cycloavandulal*), 0.51 (pink), 0.58 (red-orange) and 0.67 (bluish-purple) in visible light.

Gas chromatography:

Carry out the gas chromatography using a 30 m fused silica capillary column walls coated with FFAP maintained at 90^0 for 2 min then programmed at the rate of 7^0/min to 220^0 with injection port at 240^0 and detector at 260^0 and with a flow rate of carrier gas 1.5 ml/min.

Inject separately 0.1 μl each of oil obtained by hydro-distillation of the crude drug as well as of the *Arka* under assay along with reference.

Both the chromatograms show major peaks at R_t 7.25 corresponding to *limonene*, 12.60 corresponding to *seslin*, 15.65 corresponding to *β-cycloavandulal* and 16.69 corresponding to *cadinene*.

Physico-chemical parameters:

Specific gravity (20^0): 0.995 to 0.998, Appendix 3.2

Assay:

Vanyājamodārka contains 0.20 to 0.30 per cent of essential oil, determined for a well stirred quantity of not less than 2.0 l. (Appendix2.2,11).

Other requirements:

Microbial limits: Complies with Appendix 2.4

Aflatoxins: Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Agnimāndya (digestive impairment); Ajīrṇa (dyspepsia); Bastiroga (urinary bladder disorder); Vātakapharoga (diseases due to vāta and kapha doṣa)

Dose:

10 to 20 ml per day in divided doses

YAVĀNYARKA

(AFI Part II, 2:2)

Definition:

Yavānyarka is a liquid preparation obtained by hydro-distillation of fruits of *Trachyspermum ammi*.

Formulation Composition:

1	Yavānī API	*Trachyspermum ammi*	Fr.	1.0 kg
2	Jala API for soaking and for preparation of Arka	Potable Water	–	12.0 l

Method of preparation:

- Take Yavānī of pharmacopoeial quality.
- Wash, dry and powder the ingredient and pass through 355 μm IS Sieve (sieve number 44) to obtain coarse powder.
- Place 1.0 kg of *Yavānī* powder in a round bottom standard joint flask of 20 l capacity. Add 12.0 l of *Jala*.
- Attach the proper distillation assembly with double surface condenser and receiving flask and enough circulating water to condense the distillate i.e. *Arka*.
- Place the flask on a heating mantle. Adjust the temperature control when boiling starts and continue the distillation to collect about 7.0 l of *Arka*.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Yavānyarka is a colourless slightly cloudy liquid with the characteristic odour of *Yavānī* with a bitter burning taste

Identification:

Thin layer chromatography:

Dissolve separately 0.1 ml of the oil obtained by hydro-distillation of the *Arka* under assay and 0.1 g of *thymol* in 1 ml of *toluene*. Apply 4 μl of the solution of oil and 2 μl of reference solution on TLC plate. Develop the plate to a distance of 8 cm using *ethyl acetate*: *hexane* (3: 17) as mobile phase. After development, allow the plate to dry in air and observe under ultraviolet light (256 nm).The plate shows one blue fluorescent spot at R_f 0.54 (corresponding to *thymol*). 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 0.32 (purple), 0.54 (maroon red, corresponding to *thymol*) and 0.64 (bluish Grey) in visible light.

Gas chromatography:

Carry out the gas chromatography using a 30 m fused silica capillary column walls coated with FFAP maintained at 90^0 for 2 min. then programmed at the rate of 7^0/min to 220^0 and detector at 260^0 and with a flow rate of carrier gas 1.5 ml/ min and injection port temperature at 260^0.

Inject separately 0.1 µl each of oil obtained by hydro-distillation of drug under assay and, γ-*terpinene*, *p-cymene* and *thymol* reference standards and programme the column as given above.

The chromatogram shows major peaks at R_t 7.96 (corresponding to γ-*terpinene*), 8.32 (corresponding to *p-cymene*) and 23.93 (corresponding to *thymol*).

Physico-chemical parameters:

Specific gravity (20^0): 0.995 to 0.999, Appendix 3.2

Assay:

Yavānyarka contains 0.20 to 0.60 per cent of essential oil, determined for a well stirred quantity of not less than 2.0 l. (Appendix 2.2.11).

Other requirements:

Microbial limits: Complies with Appendix 2.4

Aflatoxins: Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Agnimāndya (digestive impairment); Trikaśūla (pain in sacral region)

Dose:

10 to 20 ml per day in divided doses

AVALEHA

General Descripition:

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) *Kaṣāya* 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.

AŚVAGANDHĀDI LEHYA

(AFI Part-I, 3:2)

Definition:

Aśvagandhādi lehya is a semisolid preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Śarkarā API	Sugar	–	1.356 kg
2	Aśvagandhā API	*Withania somnifera*	Rt.	192 g
3	Sārivā (Śveta sārivā API)	*Hemidesmus indicus*	Rt.	192 g
4	Jīraka (Śveta jīraka API)	*Cuminum cyminum*	Fr.	192 g
5	Madhusnuhī API	*Smilax glabra* *	Rt. Tr.	192 g
6	Drākṣā API	*Vitis vinifera*	Dr. Fr.	192 g
7	Ghṛta (Goghṛta API)	Clarified butter from cow milk	–	226 g
8	Madhu API	Honey	–	452 g
9	Elā (Sūkṣmailā API)	*Elettaria cardamomum*	Sd.	24 g
10	Jala API	Potable Water	–	452 ml

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Wash, clean, dry the ingredient number 2 to 5 and 9 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder.
- Wash, clean *Drākṣā,* soak in water till fully swollen and crush to make paste.
- Take *Ghṛta* in a stainless steel vessel and heat till it becomes free from moisture.
- Add soaked *Drākṣā* to the *Ghṛta* and fry it to make moisture free, then add powdered ingredients and fry till it turns to a soft bolus.
- Add sugar to water and heat, maintaining the temperature between 80^0 and 90^0. After the sugar dissolves, filter the hot syrup through *muslin cloth*.
- Add the fried paste to the syrup, heat with constant stirring, maintaining the temperature between 90^0 and 100^0 and observe the mixture for formation of soft bolus, which does not disperse in water. Stop heating and allow to cool.
- Add honey when it comes to room temperature.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

A blackish brown, semisolid paste with a spicy pleasant odour and bitter astringent taste

* Official Substitute

Identification:

Thin layer chromatography:

Extract 5 g of *Avaleha* with 75 ml *n-hexane* (25 ml x 3) under reflux on a water bath for 30 min. Pool the extracts, filter and concentrate the filtrate 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* (9: 1) as mobile phase. After developing the plate, allow it to dry. Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. The plate shows major spots at R_f 0.10, 0.15, 0.26, 0.42 (all bluish grey), 0.54 and 0.70 (both purple) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 2 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 19 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 46 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 28 per cent,	Appendix 2.2.8
pH (1% aqueous solution):	4.7 to 5.0,	Appendix 3.3

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Raktavikāra (disorders of blood), Kṛśatva (emaciation/cachexia), Arśa (piles), Unamāda (psychosis), used as Balya (tonic), Rasāyana (rejuvenating agents), Vājīkara (aphrodisiac)

Dose:

6 to 12 g with milk

HARIDRĀ KHAṆḌA

(AFI Part I, 3:31)

Definition:

Haridrā Khaṇḍa consists of Khaṇḍa in the form of granules made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Haridrā API	*Curcuma longa*	Rz.	384 g
2	Haviṣ (Goghṛta API)	Clarified butter from cow milk	–	288 g
3	Khaṇḍa (Śarkarā API)	Sugar	Syrup	2.400 kg
4	Trikaṭu			
	a. Śuṇṭhī API	*Zingiber officinale*	Rz.	48 g
	b. Marica API	*Piper nigrum*	Fr.	48 g
	c. Pippalī API	*Piper longum*	Fr.	48 g
5	Trijāta			
	a. Tvak API	*Cinnamomum zeylanicum*	St. Bk.	48 g
	b. Sūkṣmailā API	*Elettaria cardamomum*	Sd.	48 g
	c. Tvakpatra API	*Cinnamomum tamala*	Lf.	48 g
6	Kṛmighna (Viḍaṅga API)	*Embelia ribes*	Fr.	48 g
7	Trivṛtā (Trivṛt API)	*Operculina turpethum*	Rt.	48 g
8	Triphalā			
	a. Harītakī API	*Terminalia chebula*	P.	48 g
	b. Bibhītaka API	*Terminalia bellerica*	P.	48 g
	c. Āmalakī API.	*Emblica officinalis*	P.	48 g
9	Keśara (Nāgakeśara API)	*Mesua ferrea*	Stmn.	48 g
10	Mustā API	*Cyperus rotundus*	Rt. Tr.	48 g
11	Lauha (Lauha bhasma (API))	Calcined Lauha	–	48 g
12	Kṣīra (Godugdha (API))*	Cow milk	–	

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Lauha* to prepare *Lauha bhasma*.
- Wash, clean, dry the ingredients numbered 4 to 10 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder and mix them all to a homogeneous mixture along with *Lauha bhasma*.
- Wash, clean, dry *Haridrā*, powder and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder.

* To prevent spoilage of the preparation, it is advisable not to use *Godugdha* as an ingredient in the Formulation; instead, the recommended dose of the Formulation should be taken alongwith *Godugdha* as *Sahapāna*.

- Fry *Haridrā* powder in *Ghṛta* maintaining the temperature between 80^0 to 90^0 till *Haridrā* turns brown and its typical smell emanates.
- Prepare sugar syrup and filter while hot through *muslin cloth*.
- Add the fried *Haridrā* to the syrup, heat with constant stirring, maintaining the temperature at about 90^0. Stop heating when a thick bolus is formed and allow to cool to 50^0.
- Add mixture of fine powders and mix thoroughly to prepare a homogeneous mixture. Allow to cool to 35^0.
- Pass the mixture through a granulator to obtain granules of suitable size. Allow the granules to cool to room temperature.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Yellowish to brown granular material with taste and odour characteristic of turmeric along with pungency

Identification:

Thin layer chromatography:

Extract 5 g of the formulation in 75 ml *methanol* (25 ml x 3) under reflux on a water bath for 30 min. Combine the extracts, filter and concentrate 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*: *methanol*: *formic acid* (3: 3: 0.8: 0.2) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light. The plate shows major spots at R_f 0.48, 0.57, 0.66, 0.76, 0.96 under 254 nm and fluorescent spots at R_f 0.13, 0.20, 0.30, 0.37, 0.71 (all blue); 0.55, 0.60,0.76 (all yellow) under 366 nm. Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 min. The plate shows major spots at R_f 0.65, 0.72, 0.80, 0.86, (all purple) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 3 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 14 per cent,	Appendix 2.2.5
Loss on drying:	Not more than 6 per cent,	Appendix 2.2.8
pH (10 % aqueous solution):	3.3 to 3.7,	Appendix 3.3
Total Sugar estimated as Reducing Sugar:	80 to 85 per cent,	Appendix 5.1
Total Iron:	Not more than 0.05 per cent,	Appendix 5.6

Assay:

Haridrā Khaṇḍa granular material contains 1.0 to 1.4 per cent of *curcumin* when determined by the following procedure.

Dissolve 4 mg accurately weighed *curcumin* in *methanol* in a 25 ml-volumetric flask and make up the volume. 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.

Apply 10 µl each of the standard solutions prepared above on precoated TLC plate. Develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *methanol* (5: 0.5: 1) as mobile phase. Scan the plate in the TLC scanner at a wave length 429 nm. Record the peak area under curve for a peak corresponding to *curcumin* and plot the calibration curve by plotting peak area *vs* concentration of *curcumin*.

Weigh about 5 g, accurately weighed Haridrā Khaṇḍa and extract with *methanol* (25 ml x 4). Filter, pool the filtrates, concentrate and make up the volume to 25 ml with *methanol* in a volumetric flask.

Apply 5 µl of the sample solution on TLC plate and carry out thin layer chromatography. Develop, dry and scan the plate as described in preceding paragraph for calibration curve of *curcumin*. Calculate the amount *curcumin* in the sample solution from the calibration of *curcumin*.

Other requirements:

Microbial limits: Complies with Appendix 2.4
Aflatoxins: Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed amber coloured glass containers, protected from light and moisture.

Therapeutic uses:

Śītapitta (urticaria); Kaṇḍū (itching); Visphoṭa (blister); Dadru (taeniasis); Udarda (urticaria); Koṭha (urticaria)

Dose:

6 g with milk

NĀRIKELA KHAṆḌA

(AFI Part I, 3:16)

Definition:

Nārikela Khaṇḍa is a Khaṇḍa preparation cut in the form of tabloid slices, using the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Nārikela API	*Cocus nucifera*	Enm.	192 g
2	Sarpi (Goghṛta API)	Clarified butter from cow milk	–	48 g
3	Khaṇḍa (Śarkarā API)	Sugar candy	–	192 g
4	Nārikela paya (Nārikela API)	*Cocus nucifera*	Tender Coconut water	768 ml
5	Dhanyāka (Dhānyaka API)	*Coriandrum sativum*	Fr.	3 g
6	Pippalī API	*Piper longum*	Fr.	3 g
7	Payoda (Mustā API)	*Cyperus rotundus*	Rz	3 g
8	Tugā (Vaṃśalocana API)	Bamboo manna	S. C.	3 g
9	Dvijīra			
	a. Śveta jīraka API	*Cuminum cyminum*	Fr.	3 g
	b. Kṛṣṇa jīraka API	*Carum carvi*	Fr.	3 g
10	Trijāta			
	a. Tvak API	*Cinnamomum zeylanicum*	St. Bk.	3 g
	b. Tvakpatra API	*Cinnamomum tamala*	Lf.	3 g
	c. Sūkṣmailā API	*Elettaria cardamomum*	Sd.	3 g
11	Ibhakeśara (Nāgakeśara API)	*Mesua ferrea*	Stmn.	3 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Wash, clean, dry the ingredients numbered 5 to 11 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder and mix them all to a homogeneous mixture.
- Cut ingredient number 1 of the Formulation Composition into small pieces and grind to a paste.
- Fry the paste in *Ghṛta* maintaining the temperature between 80^0 to 90^0 till it turns brown and its typical smell emanates.
- Strain *Nārikela paya* through a *muslin cloth*.
- Add sugar to *Nārikela paya* and heat, maintaining the temperature between 80^0 and 90^0. After the sugar dissolves, filter the hot syrup through *muslin cloth*.
- Add the fried paste to the syrup, heat with constant stirring, maintaining the temperature about 90^0 and observe the mixture for formation of soft bolus, which does not disperse in water. Stop heating and allow to cool to 50^0.
- Add mixture of fine powders and mix thoroughly to prepare a homogeneous blend.

- Spread the paste on a plate greased with *Ghṛta* and cut into small diamond shaped pieces. Allow to cool it to room temperature.
- Store in containers and pack them air-tight to protect from light and moisture.

Description:

Brown polygonal solid brittle pieces of various shapes and sizes, sweet with smell characteristic of coconut

Identification:

Thin layer chromatography:

Extract 20 g of the formulation powder with 50 ml of *methanol* by refluxing on a water bath. Filter the extract and concentrate to 10 ml and carry out thin layer chromatography. Apply 20 µl of the extract on a TLC plate and develop the plate to distance of 8 cm using *toluene*: *ethyl acetate*: *formic acid*: *methanol* (6: 6: 1.6: 1.6) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light. The plate shows major spots at R_f 0.24, 0.71, 0.78 under 254 nm and four light fluorescent spots at R_f 0.11, 0.75, 0.78 (all blue), 0.72 (red) under 366 nm. Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating at 105^0 for about 10 minutes. The plate shows major spots at R_f 0.19 (black), 0.66 (purple), 0.73 (brown), 0.78 (green) and 0.84 (purple) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 3.0 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 1.0 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 40 per cent,	Appendix 2.2.5
Loss on drying:	Not more than 8.0 per cent,	Appendix 2.2.8
pH (5 % aqueous solution):	4.5 to 5.50,	Appendix 3.3
Total Sugar estimated as Reducing Sugars:	46 to 52 per cent,	Appendix 5.1

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed amber coloured glass containers, protected from light and moisture.

Therapeutic uses:

Aruci (tastelessness); Vami (vomiting); Śūla (pain/colic); Amlapitta (hyperacidity); Raktapitta (bleeding disorder); Kṣata (wound); Kṣaya (Pthisis); Daurbalya (weakness)

Dose:

6 to 12 g to be chewed and swallowed with milk

CŪRṆA

General Description:

Drugs in the Formulation Composition of the particular *Cūrṇa* are collected, dried, powdered individually and passed through 180 μm IS Sieve (sieve number 85) to prepare a fine powder. They are mixed in the specified proportion and stored in well closed container.

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

Raja and *Kṣoda* are the synonyms for *Cūrṇa. Cūrṇas* may be of plant origin, or mixed with other ingredients. The following points are to be noted.

If metals / minerals are used, they are in the form of *bhasma* or *sindūra* 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 aromatic drugs like *Hiṅgu* [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.

Cūrṇas 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*.

CITRAKĀDI CŪRṆA

(AFI Part-I, 7:11)

Definition:

Citrakādi Cūrṇa is a powder preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Citraka API	*Plumbago zeylanica*	Rt.	12 g
2	Nāgara (Śuṇṭhī API)	*Zingiber officinale*	Rz.	12 g
3	Hiṅgu API	*Ferula foetida*	Exd.	12 g
4	Pippalī API	*Piper longum*	Fr.	12 g
5	Pippalījaṭā (Pippalīmūla API)	*Piper longum*	St.	12 g
6	Cavya API	*Piper retrofractum*	St.	12 g
7	Ajamodā API	*Apium leptophyllum*	Fr.	12 g
8	Marica API	*Piper nigrum*	Fr.	12 g
9	Svarjikā (Svarjīkṣāra (API))	Crude alkaline earth	–	6 g
10	Yavakṣāra API	*Hordeum vulgare*	Water soluble Ash of Pl.	6 g
11	Sindhu (Saindhava Lavaṇa (API))	Rock salt	–	6 g
12	Sauvarcala (Sauvarcala Lavaṇa (API))	Black salt	–	6 g
13	Viḍa Lavaṇa	Black salt*		6 g
14	Sāmudraka (Sāmudra Lavaṇa API)	Sea salt	–	6 g
15	Romaka Lavaṇa	Rock salt*		6 g
16	Mātuluṅga API - rasa	*Citrus medica*	Fr. juice	QS

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Hiṅgu* to prepare *Hiṅgu - Śuddha* (Appendix 6.2.8.15).
- Roast *Svarjikā kṣāra* and *Yava kṣāra* in a stainless steel pan on low flame till free from moisture.
- Roast coarsely powdered *Saindhava, Sauvarcala, Viḍa, Sāmudra* and *Romaka Lavaṇas* in a stainless steel pan on low flame till free from moisture, powder separately and pass through 180 μm IS Sieve (sieve number 85).
- Wash, clean, dry the ingredients numbered 1, 2 and 4 to 8 of the Formulation Composition and powder separately. The powders should completely pass through 355 μm IS Sieve (sieve number 44) and not less than 50 per cent pass through through 180 μm IS Sieve (sieve number 85).
- Weigh each ingredient separately and mix together. Pass the *cūrṇa* through 355 μm IS Sieve (sieve number 44) to obtain a homogenous blend.

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* Official Substitute

- Cut and squeeze the *Mātuluṅga* fruits and filter the juice through muslin cloth to obtain *Mātuluṅga rasa.*
- Soak the powder mixture in *Mātuluṅga rasa* in a ceramic vessel and dry under sunlight till the powder absorbs all the juice.
- After complete drying, grind and pass the *cūrṇa* through 355 μm IS Sieve (sieve number 44).
- Store in the container and pack it air-tight.

Description:

- Brown-coloured, smooth powder with pleasant odour, sour, spicy and pungent taste. The powder completely passes through 355 μm IS Sieve (sieve number 44) and not less than 50 per cent pass through 180 μm IS Sieve (sieve number 85).

Identification:

Microscopy:

Take about 2 g of *Curṇa*, and wash it with water thoroughly to remove salt without loss of *Curṇa*. Remove water and use the washed *Curṇa* for the following mounts: warm a few mg of material with chloral hydrate, wash and mount in glycerin; treat a few mg with iodine in potassium iodide solution and mount in glycerin; heat a few mg in 2 per cent aqueous potassium hydroxide, wash in water and mount in glycerin. Observe the following characters in the different mounts.

Tangentially elongated cork cells in surface view; tiers of ray parenchyma cells in tangential view; thin walled bifurcated fibres with sharp tip upto 500 μ in length **(Citraka);** abundant large simple oval shaped starch grains with eccentric hilum upto 60 μ in size, fragments of septate fibres **(Śuṇṭhī);** uniseriate multicellular trichome, stone cells with broad lumen **(Pippalī);** abundant simple and compound starch grains having 2-7 components round to oval with central hilum appearing like a point up to 28 μ in size **(Pippalīmūla);** parenchymatous tissue with prominent intercellular space; bordered barrel shaped pitted and scalariform vessels up to 350 μ in length and 140 μ in width; elongated sclereids with narrow lumen upto 600 μ in length **(Cavya);** epidermal tissue debris showing papillose and striated cells; fragments of epidermis with papillary outgrowth; fragment of yellowish brown vittae **(Ajamodā);** beaker shaped stone cells; spiral vessels; stone cells associated with parenchyma cells from hypodermis **(Marica)**. In addition general characteristics such as abundant perisperm cells from Marica and Pippalī, vessels members and stone cells are also present.

Thin layer chromatography:

Extract 4 g of formulation powder in 75 ml alcohol (25 ml x 3) under reflux on a water bath for 30 min. Filter the extracts, pool the filtrates, concentrate to 10 ml and carry out the thin layer chromatography. Apply 10 μl of extract on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate* (5: 4) 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, 0.23, 0.35 (all pale blue), 0.50, 0.67, 0.85 (all fluorescent blue) 0.58 (dark blue) and 0.76 (blue). Spray the plate with *vanillin-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. The plate shows

major spots at R_f 0.19, 0.26, 0.73, 0.86 (all pink), 0.36 (dark grey), 0.47 (yellow), 0.50 (green), 0.60, 0.95 (both violet) and 0.82 (grey) in visible light.

Chemical tests:

Dissolve 1 g of sample in 10 ml of *water* and filter. The filtrate complies with *Tests for Sulphates* (Appendix 5.13.5) and *Sulphides* (Appendix 5.13.8).

Dissolve 1 g of sample in 10 ml of N *hydrochloric acid* and filter. The filtrate complies with *Test for* Magnesium (Appendix 5.13.3).

Physico-chemical parameters:

Total Ash:	Not more than 34 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 3.2 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 11 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 41 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 8 per cent,	Appendix 2.2.8
pH (10 % aqueous solution):	4 to 5,	Appendix 3.3

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Arocaka (tastlessness), Āmajaśūla (intestinal colic), Grahaṇī (malabsorption syndrome), Gulma (abdominal lump), Agnimāndya (digestive impairment), Kaphadoṣa (vitiation of kapha doṣa)

Dose:

3 g with warm water

GHṚTA

General Description:

Ghṛtas are preparations in which the *Ghṛta* is boiled with prescribed liquid [*Svarasa*/*Kaṣāya* etc.] and fine paste [*Kalka*] of the drugs specified in the formulation composition. Unless specified otherwise *Ghṛta* means *Goghṛta.*

General Method of Preparation:

1. There are usually three essential components in the manufacture of *Ghṛta Kalpanā*.
   a. *Drava* [Any liquid medium as prescribed in the composition]
   b. *Kalka* [Fine paste of the specified drugs]
   c. *Sneha dravya* [Fatty medium - *Ghṛta*]

      and, occasionally,

   d. *Gandha dravya* [Perfuming agents]
2. Unless otherwise specified in the verse, if *Kalka* is one part by weight, *Ghṛta* 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 *Kvātha* or *Svarasa*, the ratio of *Kalka* should be one-sixth and one-eighth respectively to that of *Ghṛta.*

      If the *Drava dravya* is either *Kṣīra* or *Dadhi* or *Māṃsa rasa* or *Takra,* the ratio of *Kalka* should be one-eighth to that of *Ghṛta.*

      When flowers are advised for use as *Kalka*, it should be one-eighth to that of *Ghṛta*.
   b. Where the numbers of Drava-dravya are four or less than four, the total quantity should be four times to that of *Ghṛta.*
   c. Where the number of *Drava-dravyas* is more than four, each *drava* should be equal to that of *Ghṛta.*
   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 *Ghṛta*.
4. In general, the *Ghṛta* 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 throughout 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 *Ghṛta* appear.
6. The whole process of *Pāka* should be carried out on a mild to moderate flame.

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

    a. *Mṛdu Pāka*: In this stage, the *Kalka* looks waxy and when rolled between fingers, it rolls like lac without sticking. The *Ghṛta* 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 *Ghṛta.* The *Ghṛta* obtained at this stage is used for *Pāna* [Internal administration] and *Basti* [Enema].

    c. *Khara Pāka*: Further heating of the *Ghṛta*, leads to *Khara paka*. *Kalka* becomes brittle when rolled between fingers. The *Ghṛta* obtained at this stage is used only for *Abhyaṅga* [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. *Kṣīra* 2 Nights

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

The medicated *Ghṛta* will have the odour, colour and taste of the drugs used in the process.

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

SUKUMĀRA GHṚTA

(AFI Part-I, 6:44)

Definition:

Sukumāra ghṛta is a medicated preparation made with the ingredients in the Formulation Composition given below with mūrcchita Ghṛta as the basic ingredient.

Formulation Composition:

1	Punarnava (Rakta Punarnavā API)	*Boerhaavia diffusa*	Pl.	4.800 kg
2	Daśamūla			
	a. Bilva API	*Aegle marmelos*	Rt./St. Bk.*	480 g
	b. Śyonāka API	*Oroxylum indicum*	Rt./St. Bk.*	480 g
	c. Gambhāri API	*Gmelina arborea*	Rt./St. Bk.*	480 g
	d. Pāṭalā API	*Stereospermum suaveolens*	Rt./St. Bk.*	480 g
	e. Agnimantha API	*Premna integrifolia***	Rt./St. Bk.*	480 g
	f. Śālaparṇī API	*Desmodium gangeticum*	Pl.	480 g
	g. Pṛśniparṇī API	*Uraria picta*	Pl.	480 g
	h. Bṛhatī API	*Solanum indicum*	Pl.	480 g
	i. Kaṇṭakārī API	*Solanum surratense*	Pl.	480 g
	k. Gokṣura API	*Tribulus terrestris*	Pl.	480 g
3	Payasyā (Kṣīrakākolī API)	*Fritillaria roylei*	Sub. Rt.	480 g
4	Aśvagandhā API	*Withania somnifera*	Rt.	480 g
5	Eraṇḍa API	*Ricinus communis*	Rt.	480 g
6	Śatāvarī API	*Asparagus racemosus*	Rt. Tr.	480 g
7	Dvidarbhamūla			
	a. Darbha API	*Imperata cylindrica*	Rt.	480 g
	b. Kuśa API	*Desmostachya bipinnata*	Rt. Stck.	480 g
8	Śaramūla (Śara API)	*Saccharum bengalense* (= *S. munja*)	Rt. & Rt. Stck.	480 g
9	Kāśamūla (Kāśa API)	*Saccharum spontaneum*	Rt. Stck.	480 g
10	Ikṣumūla (Ikṣu API)	*Saccharum officinarum*	Rt. Stck.	480 g
11	Poṭagala API	*Typha elephantina*	Rt.	480 g
12	Jala API for decoction reduced to	Potable Water	–	49.152 l 6.144 l
13	Guḍa API	Jaggery	–	1.440 kg
14	Eraṇḍa taila (API)	*Ricinus communis*	Sd. oil	768 ml
15	Ghṛta (Goghṛta API)	Clarified butter from cow milk	–	1.536 kg
16	Payas (Godugdha (API))	Cow milk	–	1.536 kg
17	Kṛṣṇā (Pippalī API)	*Piper longum*	Fr.	96 g
18	Kṛṣṇāmūla (Pippalīmūla API)	*Piper longum*	St.	96 g
19	Saindhava (Saindhava Lavaṇa (API))	Rock salt	–	96 g
20	Yaṣṭī API	*Glycyrrhiza glabra*	Rt.	96 g

* Part actually used in the formulation

** Official Substitute

21	Madhūka API	*Madhuca indica*	Fl.	96 g
22	Mṛdvīkā (Drākṣā API)	*Vitis vinifera*	Dr. Fr.	96 g
23	Yavānī API	*Trachyspermum ammi*	Fr.	96 g
24	Nāgara (Śuṇṭhī API)	*Zingiber officinale*	Rz.	96 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Ghṛta* to prepare *mūrcchita Ghṛta* (Appendix 6.2.9.2).
- Treat *Eraṇḍa taila* to prepare *mūrcchita Eraṇḍa taila* (Appendix 6.2.9.1).
- Wash, clean, dry the ingredients numbered 1 to 11 of the Formulation Composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) (*kvātha dravya*).
- Add water for decoction to the *kvātha dravya* and soak for four hours, heat and reduce the volume to one-eighth. Filter through muslin cloth to obtain *kvātha*.
- Strain the *Godugdha* through *muslin cloth*.
- Wash, clean, dry the ingredients numbered 17, 18 and 20 to 24 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder. Roast coarsely powdered *Saindhava Lavaṇa* in a stainless steel pan on low flame till free from moisture, powder and pass through 180 μm IS Sieve (sieve number 85) (*Kalka dravya*).
- Transfer the powdered ingredients to wet grinder and grind with sufficient quantity of water to prepare homogeneous blend.
- Take *mūrcchita Ghṛta* in a stainless steel vessel and heat it mildly.
- Add increments of *kalka,* stir thoroughly while adding *Kvātha, Guḍa, Eraṇḍa taila* 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.
- Continue the process of heating next day. Constantly check the *Kalka* by rolling between the fingers.
- Stop the heating when the *kalka* easily rolls into a *varti* without sticking *(Madhyama pāka lakṣaṇa)* to the fingers. Expose the *varti* and *ghṛta* to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

A greenish yellow coloured, soft, low-melting medicated fat, unctuous to touch with a pleasant odour and astringent taste

Identification:

Thin layer chromatography:

Extract 5 g of formulation in 25 ml of *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 of the

extract on 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 of plate, allow it to dry in air. Spray the plate with *anisaldehyde sulphuric acid reagent* followed by heating it at 105^0 for about 10 min. It shows major spots at R_f 0.10, 0.19 (both green), 0.26, 0.38, 0.78 (all blue) and 0.88 (bluish black) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4618 to 1.4622,	Appendix 3.1
Specific gravity at 40^0:	0.796 to 0.884,	Appendix 3.2
Congealing point:	16^0 to 22^0	Appendix 3.4.2
Saponification value:	213 to 277,	Appendix 3.7
Iodine value:	32 to 34,	Appendix 3.8
Acid value:	Not more than 3,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Viḍvibandha (constipation); Udara (diseases of abdomen); Gulma (abdominal lump); Plīhā roga (splenic diseases); Vidradhi (abcess); Śopha (oedema); Yoniśūla (pain in female genital tract); Arśa (piles); Vṛddhi (hydrocoele); Vātavyādhi (diseases due to vāta doṣa); Vātarakta (gout)

Dose:

6 - 12 g per day in divided doses with warm water /milk

GUGGULU

General Description:

Guggulu is an oleoresin *(Niryāsa)* obtained from the plant *Commiphora wightii.* Preparations having the oleo-gum resin 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, *Mahiṣākṣa* and *Kanaka Guggulu* are usually preferred for medicinal preparations. *Mahiṣākṣa 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 kaṣāya,*
    c. *Nirguṇḍīpatra Svarasa* with *Haridrā Cūrṇa,*
    d. *Vāsāpatra Kaṣāya,*
    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 with the general tests for Tablets.

SAPTĀṄGA GUGGULU

(AFI Part III, 5:3)

Definition:

Saptāṅga Guggulu vaṭī is a preparation made with the ingredients in the Formulation Composition given below with Guggulu as the basic ingredient.

Formulation Composition:

1	Guggulu API - Śuddha	*Commiphora wightii*	O. R.	6 g
2	Triphalā			
	a. Harītakī API	*Terminalia chebula*	P.	1 g
	b. Bibhītaka API	*Terminalia belerica*	P.	1 g
	c. Āmalakī API	*Emblica officinalis*	P.	1 g
3	Vyoṣa			
	a. Śuṇṭhī API	*Zingiber officinale*	Rz.	1 g
	b. Marica API	*Piper nigrum*	Fr.	1 g
	c. Pippalī API	*Piper longum*	Fr.	1 g
4	Ājya (Ghṛta API)	Clarified butter from cow milk	–	QS

Method of preparation:

- Take all ingredients of the pharmacopoeial quality.
- Treat *Guggulu* to prepare *Guggulu - Śuddha* (Appendix 6.2.8.4).
- Wash, clean, dry the ingredients numbered 2 and 3 of the formulation composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder and mix them all to a homogeneous mixture.
- Crush weighed quantity of *Śuddha-Guggulu*, add fine powder of other mixed ingredients to it and pound well. Add *Ghṛta* 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 rolling machine to obtain cylindrical threads and cut them 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 *Ghṛta* or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight 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 it and add c*hloroform* (20 ml); stir for 10 min. thoroughly 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 *glycerin*. Clarify another few mg of the material with *chloral hydrate* and mount in 50 per cent *glycerin*. Take a few mg of washed material on glass slide, moisten it with alcoholic solution of *phloroglucinol*, allow to stand until nearly dry and mount in 1-2 drops of concentrated *hydrochloric acid*. Observe the following characters in different mounts.

Fragment of thick-walled epicarp cells in surface view several showing thin septa division, a few fibres crossing each other at right angles **(Harītakī)**; simple, short trichomes with a bulbous base, epicarp tissue showing cicatrices (**Bibhītaka**); fragments of polygonal parenchyma cells containing calcium oxalate crystals, abundant crushed parenchymatous large cells showing characteristic corner thickenings **(Āmalakī)**; large oval as well as circular starch grains, upto 75 μm in length, with hilum at its broader end, resin containing yellow parenchymatous cells, non-lignified septate fibres several showing dentation on one side owing to pressure exerted by adjacent parenchyma cells, short, spiral xylem vessels **(Śuṇṭhī)**; fragmented tissue from hypodermis, with groups of stone cells interspersed among parenchyma tissue, thick-walled polygonal stone cells from testa **(Marica)**; spindle-shaped sclerenchymatous cells with large lumen and pitted walls **(Pippalī)**; in general sclereids of various sizes and shapes are also present.

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 the extract, concentrate to 25 ml and carry out the thin layer chromatography. Apply 10 μl of 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 0.17, 0.35, 0.47 and 0.56 (all fluorescent blue) under 366 nm and at R_f 0.24, 0.32, 0.38, 0.44 (all 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 0.25 (yellow), 0.30 (red), and 0.38, 0.48 (both brown) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 6 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 24 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 38 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 13 per cent,	Appendix 2.2.8
pH (1 % aqueous solution):	3.3 to 3.5,	Appendix 3.3

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Nāḍīvraṇa (sinus); Duṣṭavraṇa (non-healing ulcer); Bhagandara (fistula-in-ano); Śūla (pain)

Dose:

3 g daily in divided doses

Anupāna:

Triphalā kvātha, Phalatrikādi kvātha, Uṣṇodaka

VARĀDI GUGGULU

(AFI Part III, 5:1)

Definition:

Varādi Guggulu vaṭī is a preparation made with the ingredients in the Formulation Composition given below with Guggulu as the basic ingredient.

Formulation Composition:

1	Varā			
	a. Harītakī API	*Terminalia chebula*	P.	4 g
	b. Bibhītaka API	*Terminalia belerica*	P.	4 g
	c. Āmalakī API	*Emblica officinalis*	P.	4 g
2	Nimba API	*Azadirachta indica*	St. Bk.	12 g
3	Arjuna API	*Terminalia arjuna*	St. Bk.	12 g
4	Aśvattha API	*Ficus religiosa*	St. Bk.	12 g
5	Khadira Sāra (Khadira API)	*Acacia catechu*	Wd. extract	12 g
6	Asana API	*Pterocarpus marsupium*	Ht. Wd.	12 g
7	Vāsaka (Vāsā API)	*Adhatoda zeylanica*	Rt.	12 g
8	Guggulu API - Śuddha	*Commiphora wightii*	O. R.	84 g

Method of preparation:

- Take all the ingredients of pharmacopoeial quality.
- Treat *Guggulu* to prepare *Guggulu -Śuddha* (Appendix 6.2.8.4).
- Wash, clean, dry the ingredients numbered 1 to 7 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder and mix them all to a homogeneous mixture.
- Crush weighed quantity of *Śuddha-Guggulu*, add fine powder of other mixed ingredients to it and pound well. Add *Ghṛta* 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 rolling machine to obtain cylindrical threads and cut them 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 *Ghṛta* or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

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

Identification:

Microscopy:

Take about 5 g of the sample, powder it and add c*hloroform* (20 ml); stir for 10 min thoroughly over a water-bath; pour out c*hloroform*. 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 another few mg with *chloral hydrate* and mount in 50 per cent *glycerin*. Take a few mg of washed material on glass slide, moisten it with alcoholic solution of *phloroglucinol*, allow to stand until nearly dry and mount in 1-2 drops of concentrated *hydrochloric acid*. Observe the following characters in different mounts.

Fragment of thick-walled epicarp cells in surface view several showing thin septa division, a few fibres crossing each other at right angles **(Harītakī)**; simple, short trichomes with a bulbous base, epicarp tissue showing cicatrices (**Bibhītaka**); fragments of polygonal parenchyma cells containing calcium oxalate crystals, abundant crushed parenchymatous large cells showing characteristic corner thickenings **(Āmalakī)**; groups of parenchymatous cells containing isolated prisms of calcium oxalate crystals, large groups of well developed long thick walled lignified fibres associated with phloem elements **(Nimba);** idioblasts upto 600µm or more in size, containing abundant prisms and rhombs of calcium oxalate crystals, crystal fibres associated with phloem fibres, cells containing rosette crystals of calcium oxalate, parenchyma cells from cortical tissue containing rosette crystals **(Arjuna)**; groups of fibres associated with phloem tissue, but non lignified, thin walled along with thick walled phloem parenchyma containing prismatic crystals of calcium oxalate, crystal fibres from phloem, with prismatic crystals of calcium oxalate in each cell **(Aśvattha)**; xylem vessels filled with tyloses, associated with tracheids and fibre tracheids with thick wall, simple pits and narrow lumen **(Asana);** tissue from cortex with group of rectangular stone cells showing distinct pits and pit canals, vessel group with simple pits and without tyloses, cortical tissue with several cells showing yellow contents **(Vāsā)**; in general abundant dark brownish tissues from rhytidoma, associated with stone cells, abundant starch grains, isolated and compound within parenchymatous cells, abundant loose crystals of calcium oxalate in the form of prisms, rhombs and rosettes are also present.

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 the extract, concentrate to 25 ml and carry out the thin layer chromatography. Apply 10 µl of 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 0.17, 0.35, 0.41 and 0.56 (all fluorescent blue) under 366 nm and at R_f 0.32, 0.37 (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 0.16, 0.38, 0.48 (all brown) and 0.30 (red) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 12 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 4.0 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 18 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 29 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 14 per cent,	Appendix 2.2.8
pH (1 % aqueous solution):	3.5 to 4.2,	Appendix 3.3

Other requirements:

Microbial limits: Complies with Appendix 2.4
Aflatoxins: Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Upadaṃśa (syphilis/soft chancre); Raktadoṣa (blood disorders); Duṣṭavraṇa (non-healing ulcer)

Dose:

2 g daily in divided doses

Anupāna:

Triphalā kvātha, Mañjiṣṭhādi kvātha, Uṣṇodaka

VIḌAṄGĀDI GUGGULU

(AFI Part III, 5:2)

Definition:

Viḍaṅgādi Guggulu vaṭī is a preparation made with the ingredients in the Formulation Composition given below with Guggulu as the basic ingredient.

Formulation Composition:

1	Viḍaṅga API	*Embelia ribes*	Fr.	60 g
2	Triphalā			
	a. Harītakī API	*Terminalia chebula*	P.	20 g
	b. Bibhītaka API	*Terminalia belerica*	P.	20 g
	c. Āmalakī API	*Emblica officinalis*	P.	20 g
3	Vyoṣa			
	a. Śuṇṭhī API	*Zingiber officinale*	Rz.	20 g
	b. Marica API	*Piper nigrum*	Fr.	20 g
	c. Pippalī API	*Piper longum*	Fr.	20 g
4	Guggulu API - Śuddha	*Commiphora wightii*	O. R.	180 g
5	Sarpi (Goghṛta API)	Clarified butter from cow milk	–	QS

Method of preparation:

- Take all the ingredients of pharmacopoeial quality.
- Treat *Guggulu* to prepare *Guggulu - Śuddha* (Appendix 6.2.8.4).
- Wash, clean, dry the ingredients numbered 1 to 3 of the formulation composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder and mix them all to a homogeneous mixture.
- Crush weighed quantity of *Śuddha-Guggulu*, add fine powder of other mixed ingredients to it and pound well. Add *Ghṛta* 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 rolling machine to obtain cylindrical threads and cut them 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 *Ghṛta* or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

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

Identification:

Microscopy:

Take about 5 g of the sample, powder it and add c*hloroform* (20 ml); stir for 10 min. thoroughly 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 *glycerin*. Clarify another few mg of the washed material with *chloral hydrate* and mount in 50 per cent *glycerin*. Take a few mg of washed material on glass slide, moist it with alcoholic solution of *phloroglucinol*, allow to stand until nearly dry and mount in 1-2 drops of concentrated *hydrochloric acid*. Observe the following characters in different mounts.

Fragment of thick-walled epicarp cells in surface view several showing thin septa division, a few fibres crossing each other at right angles **(Harītakī)**; simple, short trichomes with a bulbous base, epicarp tissue showing cicatrices (**Bibhītaka**); fragments of polygonal parenchyma cells containing calcium oxalate crystals, abundant crushed parenchymatous large cells showing characteristic corner thickenings **(Āmalakī)**; large oval as well as circular starch grains, upto 75 μm in length, with hilum at its broader end, resin containing yellow parenchymatous cells, non-lignified septate fibres several showing dentation on one side owing to pressure exerted by adjacent parenchyma cells, short, spiral xylem vessels **(Śuṇṭhī)**; fragmented tissue from hypodermis, with groups of stone cells interspersed among parenchyma tissue, thick-walled polygonal stone cells from testa **(Marica)**; spindle-shaped sclerenchymatous cells with large lumen and pitted walls **(Pippalī)**; stone cell layers with prominent pits and narrow lumen from testa, lignified scelerieds with broad lumen and pitted walls from testa layers, associated with parenchymatous cells containing prisms of calcium oxalate **(Viḍaṅga);** in general sclereids of various sizes and shapes are also seen.

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 the extract, concentrate to 25 ml and carry out the thin layer chromatography. Apply 10 μl of 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 0.11, 0.27, 0.33 and 0.48 (all fluorescent blue) under 366 nm and at R_f 0.17, 0.26, 0.32, 0.38 (all 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 0.23 (red), 0.33 (black) and 0.43 (brown) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 6 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 23 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 30 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 13 per cent,	Appendix 2.2.8
pH (1 % aqueous solution):	3.0 to 4.0,	Appendix 3.3

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Duṣṭa vraṇa (non-healing ulcer); Apacī (chronic lymphadenopathy/scrofula); Meha (excessive flow of urine); Kuṣṭha (diseases of skin); Nāḍīvraṇa (sinus)

Dose:

12 g daily in divided doses

Anupāna:

Triphalā kvātha, Śigru kvātha, Madhu, Uṣṇodaka

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* [Fatty medium -*Taila*]

    and, occasionally,

    d. *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 *Kṣīra* or *Dadhi* or *Māṃsa 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* appear.
7. The whole process of *Pāka* should be carried out on a mild to moderate flame.
8. Three stages of *Pāka* are specified for therapeutic purposes.
    a. *Mṛdu 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 *Pāna* [Internal administration] and *Basti* [Enema].
    c. *Khara Pāka*: Further heating of the *Taila*, leads to *Khara Pāka*. *Kalka* becomes brittle when rolled in between fingers. The *Taila* obtained at this stage is used only for *Abhyaṅga* [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. *Kṣīra* 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.

AṆU TAILA

(AFI Part I, 8:1)

Definition:

Aṇu Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Jīvantī API	*Leptadenia reticulata*	Rt.	28 g
2	Jala (Hrīvera API)	*Coleus vettiveroides*	Rt.	28 g
3	Devadāru API	*Cedrus deodara*	Ht. Wd.	28 g
4	Jalada (Mustā API)	*Cyperus rotundus*	Rz.	28 g
5	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	28 g
6	Sevya (Uśīra API)	*Vetiveria zizanioides*	Rt.	28 g
7	Gopī (Śveta Sārivā API)	*Hemidesmus indicus*	Rt.	28 g
8	Hima (Śveta Candana API)	*Santalum album*	Ht. Wd.	28 g
9	Dārvī (Dāruharidrā API)	*Berberis aristata*	St.	28 g
10	Madhuka (Yaṣṭī API)	*Glycyrrhiza glabra*	Rt.	28 g
11	Plava (Kaivarta Mustā (API))	*Cyperus scariosus*	Rz.	28 g
12	Agaru API	*Aquilaria agallocha*	Ht. Wd.	28 g
13	Varī (Śatāvarī API)	*Asparagus racemosus*	Rt.	28 g
14	Puṇḍrāhva (Prapauṇḍarīka API)	*Nelumbo nucifera*	Fl.	28 g
15	Bilva API	*Aegle marmelos*	Rt.*/ St. Bk.	28 g
16	Utpala API	*Nymphaea stellata*	Fl.	28 g
17	Dhāvanīdvaya			
	a. Bṛhatī API	*Solanum indicum*	Pl.	28 g
	b. Kaṇṭakārī API	*Solanum surratense* (= *S. xanthocarpum*)	Pl.	28 g
18	Surabhi (Rāsnā API)	*Alpinia officinarum***	Rz.	28 g
19	Sthirādvaya			
	a. Śālaparṇī API	*Desmodium gangeticum*	Pl.	28 g
	b. Pṛśniparṇī API	*Uraria picta*	Pl.	28 g
20	Kṛimihara (Viḍaṅga API)	*Embelia ribes*	Fr.	28 g
21	Patra (Tvakpatra API)	*Cinnamomum tamala*	Lf.	28 g
22	Truṭi (Sūkṣmailā API)	*Elettaria cardamomum*	Sd.	28 g
23	Reṇukā API	*Vitex negundo*	Sd.	28 g
24	Kamalakiñjalka (Kamala API)	*Nelumbo nucifera*	Adr.	28 g
25	Jala API for decoction	Potable Water	–	72.800 l
	reduced to			7.280 l
26	Drugs 1-24 for Kalka			122 g

* Actual part used in the formulation

** Official Substitute

27	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	728 ml
28	Ājadugdha (Ajādugdha API)	Goat milk	–	QS*

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Wash, clean, dry the ingredients numbered 1 to 24 of the Formulation Composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) (*kvātha dravya*).
- Divide the *kvātha dravya* in 10 equal parts and store separately. Add water for decoction 10 times to one part of *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-tenth. Filter through *muslin cloth* to obtain *kvātha*.
- Wash, clean, dry the drugs under ingredient number 26 *(kalka dravya)* of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder. Transfer the powdered ingredients to wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *mūrcchita Tila taila* in a stainless steel vessel and heat it.
- Add increments of *kalka*, stir thoroughly while adding one part of *kvātha*.
- Heat with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Stop the heating when the *kalka* gets separated at the bottom of the vessel in the form of loose paste (*mṛdu pāka lakṣaṇa*) and at the appearance of froth (*phenodgama*) over the oil. Allow to stand overnight.
- Repeat the process for nine more times each day adding one part of freshly prepared *kvātha.* In last i.e. 10^{th} *pāka, a*long with the *kvātha,* add *Ajādugdha* .
- On the last day, constantly check the *kalka* by rolling between the fingers. Stop the heating when the *kalka* easily rolls into a *varti* without sticking *(madhyama pāka lakṣaṇa)* to the fingers and at the appearance of froth (*phenodgama*) over the oil. Expose the *varti* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, reddish brown in colour with characteristic odour

Identification:

Thin layer chromatography:

Shake 1 ml of formulation with 10 ml of *methanol.* Allow the mixture to stand till the two layers separate. Separate the methanolic layer, filter and carry out the thin layer chromatography. Apply 5 μl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *chloroform*: *methanol* (8: 0.5: 0.5: 0.2) as mobile phase. Spray the plate with 10 per cent

* equal to Taila obtained after 9^{th} Pāka

methanolic sulphuric acid followed by heating at 105^0 for about 10 min. It shows spots at R_f 0.15, 0.48, 0.60, 0.73 and 0.81 (all brown).

Physico-chemical parameters:

Refractive index at 40^0:	1.4646 to 1.4659,	Appendix 3.1
Specific gravity at 40^0:	0.760 to 0.771,	Appendix 3.2
Saponification value:	188 to 200,	Appendix 3.7
Iodine value:	88 to 106,	Appendix 3.8
Acid value:	Not more than 3,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Tvakraukṣya (dryness of skin); Palita (greying of hair); Ūrdhvajatrugata roga (diseases of head and neck); Skandha śuṣkatā (emaciation of shoulder); Grīvā śuṣkatā (wasting in cervical region); Vakṣa śuṣkatā (emaciation of chest muscles)

Dose:

5 to 10 drops per nostril as Nasya

APĀMĀRGA KṢĀRA TAILA

(AFI Part II, 8:1)

Definition:

Apāmārga Kṣāra Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with Tila taila as the basic ingredient.

Formulation Composition:

1	Mārga Kṣāra (Apāmārga Kṣāra API)	*Achyranthes aspera*	Water soluble ash of Pl.	16 parts
2	Jala API	Potable Water	–	96 parts
3	Apāmārga API	*Achyranthes aspera*	Pl.	6 parts
4	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	24 parts

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Add 6 parts of water to 1 part of *Kṣāra* (Appendix 6.2.3), and dissolve completely (*Kṣāra jala*).
- Wash, clean, dry the ingredient number 3 of the Formulation Composition, powder and pass through 180 μm IS Sieve (sieve number 85) (*kalka dravya*).
- Transfer the powder to wet grinder and grind with sufficient quantity of water to prepare homogenous blend (*kalka*).
- Take *mūrcchita Tila Taila* in a stainless steel vessel and heat it.
- Add increments of *kalka*. Stir thoroughly while adding the *Kṣāra jala*.
- 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.
- Continue the process of heating intermittently over a period of three days. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* breaks down into pieces on attempting to form a *varti* (*khara pāka lakṣaṇa*). Expose the *kalka* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, pink in colour

Identification:

Thin layer chromatography:

Shake 1 ml of formulation with 10 ml of methanol and keep the mixture over night with occasional shakings. Allow the two layers to separate 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 *dichloromethane*: *toluene*: *methanol* (7: 2: 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *Liebermann Burchard reagent* followed by heating at 105^0 for about 10 min and examine under ultraviolet light (366 nm). It shows major spots at R_f 0.45 (light purple), 0.60 (light blue), 0.65 (fluorescent blue) and 0.80 (cream).

Physico-chemical parameters:

Refractive index at 40^0:	1.4600 to 1.4805,	Appendix 3.1
Specific gravity at 40^0:	0.895 to 0.924,	Appendix 3.2
Saponification value:	182 to 202,	Appendix 3.7
Iodine value:	100 to 110,	Appendix 3.8
Acid value:	Not more than 3.0,	Appendix 3.9
Peroxide value:	Not more than 3,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Karṇanāda (tinnitus); Bādhirya (deafness)

Dose:

Ear drops - 2 to 5 drops in each ear once or twice a day

ARIMEDĀDI TAILA

(AFI Part I, 8:2)

Definition:

Arimedādi Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Khadira API	*Acacia catechu*	Wd.	9.600 kg
2	Arimedavalka (Arimeda API)	*Acacia leucophloea*	St. Bk.	4.800 kg
3	Jala API for decoction	Potable Water	–	49.152 l
	reduced to			12.288 l
4	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	3.072 l
5	Sevya (Uśīra API)	*Vetiveria zizanioides*	Rt.	12 g
6	Ambu (Hrīvera API)	*Coleus vettiveroides*	Rt.	12 g
7	Pattaṅga API	*Caesalpinia sappan*	Ht. Wd.	12 g
8	Gairika API- Śuddha	Red ochre	–	12 g
9	Candanadvaya			
	a. Śveta candana API	*Santalum album*	Ht. Wd.	12 g
	b. Rakta candana API	*Pterocarpus santalinus*	Ht. Wd.	12 g
10	Rodhra (Lodhra API)	*Symplocos racemosa*	St. Bk.	12 g
11	Puṇḍrāhva (Prapauṇḍarīka API)	*Nelumbo nucifera*	Fl.	12 g
12	Yaṣṭyāhva (Yaśṭī API)	*Glycyrrhiza glabra*	Rt.	12 g
13	Lākṣā (API)	*Lacca laccifera*	Secretion of Lac insect	12 g
14	Añjanadvaya			
	a. Rasāñjana (API)	*Berberis aristata*	St. Ext.	12 g
	b. Sauvīrāñjana (API) - Śuddha	*Lead sulphide*	–	12 g
15	Dhātakī API	*Woodfordia fruticosa*	Fl.	12 g
16	Kaṭphala API	*Myrica esculenta*	St. Bk.	12 g
17	Dviniśā			
	a. Haridrā API	*Curcuma longa*	Rz.	12 g
	b. Dāruharidrā API	*Berberis aristata*	St.	12 g
18	Triphlā			
	a. Harītakī API	*Terminalia chebula*	P.	12 g
	b. Bibhītaka API	*Terminalia belerica*	P.	12 g
	c. Āmalakī API	*Emblica officinalis*	P.	12 g
19	Caturjāta			
	a. Tvak API	*Cinnamomum zeylanicum*	St. Bk.	12 g
	b. Sūkṣmailā API	*Elettaria cardamomum*	Sd.	12 g
	c. Tvakpatra API	*Cinnamomum tamala*	Lf.	12 g
	d. Nāgakeśara API	*Mesua ferrea*	Stmn.	12 g

20	Joṅgaka (Agaru API)	*Aquilaria agallocha*	Ht. Wd.	12 g
21	Musta (Mustā API)	*Cyperus rotundus*	Rz.	12 g
22	Mañjiṣṭhā API	*Rubia cordifolia*	St.	12 g
23	Nyagrodhapraroha (Nyagrodhajaṭā API)	*Ficus benghalensis*	A. Rt.	12 g
24	Māṃsī (Jaṭāmāṃsī API)	*Nardostachys jatamansi*	Rz./ Rt.	12 g
25	Yavāsaka API	*Alhagi pseudalhagi*	Pl.	12 g
26	Padmaka API	*Prunus cerasoides*	Ht. Wd.	12 g
27	Aileya (Elavāluka API)	*Prunus avium*	St. Bk.	12 g
28	Samaṅgā (Lajjālu API)	*Mimosa pudica*	Pl.	12 g
29	Jātīpatrikā (Jātīphala API)	*Myristica fragrans*	Ar.	48 g
30	Jātīphala API	*Myristica fragrans*	Sd.	48 g
31	Lavaṅga API	*Syzygium aromaticum*	Fl. Bd.	48 g
32	Kaṅkolikā (Kaṅkola API)	*Piper cubeba*	Fr.	48 g
33	Karpūra API	*Cinnamomum camphora*	Subl. Ext. of A. Pt.	192 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Treat *Gairika* to prepare *Gairika - Śuddha* (Appendix 6.2.8.2) and *Sauvirāñjana* to prepare *Sauvīrāñjana - Śuddha* (Appendix 6.2.8.18).
- Wash, clean, dry the ingredients numbered 1 and 2 of the Formulation Composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) (*kvātha dravya*).
- Add water for decoction to the *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *kvātha*.
- Wash, dry the ingredients numbered 5 to 7, 9 to 13 and 15 to 32 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder.
- Transfer the powdered ingredients to wet grinder alongwith *Gairika - Śuddha*, *Rasāñjana* and *Sauvīrāñjana - Śuddha*, and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *mūrcchita Tila taila* in a stainless steel vessel and heat it.
- 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.
- Continue the process of heating intermittently over a period of three days. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* easily rolls into a *varti* without sticking *(Madhyama pāka lakṣaṇa)* to the fingers and at the appearance of froth (*phenodgama*) over the oil. Expose the *varti* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Powder *Karpūra*, pass through 355 μm IS Sieve, add to the oil and mix homogeneously.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, yellowish red in colour with a pleasant odour

Identification:

Thin layer chromatography:

a) Shake 1 ml of formulation with 10 ml of *methanol* for 10 min and keep the mixture for 12 h at 37^0. Filter and carry out thin layer chromatography. Apply 3 µl of the extract on a TLC plate. Develop the plate up to a distance of 8 cm using *toluene*: *ethyl acetate* (9: 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with10 per cent *methanolic sulphuric acid reagent* followed by heating at 105^0 for about 10 min. The plate shows major spots at R_f 0.16, 0.22 (both faint brown), 0.30, 0.60 (both yellow) 0.35 (faint purple), 0.42 (light purple), 0.48 (light yellow), 0.74 (light brown), 0.86 (brown) in visible light.

b) Detection of Eugenol:

Extract 0.5 ml of formulation with 10 ml of *chloroform* for 15 min and filter.

Dissolve 1 mg of *eugenol* in 10 ml of *chloroform.*

Apply 5 µl each of the sample extract and *eugenol* solution on TLC plate and develop the plate to 8 cm using *toluene*: *chloroform*: *acetone* (3: 5: 0.2) as mobile phase. After development, allow the plate to dry in air, spray *anisaldehyde reagent* followed by heating at 105^0 for about10 min. The plate shows a spot at R_f 0.62 (brown corresponding to *eugenol*) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4646 to 1.4665,	Appendix 3.1
Specific gravity at 40^0:	0.8123 g to 0.839,	Appendix 3.2
Saponification value:	180 to 190,	Appendix 3.7
Iodine value:	95 to 105,	Appendix 3.8
Acid value:	Not more than 3,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Mukha roga (diseases of mouth), Danta roga (diseases of tooth), Nāsā roga (diseases of nose)

Dose:

Nasya: 5 to 10 drops per nostril;
External use: for Kavalagraha (gargling), local application in buccal cavity and Śirodhārā

ASANABILVĀDI TAILA

(AFI Part I, 8:3)

Definition:

Asanabilvādi Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Asana API	*Pterocarpus marsupium*	Ht. Wd.	384 g
2	Bilva API	*Aegle marmelos*	Rt.* /St. Bk.	384 g
3	Balā API	*Sida cordifolia*	Pl.	384 g
4	Amṛta (Guḍūcī API)	*Tinospora cordifolia*	St.	384 g
5	Jala API for decoction	Potable Water	–	12.288 l
	reduced to			3.072 l
6	Madhuka (Yaṣṭī API)	*Glycyrrhiza glabra*	Rt.	25.6 g
7	Nāgaraka (Śuṇṭhī API)	*Zingiber officinale*	Rz.	25.6 g
8	Triphalā			
	a. Harītakī API	*Terminalia chebula*	P.	25.6 g
	b. Bibhītaka API	*Terminalia bellirica*	P.	25.6 g
	c. Āmalakī API	*Emblica officinalis*	P.	25.6 g
9	Payas (Godugdha (API))	Cow milk	–	768 ml
10	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	768 ml

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Wash, clean, dry the ingredients numbered 1 to 4 of the Formulation Composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) (*kvātha dravya*).
- Add water for decoction to the *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *kvātha*.
- Wash, dry the ingredients numbered 6 to 8 *(kalka dravya)* of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder.
- Transfer the powdered ingredients to wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *mūrcchita Tila taila* in a stainless steel vessel and heat it.
- 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.

* Part actually used in the formulation

- Next day, add *Godugdha* and continue the process of heating. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* easily rolls into a *varti* without sticking *(Madhyama pāka lakṣaṇa)* to the fingers and at the appearance of froth (*phenodgama*) over the oil. Expose the *varti* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, brown in colour with the characteristic odour of sesame oil

Identification:

Thin layer chromatography:

Shake 2 g of formulation with 10 ml of *toluene* for 10 min and keep the mixture for 12 h at 37^0. Filter and dilute the extract in *toluene* in the proportion of 1: 4. Apply 5 µl of the diluted extract on TLC plate. Develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *methanol*: *glacial acetic acid* (6: 0.5: 0.2: 0.1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *Liebermann Burchard reagent* followed by heating at 105^0 for about 10 min. The plate shows major spots at R_f 0.41, 0.47, 0.58, 0.67 and 0.77 (all brown) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4646 to 1.4665,	Appendix 3.1
Specific gravity at 40^0:	0.920 to 0.931,	Appendix 3.2
Saponification value:	180 to 190,	Appendix 3.7
Iodine value:	100 to 110	Appendix 3.8
Acid value:	Not more than 3,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Nayana roga (diseases of the eye); Karṇa roga (diseases of the ear); Śiroroga (diseases of head)

Dose:

External use - for Abhyaṅga (massage on whole body)
Nasya - 2 to 4 drops per nostril once or twice a day
Eye drops - 2 to 4 drops once or twice a day
Ear drops - 5 to 10 drops once or twice a day

BALĀ TAILA

(AFI Part I, 8:33)

Definition:

Balā Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Balā (API)	*Sida cordifolia*	Rt.	4.800 kg
2	Chinnaruhā (Guḍūcī API)	*Tinospora cordifolia*	St.	1.200 kg
3	Rāsnā API	*Alpinia officinarum**	Rz.	0.600 kg
4	Jala API for decoction	Potable Water	–	30.720 l
	reduced to			3.072 l
5	Dadhimastu (Godadhi (API))	Whey from curd of cow milk	–	3.072 l
6	Ikṣu Niryāsa (Ikṣu API)	*Saccharum officinarum*	St. juice	3.072 l
7	Śukta (Kāñjika (API))	Sour gruel	–	3.072 l
8	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	3.072 l
9	Ājapaya (Ajādugdha (API))	Goat milk	–	1.536 l
10	Śaṭhī (Śaṭī API)	*Hedychium spicatum*	Rz.	48 g
11	Sarala API	*Pinus roxburghii*	Ht. Wd.	48 g
12	Dāru (Devadāru API)	*Cedrus deodara*	Ht. Wd.	48 g
13	Elā (Sūkṣmailā API)	*Elettaria cardamomum*	Sd.	48 g
14	Mañjiṣṭhā API	*Rubia cordifolia*	Rt.	48 g
15	Aguru (Agaru API)	*Aquilaria agallocha*	Ht. Wd.	48 g
16	Candana (Rakta candana API)	*Pterocarpus santalinus*	Ht. Wd.	48 g
17	Padmaka API	*Prunus cerasoides*	Ht. Wd.	48 g
18	Atibalā API	*Abutilon indicum*	Rt.	48 g
19	Mustā API	*Cyperus rotundus*	Rz.	48 g
20	Śūrpaparṇīdvaya			
	a. Mudgaparṇī API	*Vigna trilobata*	Pl.	48 g
	b. Māṣaparṇī API	*Teramnus labialis*	Pl.	48 g
21	Hareṇu (Reṇukā (API))	*Vitex negundo**	Fr	48 g
22	Yaṣṭyāhva (Yaṣṭī API)	*Glycyrrhiza glabra*	Rt.	48 g
23	Surasa (Tulasī API)	*Ocimum sanctum*	Pl.	48 g
24	Vyāghranakha API	*Capparis sepiaria*	Fr.	48 g
25	Ṛṣabhaka (API)	*Pueraria tuberosa**	Rt. Tr.	48 g
26	Jīvaka API	*Pueraria tuberosa**	Rt .Tr.	48 g
27	Palāśa rasa (Palāśa (API))	*Butea monosperma*	Exd.	48 g

* Official Substitute

28	Nīlikā (Nīlī API)	*Indigofera tinctoria*	Pl.	48 g
29	Jātikośa (Jātipatrī (API))	*Myrstica fragrans*	Ar.	48 g
30	Spṛkkā API	*Anisomeles malabarica*	Pl.	48 g
31	Kuṅkuma API	*Crocus sativus*	Stmn./Stg.	48 g
32	Śaileya API	*Parmelia perlata*	Pl.	48 g
33	Jātikā (Jātīphala API)	*Myrstica fragrans*	Sd.	48 g
34	Kaṭphala API	*Myrica esculenta* (= *M. nagi*)	St. Bk.	48 g
35	Ambu (Hrīvera API)	*Coleus vettiveroides*	Rt.	48 g
36	Tvak API	*Cinnamomum zeylanicum*	St. Bk.	48 g
37	Kunduruka (Kunduru API)	*Boswellia serrata*	Exd.	48 g
38	Karpūra API	*Cinnamomum camphora*	Subl. Ext. of A. Pt.	48 g
39	Turuṣka API	*Altingia excelsa*[*]	Exd.	48 g
40	Śrīnivāsaka (Sarala API)	*Pinus roxburghii*	Exd.	48 g
41	Lavaṅga API	*Syzygium aromaticum*	Fr. Bd.	48 g
42	Nakha (Vyāghranakha API)	*Capparis sepiaria*	Fr.	48 g
43	Kaṅkola API	*Piper cubeba*	Fr.	48 g
44	Kuṣṭha API	*Saussurea lappa*	Rt.	48 g
45	Māṃsī (Jaṭāmāṃsī API)	*Nardostachys jatamansi*	Rz.	48 g
46	Priyaṅgu API	*Callicarpa macrophylla*	Fl.	48 g
47	Sthauṇeya API	*Taxus baccata*	Lf.	48 g
48	Tagara API	*Valeriana wallichii*	Rz.	48 g
49	Dhyāma (Rohiṣa API)	*Cymbopogon martinii*	Pl.	48 g
50	Vacā API	*Acorus calamus*	Rz.	48 g
51	Madanaka (Madana API)	*Xeromphis spinosa*	Fr.	48 g
52	Plava (Kaivarta Mustā (API))	*Cyperus scariosus*	Rz.	48 g
53	Nāgakesara (Nāgakeśara API)	*Mesua ferrea*	Stmn.	48 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- A day prior to the *sneha pāka*, initiate to prepare *Mastu* (Appendix 6.2.5).
- Wash, clean, dry the ingredients numbered 1 to 3 of the Formulation Composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) *(kvātha dravya)*.
- Add water for decoction to the *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-tenth. Filter through *muslin cloth* to obtain *kvātha*.
- Wash and clean the cut pieces of *Ikṣu*, and squeeze the juice and strain through *muslin cloth* to obtain *Ikṣu svarasa*.
- Strain the *Ajādugdha* through *muslin cloth*.

[*] Official Substitute

- Wash, dry the ingredients numbered 10 to 37 and 39 to 53 *(kalka dravya)* of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder. Transfer the powdered ingredients to wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *mūrcchita Tila taila* in a stainless steel vessel and heat it.
- Add increments of *kalka,* stir thoroughly while adding *kvātha* and *svarasa*.
- 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.
- Next day, add *Ajādugdha, Mastu* and *Kāñjika* and continue the process of heating intermittently over a period of five days. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* easily rolls into a *varti* without sticking *(madhyama pāka lakṣaṇa)* to the fingers and at the appearance of froth (*phenodgama*) over the oil. Expose the *varti* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Powder *Karpūra*, pass through 355 μm IS Sieve (sieve number 44), add to the oil and mix homogeneously.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, light golden yellow in color with a pleasant odour

Identification:

Thin layer chromatography:

Shake 2 ml of the formulation with 20 ml of *alcohol* for 3 h. Allow the two layers to separate. Separate the alcohol layer, filter and concentrate to 5 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*: *n-hexane* (6: 3: 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *ethanol-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.32, 0.43, 0.53 and 0.62 in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4651 to 1.4680,	Appendix 3.1
Specific gravity at 40^0:	0.915 to 0.940,	Appendix 3.2
Saponification value:	188 to 200,	Appendix 3.7
Iodine value:	80 to 100,	Appendix 3.8
Acid value:	Not more than 6,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Chardi (emesis); Gulma (abdominal lump); Kāsa (cough); Śvāsa (asthma); Jvara (fever); Mūrcchā (syncope); Kṣata (wound); Kṣaya (pthisis); Apasmāra (epilepsy); Vātavyādhi (diseases due to vāta doṣa); Plīhā (splenic disease); Śoṣa (emaciation/cachexia)

Dose:

5-10 ml per day in divided doses;

Also for external use

BALĀHAṬHĀDI TAILA

(AFI Part I, 8:37)

Definition:

Balāhaṭhādi Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Balā (API)	*Sida cordifolia*	Rt.	307.2 g
2	Haṭhā (Āmalakī API)	*Emblica officinalis*	P.	307.2 g
3	Amṛtā (Guḍūcī API)	*Tinospora cordifolia*	St.	307.2 g
4	Mudga API	*Phaseolus radiatus*	Sd.	307.2 g
5	Māṣa API	*Phaseolus mungo*	Sd.	307.2 g
6	Jala API for decoction	Potable Water	–	12.288 l
	reduced to			3.072 l
7	Tilodbhava (Tila Taila API)	*Sesamum indicum*	Sd. oil	768 ml
8	Candana (Rakta Candana API)	*Pterocarpus santalinus*	Ht. Wd.	42.66 g
9	Āmaya (Kuṣṭha API)	*Saussurea lappa*	Rt.	42.66 g
10	Yaṣṭi (Yaṣṭī API)	*Glycyrriza glabra*	Rt.	42.66 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Wash, clean, dry the ingredients numbered 1 to 3 of the Formulation Composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) *(kvātha dravya)*.
- Wash and clean the ingredient number 4 and 5 of the Formulation Composition and tie them in a *muslin cloth* bundle.
- Add water for decoction to the *kvātha dravya,* soak for 4 h, immerse the bundle in it and heat and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *kvātha*.
- Wash, clean, dry the ingredients numbered 8 to 10 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) (*kalka dravya*).
- Transfer the *kalka dravya* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *mūrcchita Tila Taila* in a stainless steel vessel and heat it.
- 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.
- Continue the process of heating intermittently over a period of three days. Constantly check the *kalka* by rolling between the fingers.

- Stop the heating when the *kalka* breaks down into pieces on attempting to form a *varti* (*khara pāka lakṣaṇa*) and at the appearance of froth (*phenodgama*) over the oil. Expose the *kalka* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, brownish yellow in colour with a pleasant odour

Identification:

Thin layer chromatography:

Shake 2 g of the formulation with 20 ml of *alcohol* for 3 h. Allow the two layers to separate. Separate the alcohol layer, filter and concentrate to 5 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*: *n- hexane* (6: 3: 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *ethanol-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.16, 0.22, 0.27, 0.32, 0.43, 0.53 and 0.75 (all pink changing to purple) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4650 to 1.4620,	Appendix 3.1
Specific gravity at 40^0:	0.929 to 0.936,	Appendix 3.2
Saponification value:	175 to 190,	Appendix 3.7
Iodine value:	84 to 94,	Appendix 3.8
Acid value:	Not more than 5,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Śirorujā (headache)

Dose:

External application for Śiro-abhyaṅga

BHṚṄGARĀJA TAILA

(AFI Part I, 8:42)

Definition:

Bhṛṅgarāja Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Mārkava Svarasa (Bhṛṅgarāja API)	*Eclipta alba*	Pl.	3.072 l
2	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	768 ml
3	Mañjiṣṭhā API	*Rubia cordifolia*	Rt.	48 g
4	Padmaka API	*Prunus cerasoides*	Ht. Wd.	48 g
5	Lodhra API	*Symplocos racemosa*	St. Bk.	48 g
6	Candana (Rakta Candana API)	*Pterocarpus santalinus*	Ht. Wd.	48 g
7	Gairika API - Śuddha	Red ochre	–	48 g
8	Balā API	*Sida cordifolia*	Rt.	48 g
9	Rajanīdvaya			
	a. Haridrā API	*Curcuma longa*	Rz.	48 g
	b. Dāruharidrā API	*Berberis aristata*	St.	48 g
10	Keśara (Nāgakeśara API)	*Mesua ferrea*	Stmn.	48 g
11	Priyaṅgu API	*Callicarpa macrophylla*	Fl.	48 g
12	Madhuyaṣṭikā (Yaṣṭī API)	*Glycyrrhiza glabra*	Rt.	48 g
13	Prapauṇḍarīka API	*Nelumbo nucifera*	Rt.	48 g
14	Gopī (Śveta Sārivā API)	*Hemidesmus indicus*	Rt.	48 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Treat *Gairika* to prepare *Gairika - Śuddha* (Appendix 6.2.8.2).
- Take fresh *Bhṛṅgarāja* and wash thoroughly with water. Grind and filter through *muslin cloth* to obtain *svarasa*.
- Wash, clean, dry the ingredients numbered 3 to 6 and 8 to 14 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) (*kalka dravya*).
- Transfer the *kalka dravya* to the wet grinder alongwith *Gairika - Śuddha* and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *mūrcchita Tila Taila* in a stainless steel vessel and heat it.
- Add increments of *kalka,* stir thoroughly while adding *svarasa.*
- 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.
- Continue the process of heating intermittently over a period of three days. Constantly check the *kalka* by rolling between the fingers.

- Stop the heating when the *kalka* breaks down into pieces on attempting to form a *varti* (*khara pāka lakṣaṇa*) and at the appearance of froth (*phenodgama*) over the oil. Expose the *kalka* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

A medicated oil, light brownish yellow in color with a pleasant odour

Identification:

Thin layer chromatography:

Shake 2 ml of the formulation with 20 ml of *alcohol* for 3 h. Allow the two layers to separate. Separate the alcohol layer, filter and concentrate to 5 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*: *n-hexane* (6: 3: 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *ethanol-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.18, 0.23, 0.29, 0.34, 0.44 and 0.77 (all pink changing to black) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4651 to 1.4660,	Appendix 3.1
Specific gravity at 40^0:	0.910 to 0.932,	Appendix 3.2
Saponification value:	188 to 194,	Appendix 3.7
Iodine value:	90 to 100,	Appendix 3.8
Acid value:	Not more than 6,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Keśapāta (loss of hair); Netraroga (diseases of eyes); Karṇaroga (diseases of ear); Śiroroga (diseases of head); Manyāstambha (neck rigidity/torticollis); Galagraha (difficulty in swallowing); Khālitya (premature baldness); Indralupta (alopecia areata)

Dose:

External application over the scalp for Śiro-Abhyaṅga

BṚHAT SAINDHAVĀDYA TAILA

(AFI Part I, 8:40)

Definition:

Bṛhat Saindhavādya Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Eraṇḍa taila as the basic ingredient.

Formulation Composition:

1	Saindhava (Saindhava Lavaṇa (API))	Rock salt	–	24 g
2	Śreyasī (Gajapippalī API)	*Scindapsus officinalis*	Fr.	24 g
3	Rāsnā API	*Alpinia galanga*[*]	Rz.	24 g
4	Śatapuṣpā (Śatāhvā API)	*Anethum sowa*	Fr.	24 g
5	Yamānikā (Yavānī API)	*Trachyspermum ammi*	Fr.	24 g
6	Sarjikā (Svarjīkṣāra (API))	Crude alkaline earth	–	24 g
7	Marica API	*Piper nigrum*	Fr.	24 g
8	Kuṣṭha API	*Saussurea lappa*	Rt.	24 g
9	Śuṇṭhī API	*Zingiber officinale*	Rz.	24 g
10	Sauvarcala (Sauvarcala Lavaṇa (API))	Black salt	–	24 g
11	Viḍa (Viḍa Lavaṇa (API))			24 g
12	Vacā API	*Acorus calamus*	Rz.	24 g
13	Ajamodā API	*Apium leptophyllum*	Fr.	24 g
14	Madhuka (Yaṣṭī API)	*Glycyrrhiza glabra*	Rt.	24 g
15	Jīraka (Śveta Jīraka API)	*Cuminum cyminum*	Fr.	24 g
16	Pauṣkara (Puṣkara API)	*Inula racemosa*	Rt.	24 g
17	Kaṇā (Pippalī API)	*Piper longum*	Fr.	24 g
18	Eraṇḍa Taila (API)	*Ricinus communis*	Sd. oil	768 ml
19	Śatapuṣpajāmbu (Śatāhvā API)	*Anethum sowa*	Fr.	192 g
	Jala API for phaṇṭa	Potable Water	–	768 ml
20	Kāñjika (API)	Sour gruel	–	1.536 l
21	Mastu (Godadhi (API))	Curd whey from cow milk	–	1.536 l

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Eraṇḍa taila* to prepare *mūrcchita Eraṇḍa taila* (Appendix 6.2.9.1).
- A day prior to the *sneha pāka*, initiate to prepare *Mastu* (Appendix 6.2.5).
- Wash, clean, dry the ingredient number 19 of the Formulation Composition, powder and pass through 355 μm IS Sieve (sieve number 44) (*phāṇṭa dravya*).

[*] Official Substitute

- Add boiling water to the *phāṇṭa dravya* and soak. Filter when luke warm through *muslin cloth* to obtain *phaṇṭa*.
- Wash, clean, dry the ingredients numbered 2 to 9 and 12 to 17 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85). Roast coarsely powdered *Saindhava Lavaṇa, Sauvarcala Lavaṇa* and *Viḍa Lavaṇa* in a stainless steel pan on low flame till free from moisture, powder separately and pass through 180 μm IS Sieve (sieve number 85) (*kalka dravya*).
- Transfer the *kalka dravya* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *mūrcchita Eraṇḍa Taila* in a stainless steel vessel and heat it.
- Add increments of *kalka,* stir thoroughly while adding *phāṇṭa*.
- 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.
- Next day, add *Mastu* and *Kāñjika* and continue the process of heating intermittently over a period of five days. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* easily rolls into a *varti* without sticking *(madhyama pāka lakṣaṇa)* to the fingers and at the appearance of froth (*phenodgama*) over the oil. Expose the *varti* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, golden yellow in color, odour unpleasant and characteristic of castor oil

Identification:

Thin layer chromatography:

Shake 2 ml of the formulation with 20 ml of *alcohol* for 3 h. Allow the two layers to separate. Separate the alcohol layer, filter and concentrate to 5 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*: *n-hexane* (6: 3: 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *ethanol-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.25, 0.43, 0.64 and 0.71 in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4601 to 1.4670,	Appendix 3.1
Specific gravity at 40^0:	0.947 to 0.974,	Appendix 3.2
Saponification value:	178 to 200,	Appendix 3.7
Iodine value:	70 to 90,	Appendix 3.8
Acid value:	Not more than 10,	Appendix 3.9
Peroxide value:	Not more than 5,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Ānāha (distension of abdomen); Āntravṛddhi (hernia); Mūtrakṛcchra (dysuria); Aśmarī (calculus); Hṛtśūla (angina pectoris); Pārśvaśūla (intercostal neuralgia and polydynia); Ardita (facial palsy); Āmavāta (rheumatism); Sandhigata Vāta (osteoarthropathy); Mandāgni (reduced digestive fire); Vāta roga (diseases due to vāta doṣa); Kaṭiśūla (lower backache); Jānuśūla (pain in the knee); Ūruśūla (pain in the thigh region); Pṛṣṭhaśūla (backache); Bāhyāyāma (opisthotonus)

Dose:

5 ml per day in divided doses; also used for Abhyaṅga and Basti

CITRAKĀDI TAILA

(AFI Part I, 8:16)

Definition:

Citrakādi Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Citraka API	*Plumbago zeylanica*	Rt.	16 g
2	Arkamūla (Arka API)	*Calotropis procera*	Rt.	16 g
3	Trivṛt API	*Ipomoea turpethum*	Rt.	16 g
4	Pāṭhā API	*Cissampelos pareira*	Rt.	16 g
5	Malapū (Phalgu API)	*Ficus hispida*	Rt. Bk.	16 g
6	Hayamāraka (Karavīra API)	*Nerium indicum*	Rt. Bk.	16 g
7	Sudhā (Snuhī API)	*Euphorbia neriifolia*	Rt.	16 g
8	Vacā API	*Acorus calamus*	Rz	16 g
9	Lāṅgalakī (Lāṅgalī API)	*Gloriosa superba*	Rz./Rt.	16 g
10	Saptaparṇa API	*Alstonia scholaris*	St. Bk.	16 g
11	Suvarcikā (Svarjīkṣāra (API))	Crude alkaline earth	–	16 g
12	Jyotiṣmatī API	*Celastrus paniculatus*	Sd.	16 g
13	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	768 ml
14	Jala API	Potable Water	–	3.072 l

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Treat *Citraka* to prepare *Citraka - Śuddha* (Appendix 6.2.8.11), *Karavīra* to prepare *Karavīra - Śuddha* (Appendix 6.2.8.10), and *Lāṅgalī* to prepare *Lāṅgalī - Śuddha* (Appendix 6.2.8.12); powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder.
- Wash, clean, dry the ingredients numbered 2 to 5, 7, 8, 10 and 12 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder.
- Roast *Svarjīkṣāra* in a stainless steel pan on low flame till free from moisture.
- Transfer all the ingredients to wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *mūrcchita Tila taila* in a stainless steel vessel and heat it.
- Add increments of *kalka*, 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.

- Continue the process of heating intermittently over a period of three days. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* breaks down into pieces on attempting to form a *varti* (*khara pāka lakṣaṇa*) and at the appearance of froth (*phenodgama*) over the oil. Expose the *kalka* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, reddish brown in colour with a faint odour

Identification:

Thin layer chromatography:

Shake 1 ml and carry out thin layer chromatography of formulation with 10 ml of *chloroform* and keep the mixture for 12 h at 37^0. Filter the extract. Apply 3 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *glacial acetic acid* (8: 2: 0.1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with 10 per cent *methanolic sulphuric acid reagent* followed by heating at 105^0 for about 10 min. The plate shows major spots at R_f 0.37, 0.42, 0.50 (all reddish brown) and 0.55 (brown) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4646 to 1.4665,	Appendix 3.1
Specific gravity at 40^0:	0.832 to 0.854,	Appendix 3.2
Saponification value:	185 to 200,	Appendix 3.7
Iodine value:	95 to 105,	Appendix 3.8
Acid value:	Not more than 5,	Appendix 3.9
Peroxide value:	Not more than 3,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Bhagandara (fistula- in- ano)

Dose:

External use: for Abhyaṅga (massage on whole body) and local application

HIṄGVĀDI TAILA

(AFI Part II, 8:18)

Definition:

Hiṅgvādi Taila is a medicated preparation made with the ingredients in the Formulation Composition given below with mūrcchita Sarṣapa Taila as basic ingredient.

Formulation Composition:

1	Hiṅgu API	*Ferula foetida*	Exd.	1 part
2	Tumburu API	*Zanthoxylum armatum*	Fr.	1 part
3	Śuṇṭhī API	*Zingiber officinale*	Rz.	1 part
4	Sārṣapa Taila (Sarṣapa Taila API)	*Brassica campestris*	Sd. oil	12 parts
5	Jala API	Potable Water	–	48 parts

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Sarṣapa taila* to prepare *mūrcchita Sarṣapa taila* (Appendix 6.2.9.3).
- Treat *Hiṅgu* to prepare *Hiṅgu - Śuddha* (Appendix 6.2.8.15).
- Wash, clean, dry the ingredients numbered 2 and 3 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85). Transfer the powdered ingredients to wet grinder and grind with sufficient quantity of water to prepare homogenous blend (*kalka*).
- Take *mūrcchita Sarṣapa Taila* in a stainless steel vessel and heat it.
- Add increments of *kalka*. Stir thoroughly while adding the water in specified ratio.
- 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.
- Continue the process of heating intermittently over a period of three days. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* breaks down into pieces on attempting to form a *varti* (*khara pāka lakṣaṇa*) and at the appearance of froth (phenodgama) over the oil. Expose the *kalka* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, reddish in colour with characteristic odour of asafoetida

Identification:

Thin layer chromatography:

a) Shake 0.5 ml of formulation with 10 ml of *methanol* and keep the mixture overnight at 37^0 with occasional shakings. Filter the extract 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*: *acetone*: *methanol* (8.5: 1.5: 0.2) as mobile phase. After development, allow the plate to dry in air and spray with *Liebermann Burchard reagent* followed by heating at 105^0 for about 10 min and examine the plate under ultraviolet light (366nm). It shows major spots at R_f 0.35 (fluorescent blue), 0.45 (pinkish blue), 0.50 (light blue) and 0.65, 0.75 (both light pink).

b) Extract 2 ml of formulation with 10 ml of *methanol* by keeping the mixture for about 15 min. Filter the extract and carry out the thin layer chromatography. Apply 5 µl of the extract on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *formic acid* (14: 8: 0.15) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *Liebermann Burchard reagent* followed by heating at 105^0 for about 10 min and examine the plate under ultraviolet light (366nm). It shows major spots at R_f 0.25 (fluorescent light blue), 0.30(light fluorescent blue, corresponding to ferulic acid) 0.35 (faint yellow), 0.43 (blue), 0.56 (light blue), 0.69 (fluorescent blue), 0.78 (white), 0.81, 0.84 and 0.88 (all pink).

Chemical test:

Complies with *Test for Hiṅgu* (Appendix 5.13.13)

Physico-chemical parameters:

Refractive index at 40^0:	1.4471 to 1.4781,	Appendix 3.1
Specific gravity at 40^0:	0.880 to 0.918,	Appendix 3.2
Saponification value:	180 to 190,	Appendix 3.7
Iodine value:	100 to 105,	Appendix 3.8
Acid value:	Not more than 3,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Karṇaśūla (otalgia)

Dose:

Externally as ear drops- 5-10 drops in the affected ear once or twice a day (Karṇapūraṇa)

JYOTIṢMATĪ TAILA

(Syn. SIDDHA JYOTIṢMATĪ TAILA)

(AFI Part I, 8:18)

Definition:

Jyotiṣmatī Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Mayūrakakṣāra (Apāmārgakṣāra API)	*Achyranthes aspera*	Water soluble Ash of Pl.	896 g
2	Jala API	Potable water		5.376 l
3	Jyotiṣmatī Taila (API)	*Celastrus paniculatus*	Sd. oil	768 ml

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Add 6 parts of water to 1 part of *Kṣāra* (Appendix 6.2.3), and dissolve completely (*Kṣāra jala*).
- Take *JyotiṣmatīTaila* in a stainless steel vessel and heat it.
- Add equal quantity of *Kṣāra jala*. Stir thoroughly and heat with constant stirring maintaining the temperature between 50^0 and 90^0 during the first hour of heating. Stop the heating all the water gets evaporated. Allow to stand overnight.
- Repeat the process for six more times each day adding fresh *Kṣāra jala* in equal quantity.
- Stop heating when all the water is evaporated. Expose the oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Very thick oil, reddish in colour

Identification:

Thin layer chromatography:

Shake 1 ml of formulation in 10 ml of *methanol* and keep the mixture for 12 h at 37^0. Filter the extract. Apply 4 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *glacial acetic* acid (7: 2: 0.2) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *Liebermann Burchard reagent* followed by heating at 105^0 for about 10 min and examine under ultraviolet light (366 nm). The plate shows major spots at R_f 0.15 (fluorescent green), 0.24 (faint green), 0.32 (pink), 0.35 (fluorescent green), 0.40 (pink), 0.49 (faint blue), 0.53 (light blue) and 0.67(pink).

Physico-chemical parameters:

Refractive index at 40^0:	1.4232 to 1.4556,	Appendix 3.1
Specific gravity at 40^0:	0.850 to 0.923,	Appendix 3.2
Saponification value:	100 to 110,	Appendix 3.7
Iodine value:	51 to 55,	Appendix 3.8
Acid value:	Not more than 4,	Appendix 3.9
Peroxide value:	Not more than 4,	Appendix 3.10

Other requirements:

Microbial limits:	complies with Appendix 2.4
Aflatoxins:	complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Śvitraroga (leucoderma/ vitiligo)

Dose:

Externally for Abhyaṅga (application on affected area)

KANAKA TAILA

(AFI Part I, 8:4)

Definition:

Kanaka Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Madhuka (Yaṣṭī API)	*Glycyrrhiza glabra*	Rt.	768 g
2	Jala API for decoction reduced to	Potable Water	–	3.072 ml 768 ml
3	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	192 ml
4	Priyaṅgu API	*Calicarpa macrophylla*	Fl.	6.4 g
5	Mañjiṣṭhā API	*Rubia cordifolia*	St.	6.4 g
6	Candana (Rakta Candana API)	*Pterocarpus santalinus*	Ht. Wd.	6.4 g
7	Utpala API	*Nymphaea stellata*	Fl.	6.4 g
8	Keśara (Nāgakeśara API)	*Mesua ferrea*	Stmn.	6.4 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Wash, clean, dry the ingredient number 1 of the Formulation Composition, powder and pass through 355 μm IS Sieve (sieve number 44) (*kvātha dravya*).
- Add water for decoction to the *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *kvātha*.
- Wash, dry the ingredients numbered 4 to 8 *(kalka dravya)* of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder.
- Transfer the powdered ingredients to wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *mūrcchita Tila taila* in a stainless steel vessel and heat it.
- 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.
- Continue the process of heating intermittently over a period of three days. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* easily rolls into a *varti* without sticking *(Madhyama pāka lakṣaṇa)* to the fingers and at the appearance of froth (*phenodgama*) over the oil. Expose the *varti* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, reddish brown in colour with a faint odour

Identification:

Thin layer chromatography:

Shake 2 ml of formulation with 10 ml of *ethyl acetate,* keep the mixture for 12 h and filter. Dilute the extract in *ethyl acetate* (1: 4). Apply 5 µl of the diluted extract on the TLC plate. Develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *chloroform*: *methanol* (8.5: 1.2: 0.2: 0.2) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *Liebermann Burchard reagent* followed by heating at 105^0 for about 10 min and examine under ultraviolet light (366 nm). The plate shows major spots at R_f 0.11, 0.31, 0.46, 0.54, 0.65 (all blue), 0.74 (black) and 0.80 (faint blue).

Physico-chemical parameters:

Refractive index at 40^0:	1.4641 to1.4660,	Appendix 3.1
Specific gravity at 40^0:	0. 918 to 0.923,	Appendix 3.2
Saponification value:	190 to 200,	Appendix 3.7
Iodine value:	100 to 110,	Appendix 3.8
Acid value:	Not more than 3,	Appendix 3.9
Peroxide value:	Not more than 2,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Mukha roga (diseases of oral cavity); Vyaṅga (local hyper pigmentation); Nīlikā (mole)

Dose:

External use: for Abhyaṅga (apply locally)

Nasya - 2 to 4 drops per nostril once or twice a day

MAHĀNĀRĀYAṆA TAILA

(AFI Part I, 8:45)

Definition:

Mahānārāyaṇa Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Bilva API	*Aegle marmelos*	St. Bk.	960 g
2	Aśvagandhā API	*Withania somnifera*	Rt.	960 g
3	Bṛhatī API	*Solanum indicum*	Pl.	960 g
4	Śvadaṃṣṭrā (Gokṣura API)	*Tribulus terrestris*	Pl.	960 g
5	Śyonāka API	*Oroxylum indicum*	St. Bk.	960 g
6	Vāṭyālaka (Balā (API))	*Sida cordifolia*	Rt.	960 g
7	Pāribhadra API	*Erythrina indica*	Rt.	960 g
8	Kṣudrā (Kaṇṭakārī API)	*Solanum surattense*	Pl.	960 g
9	Kaṭhillā (Rakta Punarnavā API)	*Boerhavia diffusa*	Pl.	960 g
10	Atibalā API	*Abutilon indicum*	Rt.	960 g
11	Agnimantha API	*Premna integrifolia* *	St. Bk.	960 g
12	Saraṇī (Prasāriṇī API)	*Paedaria foetida*	Pl.	960 g
13	Pāṭalī (Pāṭalā API)	*Stereospermum suaveolens*	St. Bk.	960 g
14	Jala API for decoction	Potable Water	–	98.304 l
	reduced to			24.576 l
15	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	6.144 l
16	Godugdha** (API)	Cow milk	–	6.144 l
17	Śatāvarīrasa (Śatāvarī API)	*Asparagus racemosus*	Rt. Tr. juice	6.144 l
18	Rāsnā API	*Alpinia galanga**	Rz.	96 g
19	Aśvagandhā API	*Withania somnifera*	Rt.	96 g
20	Miṣi (Miśreyā API)	*Foeniculum vulgare*	Fr.	96 g
21	Dāru (Devadāru API)	*Cedrus deodara*	Ht. Wd.	96 g
22	Kuṣṭha API	*Saussurea lappa*	Rt.	96 g
23	Parṇīcatuṣka			
	a. Śālaparṇī API	*Desmodium gangeticum*	Pl.	96 g
	b. PṛśniparṇīAPI	*Uraria picta*	Pl.	96 g
	c. Mudgaparṇī API	*Vigna trilobata*	Pl.	96 g
	d. Māṣaparṇī API	*Teramnus labialis*	Pl.	96 g
24	Agaru API	*Aquillaria agallocha*	Ht. Wd.	96 g

* Official Substitute

** Ajādugdha (Goat milk) may also be alternatively used.

25	Keśara (Nāgakeśara API)	*Messua ferrea*	Stmn.	96 g
26	Sindhūttha (Saindhava Lavaṇa (API))	Rock salt	–	96 g
27	Māṃsī (Jaṭāmāṃsī API)	*Nardostachys jatamansi*	Rt./Rz.	96 g
28	Rajanīdvaya			
	a. Haridrā API	*Curcuma longa*	Rz.	96 g
	b. Dāruharidrā API	*Berberis aristata*	St.	96 g
29	Śaileyaka (Śaileya API)	*Parmelia perlata*	Pl.	96 g
30	Candana (Rakta candana API)	*Pterocarpus santalinus*	Ht. Wd.	96 g
31	Puṣkara API	*Inula racemosa*	Rt.	96 g
32	Elā (Sūkṣmailā API)	*Elettaria cardamomum*	Sd.	96 g
33	Asra (Mañjiṣṭhā API)	*Rubia cordifolia*	St.	96 g
34	Yaṣṭī API	*Glycyrrhiza glabra*	Rt.	96 g
35	Tagara API	*Valeriana wallichii*	Rz.	96 g
36	Abda (Mustā API)	*Cyperus rotundus*	Rz.	96 g
37	Patra (Tvak patra API)	*Cinnamomum tamala*	Lf.	96 g
38	Bhṛṅga (Tvak API)	*Cinnamomum zeylanicum*	St. Bk.	96 g
39	Aṣṭavarga			
	a. Jīvaka API	*Pueraria tuberosa**	Rt. Tr.	96 g
	b. Ṛṣabhaka API	*Pueraria tuberosa* *	Rt. Tr.	96 g
	c. Medā (API)	*Asparagus racemosus**	Rt.	96 g
	d. Mahāmedā API	*Asparagus racemosus**	Rt.	96 g
	e. Kākolī API	*Withania somnifera**	Rt.	96 g
	f. Kṣīrakākolī API	*Withania somnifera**	Rt.	96 g
	g. Ṛddhi API	*Dioscorea bulbifera**	Rz.	96 g
	h. Vṛddhi API	*Dioscorea bulbifera**	Rz.	96 g
40	Ambu (Hrīvera API)	*Coleus vettiveroides*	Rt.	96 g
41	Vacā API	*Acorus calamus*	Rz.	96 g
42	Palāśa API	*Butea monosperma*	St. Bk.	96 g
43	Sthauṇeya API	*Taxus baccata*	Lf.	96 g
44	Vṛścīraka (Śveta Punarnavā API)	*Boerhaavia verticillata*	Pl.	96 g
45	Coraka API	*Angelica glauca*	Rz.	96 g
46	Karpūra API	*Cinnamomum camphora*	Subl. Ext. of A. Pt.	48 g
47	Kāśmīra (Kuṅkuma API)	*Crocus sativus*	Sty./Stg.	48 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).

* Official Substitute

- Wash, clean, dry the ingredients numbered 1 to 13 of the Formulation Composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) *(kvātha dravya)*.
- Add water for decoction to the *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *kvātha*.
- Wash and clean the cut pieces of *Śatāvarī*, grind and squeeze through *muslin cloth* to obtain *Śatāvarī svarasa*.
- Wash, clean, dry the ingredients numbered 18 to 25 and 27 to 45 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85). Roast coarsely powdered *Saindhava Lavaṇa* in a stainless steel pan on low flame till free from moisture, powder and pass through 180 μm IS Sieve (sieve number 85) (*kalka dravya*).
- Transfer the *kalka dravya* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Strain the *Godugdha* through *muslin cloth*.
- Take *mūrcchita Tila taila* in a stainless steel vessel and heat it.
- Add increments of *kalka,* stir thoroughly while adding *kvātha, svarasa*.
- 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.
- Next day, add *Godugdha* and continue the process of heating intermittently over a period of five days. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* easily rolls into a *varti* without sticking *(madhyama pāka lakṣaṇa)* to the fingers and at the appearance of froth (*phenodgama*) over the oil. Expose the *varti* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Powder *Karpūra* and *Kuṅkuma*, pass through 355 μm IS Sieve (sieve number 44), add to the oil and mix homogeneously.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, yellowish brown in color with an unpleasant odour

Identification:

Thin layer chromatography:

Shake 2 ml of the formulation with 20 ml of *alcohol* for 3 h. Allow the two layers to separate. Separate the alcohol layer, filter and concentrate to 5 ml and carry out the thin layer chromatography. Apply 10 μl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *n-hexane* (6: 3: 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *ethanol-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.28, 0. 41, 0.54 and 0.65 (all brown) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4575 to 1.4660,	Appendix 3.1
Specific gravity at 40^0:	0.926 to 0.955,	Appendix 3.2
Saponification value:	188 to 196,	Appendix 3.7
Iodine value:	80 to 100,	Appendix 3.8
Acid value:	Not more than 6,	Appendix 3.9
Peroxide value:	Not more than 5,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in air-tight containers, protected from light and moisture.

Therapeutic uses:

Ardita (facial palsy); Badhiratva (deafness); Paṅgutva (paraplegia); Gātra kampa (tremors); Manyāstambha (neck rigidity/torticollis) Hanustambha (lockjaw); Ekāṅgaśoṣa (wasting of one limb); Śukrakṣaya (oligospermia); Vandhyatva (infertility); Śiroroga (headache), Jihvāstambha (glossal palsy); Dantaśūla (toothache); Unmāda (Mania/psychosis); Kubja (humpback/ kyphosis); Jvara (fever); Jarā (senility); Kārśya (emaciation); Snāyubhagna (rupture of ligament); Asthibhagna (bone fracture)

Dose:

5-10 ml per day in divided doses; Nasya: 2 to 3 drops per nostril; Abhyaṅga (massage on affected parts) and Anuvāsana Basti

NĀLPĀMARĀDI TAILA

(AFI Part I, 8:24)

Definition:

Nālpāmarādi taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Nālpāmara			
	a. Nyagrodha API	*Ficus bengalensis*	St. Bk.	15 g
	b. Udumbara API	*Ficus racemosa*	St. Bk.	15 g
	c. Aśvattha API	*Ficus religiosa*	St. Bk.	15 g
	d. Plakṣa API	*Ficus lacor*	St. Bk.	15 g
2	Triphala			
	a. Harītakī API	*Terminalia chebula*	P.	15 g
	b. Bibhītaka API	*Terminalia bellirica*	P.	15 g
	c. Āmalakī API	*Emblica officinalis*	P.	15 g
3	Candana (Rakta candana API)	*Pterocarpus santalinus*	Ht. Wd.	15 g
4	Sevya (Uśīra API)	*Vetiveria zizanioides*	Rt.	15 g
5	Kuṣṭha API	*Saussurea lappa*	Rt.	15 g
6	Covaḷḷi (Mañjiṣṭhā API)	*Rubia cordifolia*	Rt.	15 g
7	Coram API	*Kaempferia galanga*	Rz.	15 g
8	Akil (Agaru API)	*Aquilaria agallocha*	Ht. Wd.	15 g
9	Paimañ̃ñaḷ (Haridrā (API) - Ārdra) rasa	*Curcuma longa*	Rz. fresh- juice	1.536 l
10	Parpaṭa API- rasa*	*Fumaria parviflora*	Pl. - juice	1.536 l
11	Eṇṇa (Tila Taila API)	*Sesamum indicum*	Sd. oil	768 ml

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Take fresh *Haridrā* and wash thoroughly. Grind and filter through *muslin cloth* to obtain *svarasa*.
- Wash, clean, dry the *Parpaṭa*, powder and pass through 355 μm IS Sieve (sieve number 44). Add eight times water to it and soak for 4 h. Boil and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *Parpaṭa rasa*.
- Wash, dry the ingredients numbered 4 to 16 *(kalka dravya)* of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder. Transfer the powdered ingredients to wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.

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* Dried whole plant of Parpaṭa is used and Parpaṭa rasa is prepared as per Śārṅgadhara saṃhitā-Madhyamakhaṇḍa, 1/4.

- Take *mūrcchita Tila taila* in a stainless steel vessel and heat it.
- Add increments of *kalka*, stir thoroughly while adding *Haridrā svarasa* and *Parpaṭa rasa*.
- 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.
- Continue the process of heating intermittently over a period of three days. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* breaks down into pieces on attempting to form a *varti* (*khara pāka lakṣaṇa*) and at the appearance of froth (*phenodgama*) over the oil. Expose the *kalka* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, reddish brown in colour with an odour of turmeric

Identification:

Thin layer chromatography:

Shake 5 ml of formulation with 10 ml of *methanol* and keep the mixture for 12 h. Filter and carry out the thin layer chromatography. Apply 5 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *toulene*: *ethyl acetate*: *chloroform*: *methanol* (8: 1: 0.2: 0.2) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (254 nm). The plate shows major spots at R_f 0.21, 0.46, 0.56, 0.68, 0.78 (all black).

Physico-chemical parameters:

Refractive index at 40^0:	1.4646 to 1.4665,	Appendix 3.1
Specific gravity at 40^0:	0.784 to 0.824,	Appendix 3.2
Saponification value:	190 to 200,	Appendix 3.7
Iodine value:	100 to 110,	Appendix 3.8
Acid value:	Not more than 4,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Cori-Ciraṅṅu (itches and scabies), Visarpa (erysipelas) and Kuṣṭha (skin diseases/leprosy)

Dose:

External application for Abhyaṅga

NĪLĪBHṚṄGĀDI TAILA

(AFI Part I, 8:26)

Definition:

Nīlībhṛṅgādi Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Nīlī Rasa (Nīlī API)	*Indigofera tinctoria*	Lf. juice	768 ml
2	Bhṛṅga Rasa (Bhṛṅgarāja API)	*Eclipta alba*	Pl. juice	768 ml
3	Śatakratu latā Rasa (Kākatiktā API)	*Cardiospermum halicacabum*	Pl. juice	768 ml
4	Dhātrī Phala Rasa (Āmalakī API)	*Emblica officinalis*	P. juice	768 ml
5	Ājaka Kṣīra (Ajādugdha (API))	Goat milk		768 ml
6	Nālikera Kṣīra (Nārikela (API))	*Cocos nucifera*	Milk from End.	768 ml
7	Mahiṣī Kṣīra (Mahiṣīdugdha (API))	Buffalo milk	–	768 ml
8	Dhenūdbhava (Godugdha (API))	Cow milk	–	768 ml
9	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	768 ml
10	Yaṣṭyāhva (Yaṣṭī API)	*Glycyrrhiza glabra*	Rt.	32 g
11	Guñjā API	*Abrus precatorius*	Rt.	32 g
12	Añjana (Rasāñjana (API))	*Berberis sps.*	Ext.	32 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Take fresh *Nīlī, Bhṛṅgarāja, Kākatiktā* and *Āmalakī* and wash thoroughly with water. Grind and filter separately through *muslin cloth* to obtain *svarasa*.
- Wash and clean the cut pieces of Nārikela, grind and squeeze through *muslin cloth* to obtain *Nārikela Kṣīra*.
- Strain the *Ajādugdha, Mahiṣīdugdha* and *Godugdha* separately through *muslin cloth*.
- Wash, clean, dry the ingredients numbered 10 to 12 *(kalka dravya)* of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder. Transfer the powdered ingredients to wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *mūrcchita Tila taila* in a Stainless steel vessel and heat it.
- Add increments of *kalka,* stir thoroughly while adding *svarasa*.
- 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.
- Next day, add *Nārikela Kṣīra, Ajādugdha, Mahiṣīdugdha* and *Godugdha* and continue the process of heating intermittently over a period of three days. Constantly check the *kalka* by rolling between the fingers.

- Stop the heating when the *kalka* breaks down into pieces on attempting to form a *varti* (*khara pāka lakṣaṇa*) and at the appearance of froth (*phenodgama*) over the oil. Expose the *kalka* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, dark brown in colour, odour characteristic of sesame oil

Identification:

Thin layer chromatography:

Extract 2 ml of the formulation with 20 ml of *alcohol* for 3 h. Allow the two layers to separate. Separate the alcohol layer, filter and concentrate to 5 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*: *n-hexane* (6: 3: 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *ethanol-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.18, 0.23, 0.35, 0.45 and 0.82 (all brown) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4510 to 1.4620,	Appendix 3.1
Specific gravity at 40^0:	0.905 to 0.928,	Appendix 3.2
Saponification value:	194 to 212,	Appendix 3.7
Iodine value:	80 to 90,	Appendix 3.8
Acid value:	Not more than 5,	Appendix 3.9
Peroxide value:	Not more than 4,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Keśapāta (hair fall) and Palita (premature greying of hair)

Dose:

External application for Śiro-abhyaṅga

PAÑCAGUṆA TAILA

(AFI Part II, 8:7)

Definition:

Pañcaguṇa Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila Taila as the basic ingredient.

Formulation Composition:

1	Harītakī API	*Terminalia chebula*	P.	60 g
2	Āmalakī API	*Phyllanthus emblica*	P.	60 g
3	Bibhītaka API	*Terminalia bellirica*	P.	60 g
4	Nimba patra (Nimba API)	*Azadirachta indica*	Lf.	180 g
5	Sambhālu patra (Nirguṇḍī API)	*Vitex negundo*	Lf.	180 g
6	Jala API for decoction reduced to	Potable Water	–	4.320 l 1.080 l
7	Tila Taila API	*Sesamum indicum*	Sd. oil	960 ml
8	Moma (Madhūcchiṣṭa (API))	Hive of Apis species	Bees wax	48 g
9	Gandhavirojā (Sarala API)	*Pinus roxburghii*	Resin	48 g
10	Śilārasa (Turuṣka (API))	*Altingia excelsa* *	Exd.	48 g
11	Rāla (Śāla API)	*Shorea robusta*	Exd.	48 g
12	Guggulu API - Śuddha	*Commiphora wightii*	O.R.	48 g
13	Karpūra API	*Cinnamomum camphora*	Subl. Ext. of A. Pt.	60 g
14	Tārapīna Taila (API)	*Pinus roxburghii*	Volatile Oil	30 ml
15	Tailaparṇa Taila API	*Eucalyptus globulus*	Volatile Oil	30 ml
16	Kejoputī Taila (API)	*Melaleuca leucadendron*	Fixed Oil	30 ml

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Treat *Guggulu* to get *Guggulu* - Śuddha. (Appendix 6.2.8.4).
- Wash, clean, dry the ingredients numbered 1 to 5 of the Formulation Composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) (*kvātha dravya*).
- Add water for decoction to the *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *kvātha*.
- Take *mūrcchita Tila taila* in a Stainless steel vessel and heat it.
- Add increments of ingredients numbered 8 to 12 of the Formulation Composition, stir thoroughly while adding *kvātha*.

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- 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.
- Continue the process of heating intermittently over a period of three days.
- Expose the oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth,* add powdered *Karpūra* and allow to cool.
- Add *Tārapīna Taila*, *Tailaparna Taila* and *Kejoputī Taila* and mix thoroughly.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, thick, reddish yellow in colour with characteristic odour of Eucalyptus

Identification:

Thin layer chromatography:

Shake 1 ml of formulation with 10 ml of *methanol* and keep the mixture for 12 h. Filter the extract and carry out thin layer Chromatography. Apply 3 µl of the diluted extract on TLC plate. Develop the plate upto a distance of 8 cm using *toluene*: *ethyl acetate*: *methanol*: *glacial acetic acid* (8.5: 0.5: 0.2: 0.1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *Liebermann Burchard reagent* followed by heating at 105^0 for 10 min. The plate shows major spots at R_f 0.21, 0.27, 0.32, 0.38, 0.42, 0.48, 0.55, 0.71, 0.81, 0.84 (all brown) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4703 to 1.5030,	Appendix 3.1
Specific gravity at 40^0:	0.910 to 0.926,	Appendix 3.2
Saponification value:	160 to 184,	Appendix 3.7
Iodine value:	100 to 110,	Appendix 3.8
Acid value:	Not more than 3,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Sandhivāta (osteoarthropathy); Karṇaśūla (otalgia); Vraṇopacāra (wounds)

Dose:

Externally on wound and for Abhyaṅga on whole body

PRABHAÑJANA VIMARDANA TAILA

(AFI Part I, 8:30)

Definition:

Prabhañjana Vimardana taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Balā (API)	*Sida cordifolia*	Rt.	102.4 g
2	Śatāvarī API	*Asparagus racemosus*	Rt. Tr.	102.4 g
3	Śigru API	*Moringa oleifera*	St. Bk.	102.4 g
4	Varuṇa API	*Crataeva nurvala*	St. Bk.	102.4 g
5	Arka API	*Calotropis procera*	Rt.	102.4 g
6	Karañjaka (Karañja API)	*Pongamia pinnata*	St. Bk.	102.4 g
7	Eraṇḍa API	*Ricinus communis*	Rt.	102.4 g
8	Koraṇṭa (Sahacara API)	*Barleria prionitis*	Pl.	102.4 g
9	Vājigandhā (Aśvagandhā API)	*Withania somnifera*	Rt.	102.4 g
10	Prasāriṇī API	*Paederia foetida*	Pl.	102.4 g
11	Variṣṭha Pañcamūla			
	a. Bilva API	*Aegle marmelos*	St. Bk.	102.4 g
	b. Śyonāka API	*Oroxylum indicum*	Rt.	102.4 g
	c. Gambhārī API	*Gmelina arborea*	St. Bk.	102.4 g
	d. Pāṭalā API	*Stereospermum suaveolens*	St. Bk.	102.4 g
	e. Agnimantha API	*Premna integrifolia*[*]	Rt.	102.4 g
12	Jala API for decoction	Potable Water	–	24.576 l
	reduced to			6.144 l
13	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	1.536 l
14	Kṣīra (Godugdha (API))	Cow milk	–	3.072 l
15	Dadhi (Godadhi (API))	Curd from cow milk	–	1.536 l
16	Kāñjika (API)	Sour gruel	–	1.536 l
17	Tagara API	*Valeriana wallichii*	Rz.	12 g
18	Amarakāṣṭha (Devadāru API)	*Cedrus deodara*	Ht. Wd.	12 g
19	Elā (Sūkṣmailā API)	*Elettaria cardamomum*	Sd.	12 g
20	Śuṇṭhī API	*Zingiber officinale*	Rz.	12 g
21	Sarṣapa API	*Brassica campestris*	Sd.	12 g
22	Coraka API	*Angelica glauca*	Rz.	12 g
23	Śatāhvā API	*Anethum sowa*	Fr.	12 g
24	Kuṣṭha API	*Saussurea lappa*	Rt.	12 g

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25	Sindhūttha (Saindhava Lavaṇa (API))	Rock salt	–	12 g
26	Rāsnā API	*Alpinia galanga*[*]	Rz.	12 g
27	Kālānusārikā (Methī API)	*Trigonella foenum-graecum*	Sd.	12 g
28	Vacā API	*Acorus calamus*	Rz.	12 g
29	Citraka API	*Plumbago zeylanica*	Rt.	12 g
30	Māṃsī (Jaṭāmāṃsī API)	*Nardostachys jatamansi*	Rz.	12 g
31	Sarala API	*Pinus roxburghii*	Ht. Wd.	12 g
32	Kaṭurohiṇī (Kaṭukā API)	*Picrorhiza kurroa*	Rz.	12 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- A day prior to the *sneha pāka*, prepare *Godadhi*.
- Wash, clean, dry the ingredients numbered 1 to 11 of the Formulation Composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) (*kvātha dravya*).
- Add water for decoction to the *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *kvātha*.
- Wash, clean, dry the ingredients numbered 17 to 24 and 26 to 32 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85). Roast coarsely powdered *Saindhava Lavaṇa* in a stainless steel pan on low flame till free from moisture, powder separately and pass through 180 μm IS Sieve (sieve number 85) (*kalka dravya*).
- Transfer the *kalka dravya* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Strain the *Godugdha* through *muslin cloth*.
- Take *mūrcchita Tila taila* in a stainless steel vessel and heat it.
- 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.
- next day, add *Godugdha, Godadhi* and *Kāñjika* and continue the process of heating intermittently over a period of five days. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* breaks down into pieces on attempting to form a *varti* (*khara pāka lakṣaṇa*) and at the appearance of froth (*phenodgama*) over the oil. Expose the *kalka* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, golden yellow in color with a pleasant odour

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Identification:

Thin layer chromatography:

Extract 2 ml of the formulation with 20 ml of *alcohol* for 3 h. Allow the two layers to separate. Separate the alcohol layer, filter and concentrate to 5 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*: *n-hexane* (6: 3: 1) as mobile phase. After development, allow the plate to dry in air and spray the plate with *ethanol-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.39 (light green), and 0. 47, 0.59 (both light black) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4510 to 1.4640,	Appendix 3.1
Specific gravity at 40^0:	0.908 to 0.945,	Appendix 3.2
Saponification value:	187 to 204,	Appendix 3.7
Iodine value:	84 to 95,	Appendix 3.8
Acid value:	Not more than 5,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Vātagulma (abdominal lump due to vāta doṣa); Vātavidradhi (abscess due to vāta doṣa); Antravṛddhi (Hernia); Śūla (pain); Ardita (facial palsy); Vātaroga (diseases due to vāta doṣa /neurological disease); Kaṭiśūla (lower backache); Pṛṣṭhaśūla (lumbago); Mūḍhagarbha (malpresentation of the foetus)

Dose:

External application for Abhyaṅga

PRASĀRIṆĪ TAILA

(AFI Part I, 8:32)

Definition:

Prasāriṇī taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with mūrcchita Tila taila as the basic ingredient.

Formulation Composition:

1	Prasāraṇī (Prasāriṇī API)	*Paederia foetida*	Pl.	4.8 kg
2	Jala API for decoction	Potable water	–	12.288 l
	reduced to			3.072 l
3	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	3.072 l
4	Dadhi (Godadhi (API))	Curd from cow milk	–	3.072 l
5	Kāñjika (API)	Sour gruel	–	3.072 l
6	Kṣīra (Godugdha (API))	Cow milk	–	12.288 l
7	Madhuka (Yaṣṭī API)	*Glycyrrhiza glabra*	Rt.	32 g
8	Pippalīmūla API	*Piper longum*	St.	32 g
9	Citraka API	*Plumbago zeylanica*	Rt.	32 g
10	Saindhava (Saindhava Lavaṇa (API))	Rock salt	–	32 g
11	Vacā API	*Acorus calamus*	Rz.	32 g
12	Prasāriṇī API	*Paederia foetida*	Pl.	32 g
13	Devadāru API	*Cedrus deodara*	Ht. Wd.	32 g
14	Rāsnā API	*Alpinia galanga* *	Rz.	32 g
15	Gajapippalī API	*Scindapsus officinalis*	Fr.	32 g
16	Bhallāta (Bhallātaka API) - Śuddha	*Semecarpus anacardium*	Fr.	32 g
17	Śatapuṣpā (Śatāhvā API)	*Anethum sowa*	Fr.	32 g
18	Māṃsī (Jaṭāmāṃsī API)	*Nardostachys jatamansi*	Rz.	32 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- A day prior to the *sneha pāka*, iniate to prepare *Godadhi*.
- Wash, clean, dry the ingredients numbered 1 of the Formulation Composition, powder and pass through 355 μm IS Sieve (sieve number 44) *(kvātha dravya)*.
- Add water for decoction to the *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *kvātha*.
- Wash, clean, dry the ingredients numbered 7 to 9 and 11 to 18 of the formulation composition, powder separately and pass through 180 μm IS Sieve (sieve number 44). Roast

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coarsely powdered *Saindhava Lavaṇa* in a stainless steel pan on low flame till free from moisture, powder separately and pass through 180 μm IS Sieve (sieve number 85) (*kalka dravya*).

- Transfer the *kalka dravya* to the wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Strain the *Godugdha* through *muslin cloth*.
- Take *mūrcchita Tila Taila* in a stainless steel vessel and heat it.
- 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.
- Next day, add *Godadhi, Kāñjika* and *Godugdha* and continue the process of heating intermittently over a period of five days. Constantly check the *kalka* by rolling between the fingers.
- Stop heating when the *kalka* breaks down into pieces on attempting to form a *varti* (*khara pāka lakṣaṇa*) and at the appearance of froth (*phenodgama*) over the oil. Expose the *kalka* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, brownish yellow in colour with a pleasant odour

Identification:

Thin layer chromatography:

Shake 2 ml of the formulation with 20 ml of *alcohol* for 3 h. Allow the two layers to separate. Separate the alcohol layer, filter and concentrate to 5 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*: *n-hexane* (6: 3: 1) as mobile phase. After development, allow the plate to dry in air and spray the plate with *ethanol-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.21, 0.35, 0.46 and 0.83 (all pink changing to purple) in visible light.

Physico-chemical parameters:

Refractive index at 40^0:	1.4570 to 1.4650,	Appendix 3.1
Specific gravity at 40^0:	0.906 to 0.936,	Appendix 3.2
Saponification value:	190 to 200,	Appendix 3.7
Iodine value:	80 to 90,	Appendix 3.8
Acid value:	Not more than 6,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Hanustambha (lockjaw); Kaṭistambha (restricted movement of the lumbo-sacral region); Gṛdhrasī (Sciatica); Khañja (limp); Kaubja (hump/kyphosis); Paṅgutva (paraplegia); Vātaśleṣmaroga (diseases due to vāta and kapha doṣa); Ardita (facial palsy); Pṛṣṭhastambha (stiffness of back); Śiro-grīvā-stambha (stiffness of head and neck)

Dose:

External application for Abhyaṅga

TUVARAKA TAILA

(AFI Part I, 8:20)

Definition:

Tuvaraka Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Tuvaraka taila (API)	*Hydnocarpus laurifolia*	Sd. oil	768 ml
2	Khadira API	*Acacia catechu*	Ht. Wd.	576 g
3	Jala API for decoction	Potable Water	–	9.2160 l
	reduced to			2.304 l
4	Tuvaraka API - Kalka	*Hydnocarpus laurifolia*	Sd.	128 g

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Wash, clean, dry the ingredient number 2 of the formulation composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) (*kvātha dravya*).
- Add water for decoction to the *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *kvātha*.
- Wash, clean, dry the ingredient number 4 *(kalka dravya)* of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder.
- Transfer the powdered ingredient to wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *Tuvaraka taila* in a stainless steel vessel and heat it 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.
- Next day, continue the process of heating. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* easily rolls into a *varti* without sticking *(madhyama pāka lakṣaṇa)* to the fingers and at the appearance of froth (*phenodgama*) over the oil. Expose the *varti* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, dark reddish in colour

Identification:

Thin layer chromatography:

Shake 5 ml of formulation with 10 ml of *methanol* for 30 min. Allow the two layers to separate and draw the methanolic layer. Filter and carry out the thin layer chromatography. Apply 10 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *glacial acetic acid*: *methanol* (8: 1.5: 0.3: 0.3) as mobile phase. Spray the plate with 10 per cent *methanolic sulphuric acid* followed by heating at 105^0 for about 10 min. Examine the plate under ultraviolet light (366 nm). It shows major spots at R_f 0.39 (blue), 0.58 (white) and 0.70 (blue).

Physico-chemical parameters:

Refractive index at 40^0:	1.4635 to 1.4748,	Appendix 3.1
Specific gravity at 40^0:	0.831 to 0.881,	Appendix 3.2
Saponification value:	190 to 200,	Appendix 3.7
Iodine value:	75 to 85,	Appendix 3.8
Acid value:	Not more than 6,	Appendix 3.9
Peroxide value:	Not more than 6,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Kṣudrakuṣṭha (group of minor skin diseases); Mahakuṣṭha (group of major skin diseases); Meha (excessive flow of urine)

Dose:

10 to 20 drops with cow milk or butter; used externally for abhyanga also.

Pathya:

Milk, sweet, citrus fruits, apple, banana, sweet grapes, old boiled rice, barley, wheat bread, butter milk

Apathya:

Amla, Lavaṇa and Kaṭu rasa

YAṢṬĪMADHUKA TAILA

(AFI Part I, 8:47)

Definition:

Yaṣṭīmadhuka Taila is a medicated oil preparation made with the ingredients in the Formulation Composition given below with Tila taila as the basic ingredient.

Formulation Composition:

1	Yaṣṭīmadhuka (Yaṣṭī API)	*Glycyrrhiza glabra*	Rt.	96 g
2	Kṣīra (Godughda API)	Cow milk	–	3.072 l
3	Dhātrīphala (Āmalakī API) - Svarasa	*Emblica officinalis*	P.	3.072 l
4	Taila (Tila Taila API)	*Sesamum indicum*	Sd. oil	768 ml

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Tila taila* to prepare *mūrcchita Tila taila* (Appendix 6.2.9.4).
- Take fresh *Āmalakī* and wash thoroughly with water. Grind and filter through *muslin cloth* to obtain *svarasa*.
- Strain the *Godugdha* through *muslin cloth*.
- Wash, clean, dry the ingredient number 1 of the formulation composition, powder it and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder *(kalka dravya)*.
- Transfer the powdered ingredient to wet grinder and grind with sufficient quantity of water to prepare homogeneous blend *(kalka)*.
- Take *mūrcchita Tila taila* in a stainless steel vessel and heat it.
- Add increments of *kalka*, stir thoroughly while adding the *Āmalakī rasa* 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.
- Continue the process of heating intermittently over a period of three days. Constantly check the *kalka* by rolling between the fingers.
- Stop the heating when the *kalka* easily rolls into a *varti* without sticking *(madhyama pāka lakṣaṇa)* to the fingers and at the appearance of froth (*phenodgama*) over the oil. Expose the *varti* and oil to flame and confirm the absence of crackling sound indicating absence of moisture.
- Filter while hot (about 80^0) through a *muslin cloth* and allow to cool.
- Store it in glass containers and pack them air-tight to protect from light and moisture.

Description:

Medicated oil, reddish yellow in colour with a pleasant odour

Identification:

Thin layer chromatography:

Shake 0.5 ml of formulation in 10 ml of *methanol* and keep the mixture for 12 h. Filter and carry out thin layer chromatography. Apply 10 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *methanol*: *glacial acetic acid* (8: 1: 0.5: 0.2) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *Liebermann Burchard reagent* followed by heating at 105^0 for about 10 min and observe under ultraviolet light (366 nm). It shows major spots at R_f 0.50, 0.55 (both light blue) and 0.65 (fluorescent).

Physico-chemical parameters:

Refractive index at 40^0:	1.4470 to 1.4740,	Appendix 3.1
Specific gravity at 40^0:	0.899 to 0.925,	Appendix 3.2
Saponification value:	190.0 to 200,	Appendix 3.7
Iodine value:	105 to 115,	Appendix 3.8
Acid value:	Not more than 3.0,	Appendix 3.9
Peroxide value:	Not more than 3.0,	Appendix 3.10

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6
Mineral oil:	Absent, Appendix 3.12

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Palita (premature greying of hair); Keśapatana (hair-fall)

Dose:

For Nasya, external application on scalp, face and whole body

VAṬĪ AND GUṬIKĀ

General Description:

Medicines prepared in the form of pills are known as *Vaṭī* and *Guṭikās*. Such pills are small, spherical, solid dosage forms, containing one or more drugs of plant, animal or mineral origin. Pills form a convenient way of administering bitter or unpleasant substances as medicines in a pre-defined dose. In earlier days, pills were made extemporaneously by the Vaidya-Pharmacist in the following manner. The drugs of plant origin are dried and made into fine powders, separately. The minerals are made into *Bhasma* or *Sindūra*, unless otherwise mentioned. In case where *Pārada* and *Gandhaka* are mentioned, *Kajjalī* is made first and other drugs are added, one by one, according to the formula. These are put into a *Khalva* and ground to a soft paste with the prescribed fluids. When more than one liquid is mentioned for grinding, they are used in succession. *Sugandha Dravyas*, like *Kastūrī*, *Karpūra*, which are included in the formula, are added. When the mass is properly ground and kneaded to a bolus, it is in a condition to be made into pills. In cases where sugar or jaggery (*Guḍa*) is mentioned, *Pāka* of these should be made on mild fire and removed from the oven. The powders of the ingredients are added to the *Pāka* and briskly mixed. When still warm, *Vaṭī/Guṭikās* should be rolled and dried in shade. The criterion to determine the final stage of the formulation before making pills is that it should not stick to the fingers when rolled. In contemporary times, pill making machine may be recommended for turning out larger batches by the pharmacists. In this method, the prepared mass may be expelled in the form of cylindrical threads of required size, which are cut at regular intervals to give units of a pre set size. These are rolled to a spherical form by hand and dried in shade or in sun as specified in the texts.

Characteristics and Preservation

Pills made of plant drugs when kept in air tight containers can be used for two years. Pills containing minerals and metals e.g. mercurycan be used for longer period as *Rasauṣadhi*.

Pills and *Vaṭīs* should not lose their original colour, smell, taste and form. When sugar, salt or *Kṣāra* is an ingredient, the pills should be protected from moisture.

The average weight of vati and gutika should be $\pm$ 10 percent of the labeled weight and disintegration time should not be more than an hour, unless specified otherwise.

ARKA VAṬĪ

(AFI Part II, 10:2)

Definition:

Arka Vaṭī is a pill preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Sauvarcala (Sauvarcala Lavaṇa (API))	Black salt	–	1 part
2	Sādara (Narasāra API) - Śuddha	Sal ammoniac	–	1 part
3	Arkapuṣpa (Arka (API))	*Calotropis procera*	Fl. Bd.	1 part
4	Marica API	*Piper nigrum*	Fr.	1 part
5	Jala API	Potable Water	–	QS

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Narasāra* to get *Narasāra - Śuddha* (Appendix 6.2.8.19).
- Roast coarsely powdered *Sauvarcala Lavaṇa* in a stainless steel pan on low flame till free from moisture, powder and pass through 180 μm IS Sieve (sieve number 85).
- Wash, clean, dry the ingredients numbered 3 and 4 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85).
- Mix all the ingredients thoroughly to prepare a homogenous blend.
- Add *Jala* in required quantity and triturate well to prepare a bolus.
- Expel the mass through rolling machine to obtain cylindrical threads and cut them to a desired weight.
- Roll the *vaṭīs* on flat surface to round them by circular motion of palm covered with a glove or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

Spherical pills, cream coloured, with characteristic odour and taste of black salt

Identification:

Microscopy:

Take about 10 g of the formulation, powder and wash thoroughly in water, till the added salts are totally removed. Filter without loss of powder. Take a small quantity of the washed powder, add a little chloral hydrate solution and warm; wash to remove chloral hydrate and mount in 50 per cent glycerin. Take another small portion of this washed powder and mount in iodine water. Observe the following characters in different mounts:

Trichomes, epidermal cells, fibrous layer from staminal corona, rosettes of calcium oxalate, xylem vessels with spiral thickenings, cortical cells of the pedicel, fragments of pollinium, thickwalled cells, pollen grains (**Arka Puṣpa);** polygonal hypodermal cells interspersed with group of stone cells, isodiametric stone cells with thick walls, fibres, polygonal perisperm cells with starch grains and oil globules (**Marica**).

Thin layer chromatography:

Extract 1 g of sample in 10 ml of *methanol* under reflux on a water-bath for about 30 min. Filter the extract and carry out the thin layer chromatography. Apply 5 µl of the extract on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *methanol*: *glacial acetic acid* (8: 0.6: 1: 0.2) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *Liebermann Burchard reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.25, 0.31, 0.66 (all faint blue) 0.53 (black) and 0.60, 0.79 (both faint green) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 25 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 3.0 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 10 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 40 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 8 per cent,	Appendix 2.2.8
pH (1 % aqueous solution):	5 to 6.,	Appendix 3.3

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Kaphaja Agnimāndya (digestion impairment due to kapha doṣa)

Dose:

500 mg - 1 g per day in divided doses with warm water

CITRAKĀDI GUṬIKĀ

(AFI Part I, 12:11)

Definition:

Citrakādi Guṭikā is a pill preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Citraka API	*Plumbago zeylanica*	Rt.	1 part
2	Pippalīmūla API	*Piper longum*	St.	1 part
3	Dvikṣāra			
	a. Yavakṣāra API	*Hordeum vulgare*	Water soluble ash of Pl.	1 part
	b. Sarjikṣāra (Svarjīkṣāra (API))	Crude alkaline earth	–	1 part
4	Pañcalavaṇa			
	a. Sauvarcala Lavaṇa (API)	Black salt	–	1 part
	b. Saindhava Lavaṇa (API)	Rock salt	–	1 part
	c. Viḍa Lavaṇa	Black salt*		1 part
	d. Sāmudra Lavaṇa API	Sea salt	–	1 part
	e. Audbhida Lavaṇa	Rock salt*		1 part
5	Vyoṣa			
	a. Śuṇṭhī API	*Zingiber officinale*	Rz.	1 part
	b. Marica API	*Piper nigrum*	Fr.	1 part
	c. Pippalī API	*Piper longum*	Fr.	1 part
6	Hiṅgu API - Śuddha	*Ferula foetida*	Exd.	1 part
7	Ajamodā API	*Apium leptophyllum*	Fr.	1 part
8	Cavya API	*Piper chaba*	St.	1 part
9	Mātuluṅga♣ API - rasa	*Citrus aurantifolia*	Fr. Juice	QS

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Hiṅgu* to get *Hiṅgu -Śuddha*. (Appendix 6.2.8.15).
- Wash, clean, dry the ingredients number 1, 2, 5, 7 and 8 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85).
- Roast coarsely powdered ingredients numbered 4 of the Formulation Composition in a stainless steel pan on low flame till free from moisture, powder separately and pass through 180 μm IS Sieve (sieve number 85).
- Roast ingredients numbered 3 of the Formulation Composition in a stainless steel pan on low flame till free from moisture.

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* Official Substitute

♣ Dāḍima rasa from seeds with flesh intact may also be alternatively used.

- Wash and clean fresh *Mātuluṅga* fruits, cut into halves, squeeze and strain the juice through *muslin cloth* to obtain *Mātuluṅga svarasa*.
- Mix all the ingredients thoroughly to prepare a homogenous blend.
- Add *svarasa* in required quantity and triturate well to prepare a bolus.
- Expel the mass through rolling machine to obtain cylindrical threads and cut them to a desired weight.
- Roll the *vaṭīs* on flat surface to round them by circular motion of palm covered with a glove or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

Light brown coloured pills with characteristic asafoetida odour and bitter taste

Identification:

Microscopy:

Take about five *Vaṭīs*, crush, wash in water repeatedly to get rid of salts; collect the residue and dry; stain a small portion in *iodine* and mount in *glycerin* (80 per cent), clear a portion in *chloral hydrate*, wash in water and mount in *glycerin* (80 per cent); clear another portion in 2 per cent *potassium hydroxide* solution, wash in water and mount in *glycerin*; observe the following characters:

Fragments of yellowish brown vittae (**Ajamodā**); a few needle and spindle shaped fibers with thick walls and narrow lumen, and isolated, circular, pitted stone cells (**Cavya**); group of isodiameric or slightly elongated stone cells with moderately thickened walls, interspersed with thin walled polygonal parenchyma cells (**Marica**), group of elongated, spindle shaped, wide lumened lignified stone cells often associated with spiral vessel units (**Pippalī**); abundant elliptic, oblong starch grains upto 60 microns in length with hilum nearer the narrower, beaked end (**Śuṇṭhī**); simple and compound starch grains having 2-7 components, round to oval with central hilum appearing like a point (**Pippalīmūla**); narrow long reticulately pitted tracheids and very long lignified pitted fibres (**Citraka**).

Thin layer chromatography:

Extract 5 g of the powdered formulation with 70 ml of *ethanol* in a Soxhlet apparatus on a water bath for 6 h, filter the extract and carry out thin layer chromatography. Apply 20 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *n-hexane*: *acetone* (7.5: 2.5) as mobile phase. After development, allow to dry in a current of cold air and examine under ultraviolet light (254 nm). It shows spots at R_f 0.17, 0.22 and 0.38 (all black). Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 C for about 10 min. The plate shows major spots at R_f, 0.28 (black), 0.39 (red) and 0.63, 0.69 (both pink) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 51 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 5 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 8 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 46 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 10 per cent,	Appendix 2.2.8
pH (10 % aqueous solution):	3. 5 to 4.5,	Appendix 3.3

Assay:

Contains not less than 0.10 per cent of *piperine* when assayed by the following method.

Dissolve 1.0 mg of *piperine* in a mixture of *methanol*: *chloroform* (1: 1) and make up the volume to 10 ml in a volumetric flask. Apply 1, 2, 6, 10, 14, 18 µl of solution on TLC plate and develop the plate to 8 cm using *n-hexane*: *acetone* (7: 3) as mobile phase. After development, dry the plate in a current of hot air and scan in the TLC scanner at a wavelength of 338 nm. Note the peak area and prepare the calibration curve by plotting peak area vs concentration of piperine.

Extract accurately weighed 2g powder of vati in 75 ml of alcohol in Soxhlet apparatus for 6 h. Filter the extract while hot and dry completely and weigh. Take 100 mg in volumetric flask and dissolve in a mixture of methanol-chloroform (1:1) and make up the volume to 25 ml. Apply 25 µl of the test solutions on TLC plate. Develop, dry and scan the plate as described in the proceeding paragraph for calibration curve of piperine. Record the area under the curve for a peak corresponding to piperine in the test solution. Calculate the amount of piperine in the test solution from the calibration curve of piperine.

Sodium:	Not less than 12.0 per cent w/w,	Appendix 5.10
Potassium:	Not less than 5.0 per cent w/w,	Appendix 5.10
Chloride:	Not less than 21.00 per cent w/w,	Appendix 5.11

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Agnimāndya (digestive impairment); Āmadoṣa (products of impaired digestion and metabolism); Grahaṇī (malabsorption syndrome)

Dose:

500 mg - 1 g per day in divided doses with warm water/ Butter milk

ELĀDI GUṬIKĀ

(AFI Part I, 12:3.)

Definition:

Elādi Guṭikā is a pill preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Elā (Sūkṣmailā API)	*Elettaria cardamomum*	Sd.	6 g
2	Patra (Tvakpatra API)	*Cinamomum tamala*	Lf.	6 g
3	Tvak API	*Cinamomum verum* (= *C. zeylanicum*)	St. Bk.	6 g
4	Pippalī API	*Piper longum*	Fr.	24 g
5	Sitā (Śarkarā API)	Sugar candy	–	48 g
6	Madhuka (Yaṣṭī API)	*Glycyrrhiza glabra*	Rt.	48 g
7	Kharjūra API	*Phoenix sylvestris*	P.	48 g
8	Mṛdvīkā (Drākṣā API)	*Vitis vinifera*	Dr. Fr.	48 g
9	Madhu API	Honey	–	QS

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Wash, clean, dry the ingredients numbered 1 to 4 and 6 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85).
- Wash, clean the ingredients numbered 7 and 8 of the Formulation Composition and grind separately to prepare soft pulp.
- Roast coarsely powdered *Sitā* in a stainless steel pan on low flame till free from moisture, powder and pass through 180 μm IS Sieve (sieve number 85).
- Add powdered Sitā to the soft pulp and grind well.
- Add powdered ingredients numbered 1 to 4 and 6 of the Formulation Composition to the pulp and triturate with *Madhu* to prepare a bolus.
- Expel the mass through rolling machine to obtain cylindrical threads and cut them to a desired weight.
- Roll the *vaṭīs* on flat surface to round them by circular motion of palm covered with a glove or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

A soft spherical pill, blackish brown in colour, odour cinnamon like with a sweet and pungent taste

Identification:

Microscopy:

Take about 10 *Vaṭīs*, keep in lukewarm water for 15 minutes, stir and centrifuge at 2000 rpm for five minutes and decant the supernatant without loss of sediment. Take the sediment, wash in water and repeat the centrifuging; mount a small quantity of sediment in 50 per cent *glycerin*, mount another small quantity of sediment each in *Iodine* and 0.001 per cent *saffranin water*. Observe the following characters in the different mounts.

Epidermal cells with oil cells, sclerenchymatous cells from testa **(Sūkṣmailā)**, sclereids with inner walls thickened; short, very thick fibres **(Tvak)**; lower epidermis with stomata, fragments of spiral vessels, short trichomes, thick-walled cells of upper epidermis, schizogenous mucilage cells (**Tvakpatra**); spindle shaped and wide lumened sclereids, perisperm cells in abundance **(Pippalī)**; calcium oxalate crystals, fragments of large vessels, lignified xylem parenchyma, groups of fibres with crystal sheath, elongated fibres **(Yaṣṭī)**; stone cells, vessels with spiral thickening, loose fibrous mass **(Kharjūra)**; parenchyma cells with clusters of raphides and spherical pigmented cells, medullary rays, xylem vessels with spiral thickening **(Drākṣā)**.

Thin layer chromatography:

Extract 1 g of formulation in 10 ml of *methanol* under reflux for about 30 min. Filter the extract and carry out the thin layer chromatography. Apply 4 µl of the extract on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *methanol*: *glacial acetic acid* (8:1:0.7:0.2) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *Liebermann Burchard reagent* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.25, 0.31, 0.49, 0.51, 0.66 (all faint blue) 0.53 (black), 0.56 (blue) and 0.60, 0.79 (both faint green) in visible light.

Extract 1 g of formulation in 10 ml of *methanol* under reflux for about 2 h. Filter the extract and carry out the thin layer chromatography. Apply 5 µl of the extract on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: (7:3) as mobile phase. After development, allow the plate to dry in air. Spray the plate in *Liebermann Burchard reagent* followed by heating at 105^0 for about 10 min and examine the plate under ultraviolet light (366nm). It shows major spots at R_f 0.11, 0.19, 0.28 (all fluorescent blue), 0.16 (faint pink), 0.24 (fluorescent green), 0.32 (black), 0.37 (light blue), 0.49 (fluorescent green, corresponding to piperine), 0.66 (faint yellow).

Physico-chemical parameters:

Total Ash:	Not more than 3.0 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 1.0 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 40 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 48 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 14 per cent,	Appendix 2.2.8
pH (1 % aqueous solution):	5 to 6,	Appendix 3.3

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Chardi (emesis); Hikkā (hiccup); Kāsa (cough); Śvāsa (asthma); Bhrama (vertigo); Mūrcchā (syncope); Raktapitta (bleeding disorder); Raktaniṣṭhīvana (haemoptysis); Jvara (fever); Mada (intoxication); Tṛṣṇā (thirst); Aruci (anorexia); Pārśvaśūla (pleurodyria); Śoṣa (cachexia); Plīhāroga (splenic disease); Āmavāta (rheumatism); Svarabheda (hoarseness of voice); Kṣatakṣaya (emaciation due to injury); Śukrakṣaya (oligospermia)

Dose:

2- 4 g per day in divided doses with honey

LAŚUNĀDI VAṬĪ

(AFI Part I, 12:27)

Definition:

Laśunādi vaṭī is a pill preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Laśuna API	*Allium sativum*	Bl.	1 part
2	Jīraka (Śveta Jīraka API)	*Cuminum cyminum*	Fr.	1 part
3	Saindhava (Saindhava Lavaṇa (API))	Rock salt	–	1 part
4	Gandhaka API-Śuddha	Sulphur	–	1 part
5	Trikaṭu			
	a. Śuṇṭhī API	*Zingiber officinale*	Rz.	1 part
	b. Marica API	*Piper nigrum*	Fr.	1 part
	c. Pippalī API	*Piper longum*	Fr.	1 part
6	Rāmaṭha (Hiṅgu API) - Śuddha	*Ferula foetida*	Exd.	1 part
7	Nimbu (Nimbū API) - rasa	*Citrus limon*	Fr.	QS

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Gandhaka* to get *Gandhaka - Śuddha*. (Appendix 6.2.8.3).
- Treat *Hiṅgu* to get *Hiṅgu* - Śuddha. (Appendix 6.2.8.15).
- Wash, clean, dry the ingredients numbered 2 and 5 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85).
- Roast coarsely powdered *Saindhava Lavaṇa* in a stainless steel pan on low flame till free from moisture, powder and pass through 180 μm IS Sieve (sieve number 85).
- Clean *Rasona* and grind to prepare fine paste.
- Wash and clean fresh *Nimbū* fruits, cut into halves, squeeze and strain the juice through *muslin cloth* to obtain *Nimbū svarasa*.
- Mix all the ingredients thoroughly to prepare a homogenous blend.
- Add svarasa in required quantity and triturate well to prepare a bolus.
- Expel the mass through rolling machine to obtain cylindrical threads and cut them to a desired weight.
- Roll the *vaṭīs* on flat surface to round them by circular motion of palm covered with a glove or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

Brown coloured pills with characteristic garlic odour and saline taste

Identification:

Microscopy:

Take about 5 or 6 *Vaṭīs* and crush to a powder; add *chloroform* and stir thoroughly; let stand for some time to allow the heavier sulphur to settle down and the lighter plant debris to remain on top; pour the supernatant with the plant debris in another container, and repeat the process with *chloroform*; remove supernatant with plant debris to a dish, and allow chloroform to evaporate; wash the debris in alcohol once,followed by washing in water 2 or 3 times, to remove the salt; dry the debris and prepare mounts for microscopy by staining a small portion in *iodine*, and clearing another portion in *chloral hydrate*. Observe the following characteristics in the mounts.

A few fragments of thin walled elongated parenchyma cells showing stomata with spiral vessels and cells containing rhomboid crystals of calcium oxalate (**Laśuna**); group of elongated stone cells from the mesocarpic layer and multicellular, multiseriate trichome (**Śveta Jīraka**); parenchyma cells, rounded to oval with small intercellular spaces, with a few cells loosely packed with cells filled with oleoresin, abundant starch granules, individual grain elliptic oblong with hilum nearer the narrower, beaked end (**Śuṇṭhī**); group of isodiameric or slightly elongated stone cells with moderately thickened walls, interspersed with thin walled polygonal parenchyma cells from hypodermis (**Marica**); groups of elongated, spindle shaped, wide lumened lignified stone cells, often associated with narrow groups of spiral vessels (**Pippalī**). In addition, abundant perisperm cells, packed with minute starch grains, characteristic of **Pippalī** and **Marica**, and loose oval starch grains upto 60 microns long from **Śuṇṭhī** are also observed.

Thin layer chromatography:

Extract 5 g of the powdered sample with 70 ml of *ethanol* in a Soxhlet apparatus on a water bath for 6 h, filter and carry out thin layer chromatography of the filtrate.

Apply 20.0 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *n-hexane*: *acetone* (7.6: 2.4) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (254 nm). It shows spots at R_f 0.17, 0.22, 0.39 and 0.75 (all black). Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. The plate shows major spots at R_f 0.15 (violet), 0.21 (yellow), 0.29, 0.77 (both black) and 0.37, 0.44 (both purple) in visible light.

Chemical tests:

Test for Sulphur:

Extract 1.0 g of the sample with 10 ml of *carbon disulphide*. Filter the carbon disulphide solution and evaporate the solvent. The residue complies with the *Test for sulphur* (Appendix 5.13.11)

Dissolve 1 g of sample in 10 ml of deionised water and filter. The filtrate complies with the *Test for Chlorides* (Appendix 5.13.6).

Complies with the *Test for Hiṅgu* (Appendix 5.13.13)

Physico-chemical parameters:

Total Ash:	Not more than 17 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 5 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 14 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 23 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 8 per cent,	Appendix 2.2.8
pH (10 % aqueous solution):	3 to 4,	Appendix 3.3

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Visūcikā (gastro-enteritis with piercing pain); Ajīrṇa (dyspepsia); Atisāra (diarrhoea)

Dose:

500 mg - 1 g per day in divided doses with warm water

LAVAṄGĀDI VAṬĪ

(AFI Part I, 12:26)

Definition:

Lavaṅgādi Vaṭī is a pill preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Lavaṅga API	*Syzigium aromaticum*	Fl. Bd.	1 part
2	Marica API	*Piper nigrum*	Fr.	1 part
3	Akṣaphalatvak (Bibhītaka API)	*Terminalia belerica*	P.	1 part
4	Khadirasāra (Khadira API)	*Acacia catechu*	Wd. Ext.	3 parts
5	Babbūlavṛkṣaja (Babbūla API) Kaṣāya	*Acacia nilotica*	St. Bk.	QS

Method of preparation:

- Take all ingredients of pharmacopeial quality.
- Wash, clean, dry the ingredients numbered 1 to 3 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85).
- Powder separately the ingredient number 4 of the Formulation Composition and pass through 180 μm IS Sieve (sieve number 85).
- Wash, clean, dry the ingredient number 5 of the Formulation Composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) *(kvātha dravya)*.
- Add four times water for decoction to the *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *kvātha*.
- Mix all the ingredients thoroughly to prepare a homogenous blend.
- Add *kvātha* in required quantity and triturate well to prepare a bolus.
- Expel the mass through rolling machine to obtain cylindrical threads and cut them to a desired weight.
- Roll the *vaṭīs* on flat surface to round them by circular motion of palm covered with a glove or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

Spherical pill, blackish brown in colour with a pleasant odour, taste bitter and astringent

Identification:

Microscopy:

Take about 10 *Vaṭīs*, powder and wash thoroughly in water. Filter without loss of powder. Take a small quantity of the washed powder, add a little *chloral hydrate* solution, warm and wash to

remove *chloral hydrate*. Take a small quantity of residue and mount in 50 per cent *glycerin*, mount another small quantity each of residue in *iodine* and in 0.001 per cent *saffranin water*. Observe the following characters in the different mounts.

Polygonal perisperm cells with starch grains and oil globules, polygonal hypodermal cells, pericarp, elongated and isodiametric stone cells, fibres **(Marica);** short trichomes with a swollen basal cell, stone cells **(Bibhītaka);** tricolpate pollen grains, fibres, spiral tracheids, calcium oxalate crystals in rosette aggregates, schizolysigenous oil cavity embedded in parenchyma, **(Lavaṅga)**.

Thin layer chromatography:

Extract 1 g of powdered sample with 10 ml of *n-hexane* by keeping the mixture for 2 h with occasional shakings, filter the extract and evaporate the filtrate on water bath at 60^0. Dissolve the residue in 10 ml of methanol, filter 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*: *glacial acetic acid* (8: 2: 0.2) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *anisaldehyde sulphuric acid* followed by heating at 105^0 for about 10 min. It shows major spots at R_f 0.20 (pink), 0.24 (faint brown), 0.29 (light blue corresponding to piperine), 0.35, 0.43 (both black), 0.54 (brown), 0.74 (dark brown corresponding to eugenol) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 5.0 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 1.0 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 26 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 22 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 14 per cent,	Appendix 2.2.8
pH (1% aqueous solution):	4 to 5,	Appendix 3.3

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Kāsa (cough); Śvāsa (asthma)

Dose:

500 mg - 1 g per day in divided doses (to be kept in mouth till it dissolves)

PLĪHĀRI VAṬIKĀ

(AFI Part I, 12:17)

Definition:

Plīhāri Vaṭikā is a pill preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Sahāsāra (Kumārī (API))	*Aloe barbadensis*	Fresh Lf. P.*	1 part
2	Abhra (Abhraka Bhasma (API))	Calcined Mica	–	1 part
3	Kāsīsa (Kāśīśa API) - Śuddha	Green vitreol	–	1 part
4	Laśuna API	*Allium sativum*	Bl.	1 part
5	Droṇapuṣpī API - Svarasa	*Leucas cephalotus*	Juice of fresh Pl.	QS

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Kāśīśa* to get *Kāśīśa* - Śuddha (Appendix 6.2.8.17).
- Treat *Abhraka* to get *Abhraka bhasma*.
- Clean *Rasona* and grind to prepare fine paste. .
- Take fresh *Droṇapuṣpī* and wash thoroughly with water. Grind and filter through *muslin cloth* to obtain *svarasa*.
- Wash and clean fresh *Kumārī* and separate the pulp to obtain *Kumārī svarasa.*
- Mix all the ingredients thoroughly to prepare a homogenous blend.
- Add svarasa in required quantity and triturate well to prepare a bolus.
- Expel the mass through rolling machine to obtain cylindrical threads and cut them to a desired weight.
- Roll the *vaṭīs* on flat surface to round them by circular motion of palm covered with a glove or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

Reddish brown coloured pills with characteristic garlic odour and bitter taste

Identification:

Microscopy:

Take about five *Vaṭīs*, crush, wash in slow running water on a 150 μm IS Sieve (sieve number 100) to allow minerals to be washed away. Collect the material left on the sieve, without loss of material; take a small amount, clear in *chloral hydrate* solution, wash in water and mount in *glycerin* (80 per cent), observe the following characters:

* Kanyāsāra may alternatively be used.

A few fragments of thin walled elongated parenchyma cells with stomata, spiral vessels and parenchymatous cells containing rhomboid crystals of calcium oxalate (**Laśuna**); isolated acicular needles of calcium oxalate crystals (**Sahāsāra**).

Thin layer chromatography:

Extract 5 g of the powdered sample with 70 ml of *ethanol* in a Soxhlet apparatus on a water bath for 6 h, filter and carry out thin layer chromatography. Apply 20 µl of the filtrate on TLC plate. Develop the plate to a distance of 8 cm using *n-butanol*: *isopropanol*: *acetic acid*: *water* (3: 1: 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. The plate shows major spots at R_f 0.41 (deep green), 0.56 (light green), 0.67 and 0.90 (pink) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 60 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 14 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 8 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 45 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 12 per cent,	Appendix 2.2.8
pH (10 % aqueous solution):	3 to 4,	Appendix 3.3

Assay:

Not less than 0.25 per cent of aloin when assayed by the following method.

Dissolve 2.5 mg of aloin in mixture of *methanol*: *chloroform* (1: 1) and make up the volume to 25 ml in another volumetric flask. Apply 2, 4, 6, 8, 10, 12 µl of solution on TLC plate and develop the plate to 8 cm using *ethyl acetate*: *methanol*: *water* (8: 1.35: 1) as mobile phase. After development dry the plate in a current of hot air and scan in the TLC scanner at a wavelength of 366 nm. Note the peak area and prepare the calibration curve by plotting peak area vs concentration of aloin.

Extract accurately weighed about 7 g of powdered *Vaṭīs* in 100 ml of *alcohol* in a Soxhlet apparatus for 6 h. Filter the extract while hot and dry completely and weigh. Take 25 mg of extract in volumetric flask and dissolve in a mixture of *methanol*: *chloroform* (1: 1) and make up the volume to 25 ml. Apply 7 µl of the test solutions on TLC plate. Develop, dry and scan the plate as described in the proceeding paragraph for calibration curve of aloin. Record the area under the curve for a peak corresponding to aloin in the test solution. Calculate the amount of aloin in the test solution from the calibration curve of aloin.

Total Iron:	Not less than 18.5 per cent w/w,	Appendix 5.6
Aluminum:	Not less than 1.5 per cent w/w,	Appendix 5.
Magnesium:	Not less than 0.9 per cent w/w,	Appendix 5.7
Potassium:	Not less than 1.9 per cent w/w,	Appendix 5.10
Silicates:	Not less than 9.5 per cent w/w,	Appendix 5.9

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Plihā-yakṛdroga (spleno-hepato disease); Gulma (abdominal lump); Agnimāndya (digestive impairment); Śotha (inflammation); Kāsa (cough); Śvāsa (asthma); Tṛṣṇā (thirst); Kampa (tremor); Dāha (burning sensation); Chardi (emesis); Bhrama (vertigo)

Dose:

500 mg per day in divided doses

PRABHĀKARA VAṬĪ

(AFI Part I, 12:15)

Definition:

Prabhākara Vaṭī is a pill preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Mākṣika (Svarṇamākṣika Bhasma (API))	*Calcined Chalcopyrite*	–	1 part
2	Lauha (Lauha Bhasma (API))	*Calcined Lauha*	–	1 part
3	Abhra (Abhraka Bhasma (API))	*Calcined Abhraka*	–	1 part
4	Tugākṣīrī (Vaṃśalocana (API))	*Bamboo manna*	S. C.	1 part
5	Śilājatu (API) - Śuddha			1 part
6	Pārthavāri (Arjuna API) - Kvātha	*Terminalia arjuna*	St. Bk.	QS

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Svarṇamākṣika* to get *Svarṇamākṣika bhasma*.
- Treat *Lauha* to get *Lauha bhasma*.
- Treat *Abhraka* to get *Abhraka bhasma*.
- Treat *Śilājatu* to get *Śilājatu- Śuddha* (Appendix 6.2.8.13)
- Wash, clean, dry the ingredient number 6 of the Formulation Composition, powder separately and pass through 355 μm IS Sieve (sieve number 44) (*kvātha dravya*).
- Add four times water for decoction to the *kvātha dravya* and soak for 4 h, heat and reduce the volume to one-fourth. Filter through *muslin cloth* to obtain *kvātha*.
- Mix all the ingredients thoroughly to prepare a homogenous blend.
- Add *kvātha* in required quantity and triturate well to prepare a bolus.
- Expel the mass through rolling machine to obtain cylindrical threads and cut them to a desired weight.
- Roll the *vaṭīs* on flat surface to round them by circular motion of palm covered with a glove or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

Reddish brown pills with a faint odour and acrid taste

Identification:

Microscopy:

Take about 5 *Vaṭīs*, triturate with water in a mortar, collect in a beaker stir with glass rod, swirl gently and pour off the supernatant in to another beaker; repeat this process 3 to 4 times, so that as much of the bhasmas and minerals components can be floated and removed. Add *strong sulphuric*

acid, stir, and remove sulphuric acid by pouring it off. Wash the residue, and mount a small quantity in water and another in *glycerin*; observe the characters:

Angular, flat, structure less plates, appear in good relief in lower powers in water mounts, but only faintly visible in glycerin mounts; it is invisible between crossed polars in the polarising microscope in both mounts (**Vaṃśalocana**).

Thin layer chromatography:

Extract 5 g of the powdered formulation with 50 ml of *ethanol* in a Soxhlet apparatus on a water bath for 6 h, filter and carry out thin layer chromatography. Apply 20.0 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *chloroform*: *methanol* (9: 1) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (366 nm). It showed spots at 0.29 (dark blue) and 0.40, 0.45, 0.54, 0.63 (all faint blue). Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. The plate shows major spots at R_f 0.26 (red), 0.31, 0.41 (both brown), and 0.37 (black) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 70 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 7 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 14 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 13 per cent,	Appendix 2.2.8
pH (10 % aqueous solution):	7.0 to 8.5,	Appendix 3.3

Assay:

Total Iron:	Not less than 21.5 per cent w/w,	Appendix 5.6
Calcium:	Not less than 3.0 per cent w/w,	Appendix 5.4
Copper:	Not less than 0.05 per cent w/w	Appendix 5.5
Silicates:	Not less than 36.5 per cent w/w	Appendix 5.9
Sulphur:	Not less than 6.0 per cent w/w	Appendix 5.12

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Hṛdroga (heart disease)

Dose:

250 mg - 500 mg per day in divided doses with water/ Arjuna kvātha/milk

RAJAḤPRAVARTINĪ VAṬĪ

(AFI Part I, 12:25)

Definition:

Rajaḥpravartinī Vaṭī is a pill preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Kanyāsāra (API)	*Aloe barbadensis*	Dry Ext.	1 part
2	Kāsīsa (Kaśīśa API) - Śuddha	Green vitreol	–	1 part
3	Rāmaṭha (Hiṅgu API) - Śuddha	*Ferula foetida*	Exd.	1 part
4	Ṭaṅkaṇa API - Śuddha	Borax	–	1 part
5	Kanyakā (Kumārī (API)) - Svarasa	*Aloe barbadensis*	Lf.	QS

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Kāsīsa* to get *Kaśīśa - Śuddha*. (Appendix 6.2.8.17)
- Treat *Hiṅgu* to get *Hiṅgu - Śuddha*. (Appendix 6.2.8.15).
- Treat *Taṅkaṇa* to get *Taṅkaṇa - Śuddha*. (Appendix 6.2.8.5).
- Wash and clean fresh *Kumārī* and separate the pulp to obtain *Kumārī svarasa.*
- Dissolve the *Kanyāsāra* in *Kumārī svarasa.*
- Mix all the ingredients thoroughly to prepare a homogenous blend.
- Add *svarasa* in required quantity and triturate well to prepare a bolus.
- Expel the mass through *vaṭī* machine to obtain cylindrical threads and cut the *vaṭīs* to a desired weight.
- Expel the mass through rolling machine to obtain cylindrical threads and cut them to a desired weight.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

Blackish grey coloured pills with a characteristic asafoetida odour and saline taste

Identification:

Thin layer chromatography:

Extract 5 g of the powdered sample with 50 ml of *ethanol* in a Soxhlet apparatus on a water bath for 6 h, filter and carry out thin layer chromatography.

a) Apply 20 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *n-hexane*: *acetone* (7. 5: 2.5) as mobile phase. After development, allow the plate to dry in air and examine under ultraviolet light (366 nm). It shows spots at R_f 0.25 (dark blue) and 0.30, 0.39

(both faint blue). Spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. The plate shows major spots at R_f 0.25 (reddish brown), 0.34 (pale brown), 0.43 and 0.61 (brown) in visible light.

b) Apply 20 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *ethyl acetate*: *methanol*: *water* (10: 1.35: 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *ethanolic potassium hydroxide reagent* followed by heating at 105^0 for about 10 min. The plate shows major spots at R_f 0.27 (reddish yellow) and 0.72 (red) in visible light.

Chemical Test:

Complies with *Tests for Hiṅgu* (Appendix 5.13.13), *Borax* (Appendix 5.13.10) and *Anthraquinones* (Appendix 5.13.12)

Physico-chemical parameters:

Total Ash:	Not more than 36 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 26 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 3.0 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 30 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 12 per cent,	Appendix 2.2.8
pH (10 % aqueous solution):	6.5 to 7.5,	Appendix 3.3

Assay:

Not less than 0.56 per cent of aloin when assayed by the following method.

Dissolve accurately weighed about 2.5 mg of aloin in *methanol-chloroform* (1: 1) and make up the volume to 25 ml in another volumetric flask. Apply 2, 4, 6, 8, 10, 12 µl of solution on TLC plate and develop the plate to 8 cm using *ethyl acetate*: *methanol*: *water* (8: 1.35: 1) as mobile phase. After development dry the plate in a current of hot air and scan in the TLC scanner at a wavelength of 366 nm. Note the peak area and prepare the calibration curve by plotting peak area vs concentration of aloin.

Extract accurately weighed about 7 g powder of *Vaṭīs* in 100 ml of alcohol in Soxhlet apparatus for 6 h. Filter the extract while hot and dry completely and weigh. Take 25 mg in volumetric flask. Make the volume to 25 ml with *methanol-chloroform* (1: 1). Apply 10 µl of the test solutions on TLC plate. Develop, dry and scan the plate as described in the proceeding paragraph for calibration curve of aloin. Record the area under the curve for a peak corresponding to aloin in the test solution. Calculate the amount of aloin in the test solution from the calibration curve of aloin.

Sodium:	Not less than 4.5 per cent w/w,	Appendix 5.10
Total Iron:	Not less than 3.5 per cent w/w,	Appendix 5.6

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Rajorodha (obstructed menstrual flow); Kaṣṭārtava (dysmenorrhoea); Ārtavavedanā (dysmenorrhoea)

Dose:

500 mg - 1 g per day in divided doses with Warm water/ Tila kvātha/Kulattha kvātha

SAÑJĪVANĪ VAṬĪ

(AFI Part I, 12:35)

Definition:

Sañjīvanī Vaṭī is a pill preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Viḍaṅga API	*Embelia ribes*	Fr	1 part
2	Nāgara (Śuṇṭhī API)	*Zingiber officinale*	Rz.	1 part
3	Kṛṣṇā (Pippalī API)	*Piper longum*	Fr.	1 part
4	Pathyā (Harītakī API)	*Terminalia chebula*	P.	1 part
5	Āmala (Āmalakī API)	*Emblica officinalis*	P.	1 part
6	Bibhītaka API	*Terminalia bellirica*	P.	1 part
7	Vacā API	*Acorus calamus*	Rz.	1 part
8	Guḍūcī API	*Tinospora cordifolia*	St.	1 part
9	Bhallātaka API - Śuddha	*Semecarpus anacardium*	Fr.	1 part
10	Viṣa (Vatsanābha API) - Śuddha	*Aconitum chasmanthum*	Rt. Tr.	1 part
11	Gomūtra (API)	Cow urine	–	QS

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Bhallātaka* to get *Bhallātaka - Śuddha*. (Appendix 6.2.8.7).
- Treat *Vatsanābha* to get *Vatsanābha - Śuddha*. (Appendix 6.2.8.9).
- Wash, clean, dry the ingredients numbered 1 to 8 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85).
- Mix all the ingredients thoroughly to prepare a homogenous blend.
- Powder *Bhallātaka - Śuddha* and *Vatsanābha- Śuddha* separately and pass through 180 μm IS Sieve (sieve number 85) and add to the mixture to prepare a homogenous blend.
- Strain the *Gomūtra* through *muslin cloth*.
- Add *Gomūtra* in required quantity and triturate well to prepare a bolus.
- Expel the mass through rolling machine to obtain cylindrical threads and cut them to a desired weight.
- Roll the *vaṭīs* on flat surface to round them by circular motion of palm covered with a glove or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

Black coloured pills with a pleasant odour and acrid taste

Identification:

Microscopy:

Take about 5 *Vaṭīs*, crush, take in a beaker containing *chloroform* sufficient to wash the powder two times; remove chloroform, allow to dry; wash the powder once in *alcohol* and again dry; take a small amount and wash in water and mount in *glycerin* (80 per cent); take another small portion, clear in *chloral hydrate* solution, wash in water and mount in *glycerin*; observe the following characters:

Groups of stone cells from testa with very thick walls and radiating pit canals (**Viḍaṅga**); abundant thin walled parenchyma cells, rounded to oval with small intercellular spaces, with a few cells loosely packed with starch grains upto 60 microns, individual grain elliptic, oblong, with hilum nearer the narrower, beaked end and some cells filled with oleoresin (**Śuṇṭhī**); group of elongated, spindle shaped, wide lumened lignified stone cells often associated with spiral narrow vessels (**Pippalī**); polygonal epidermal cells from pericarp, where walls are slightly beaded, with thin septa dividing the cells (**Harītakī**); a few short stout unicellular thick walled trichomes with a basal epidermal cell (**Bibhītaka**); large mesocarpic parenchyma cells, with typical corner thickenings, cells of epidermal tissue with small crystals of calcium oxalate (**Āmalakī**); tissue debris showing moderately thick walled parenchymatous cells sorrounding large, irregularly shaped air spaces, cells contain spherical starch grains (**Vacā**); rounded, hemispherical and irregularly ovoid starch grains with central hilum and isolated crystal fibres (**Guḍūcī**); a few large isolated or group of rectangular or angular stone cells with thin walls and wide pitted lumen (**Vatsanābha**);large lysigenous cavities without contents,radially elongated thick walled sclerides from endocarp, and occasional papillary oil cell from epicarp (**Bhallātaka**).

Thin layer chromatography:

Extract 5 g of the powdered sample with 70 ml of *ethanol* in a Soxhlet apparatus on a water bath for 6 h, filter and carry out thin layer chromatography.

a) Apply 20.0 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *n-hexane*: *acetone* (7.5: 2.5) as mobile phase. After development, allow the plate to dry in air and spray the plate with *anisaldehyde-sulphuric acid reagent* followed by heating at 105^0 for about 10 min. The plate shows major spots at R_f 0.36, 0.41 (both dark pink), 0.48 (brown), 0.62, 0.69 (both purple) and 0.75 (violet) in visible light.

b) Apply 20 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *diethyl amine* (7: 2: 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *Dragendroff reagent* and dry the plate followed by dipping in 5 per cent *ethanolic sulphuric acid*. The plate shows major spots at R_f 0.49 and 0.59 (both orange) in visible light.

Physico-chemical parameters:

Total Ash:	Not more than 4 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 18 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 17 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 10 per cent,	Appendix 2.2.8
pH (10 % aqueous solution):	4.0 to 5.5,	Appendix 3.3

Assay:

Not less than 0.047 per cent of piperine when assayed by the following method.

Dissolve 1.0 mg of piperine in a mixture of *methanol*: *chloroform* (1: 1) and make up the volume to 10 ml in another volumetric flask. Apply 1, 2, 6, 10, 14, 18 µl of solution on TLC plate and develop the plate to 5.5 cm using *n-hexane*: *acetone* (7: 3) as mobile phase. After development, dry the plate in a current of hot air and scan in the TLC scanner at a wavelength of 338 nm. Note the peak area and prepare the calibration curve by plotting peak area vs concentration of piperine.

Extract accurately weighed 2 g powder of *Vaṭīs* in 75 ml of alcohol in Soxhlet apparatus for 6 h. Filter the extract while hot and dry completely and weigh. Take 100 mg in volumetric flask and dissolve in a mixture of *methanol*: *chloroform* (1: 1) and make up the volume to 25 ml. Apply 25 µl of the test solutions on TLC plate. Develop, dry and scan the plate as described in the proceeding paragraph for calibration curve of piperine. Record the area under the curve for a peak corresponding to piperine in the test solution. Calculate the amount of piperine in the test solution from the calibration curve of piperine.

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Ajīrṇa (indigestion); Gulma (abdominal lump); Visūcikā (gastroenteritis with piercing pain); Sarpadaṃśa (snake bite)

Dose:

250 - 500 mg per day in divided doses with warm water/ Ārdraka svarasa

ŚAṄKHA VAṬĪ

(AFI Part I, 12:32)

Definition:

Śaṅkha Vaṭī is a pill preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Ciñcā API -kṣāra	*Tamarindus indica*	St. Bk.	48 g
2	Paṭuvraja (Pañca lavaṇa each in equal quantity)			48 g
	a. Saindhava Lavaṇa (API)	Rock salt	–	
	b. Sāmudra Lavaṇa API	Sea salt	–	
	c. Sauvarcala Lavaṇa (API)	Black salt	–	
	d. Viḍa Lavaṇa	Black salt*		
	e. Audbhida Lavaṇa	Rock salt*		
3	Śaṅkha (Śaṅkha Bhasma (API))	Calcined Conch	–	48 g
4	Hiṅgu API - Śuddha	*Ferula foetida*	Exd.	48 g
5	Vyoṣa			
	a. Śuṇṭhī API	*Zingiber officinale*	Rz.	48 g
	b. Marica API	*Piper nigrum*	Fr.	48 g
	c. Pippalī API	*Piper longum*	Fr.	48 g
6	Rasa (Pārada API) - Śuddha	Mercury	–	3 g
7	Amṛta (Vatsanābha API) - Śuddha	*Aconitum chasmanthum*	Rt. Tr.	3 g
8	Valī (Gandhaka API) - Śuddha	Sulphur	–	3 g
9	Nimbū API - Svarasa	*Citrus limon*	Fr. juice	QS

Method of preparation:

- Take all ingredients of pharmacopoeial quality.
- Treat *Śaṅkha* to prepare *Śaṅkha* bhasma.♣
- Treat *Hiṅgu* to get *Hiṅgu - Śuddha* (Appendix 6.2.8.15), *Vatsanābha* to get *Vatsanābha - Śuddha* (Appendix 6.2.8.9), *Pārada* to get *Pārada - Śuddha* (Appendix 6.2.8.20) and *Gandhaka* to get *Gandhaka - Śuddha* (Appendix 6.2.8.3).
- Triturate *Pārada - Śuddha* and *Gandhaka - Śuddha* together in a *Khalvayantra* to prepare *Kajjalī*. (Appendix 6.2.1).
- Wash, clean, dry the ingredients numbered 5 of the Formulation Composition, powder separately and pass through 180 μm IS Sieve (sieve number 85).
- Powder *Vatsanābha - Śuddha* and pass through 180 μm IS Sieve (sieve number 85).

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* Official Substitute

♣ Alternative method: Make thin paste of *Ciñcā kṣāra* and *Pañca Lavaṇa* in *Nimbū Svarasa*. Heat and quench *Śaṅkha - Śuddha* repeatedly in this paste till it disintegrates to powder.

- Roast coarsely powdered *Saindhava*, *Sāmudra*, *Sauvarcala*, *Viḍa* and *Audbhida Lavaṇas* in a stainless steel pan on low flame till free from moisture, powder separately and pass through 180 μm IS Sieve (sieve number 85).
- Prepare *Ciñcā kṣāra* (Appendix 6.2.3) and roast in a stainless steel pan on low flame till free from moisture.
- Wash and clean fresh *Nimbū* fruits, cut into halves, squeeze and strain the juice through *muslin cloth* to obtain *Nimbū svarasa*.
- Mix all the ingredients thoroughly to prepare a homogenous blend.
- Add *svarasa* in required quantity and triturate well to prepare a bolus.
- Expel the mass through rolling machine to obtain cylindrical threads and cut them to a desired weight.
- Roll the *vaṭīs* on flat surface to round them by circular motion of palm covered with a glove or use suitable mechanical device.
- Dry the rounded *vaṭīs* in a tray-dryer at a temperature not exceeding 60^0 for 10 to 12 h.
- Store *vaṭīs* in containers and pack them air-tight to protect from light and moisture.

Description:

Light grey pills with a characteristic asafoetida odour and salty taste.

Identification:

Microscopy:

Take about five *Vaṭīs*, crush, wash in slow running water on a 150 μm IS Sieve (sieve number 100) to allow mineral and water soluble matter to be washed away. Collect the material on sieve, wash repeatedly in water and mount a small portion in *glycerin* (80 per cent); warm a small portion in *chloral hydrate* solution, wash and mount in *glycerin*; observe the following characters:

Groups of isodiametric or slightly elongated stone cells with moderately thickened walls, interspersed with thin walled polygonal parenchyma cells from hypodermis (**Marica**); group of elongated, spindle shaped, wide lumened lignified stone cells (**Pippalī**); a few large isolated or group of rectangular or angular stone cells with thin walls and wide pitted lumen (**Vatsanābha**); abundant thin walled parenchyma cells, rounded to oval with small intercellular spaces, with a few cells loosely packed with starch grains, individual grain elliptic, oblong, varying upto 60 microns with hilum nearer the narrower, beaked end and some cells filled with oleoresin (**Śuṇṭhī**); abundant loose starch grains and perisperm cells are general characters.

Thin layer chromatography:

Extract 5 g of the powdered formulation with 70 ml of *ethanol* in a Soxhlet apparatus on a water bath for 6 h, filter and carry out thin layer chromatography.

a) Apply 20.0 μl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *n-hexane*: *acetone* (7.5: 2.5) 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. The plate shows major spots at R_f , 0.13 (brown), 0.19, 0.23 (both green), 0.35 (purple), 0.40 (blue), 0.58 (pink) and 0.60 (violet)in visible light.

b) Apply 20.0 µl of the extract on TLC plate. Develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *diethyl amine* (7: 2: 1) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *Dragendroff reagent* and dry the plate followed by dipping in 5 per cent *ethanolic sulphuric acid*. The plate shows two major spots at R_f. 0.49 and 0.59 (both orange) in visible light.

Chemical tests:

Complies with *Tests for Hiṅgu* (Appendix 5.13.13) and *Sulphur* (Appendix 5.13.11)

Physico-chemical parameters:

Total Ash:	Not more than 43 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 6 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 8 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 53 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 12 per cent,	Appendix 2.2.8
pH (10 % aqueous solution):	8.0 to 9.0,	Appendix 3.3

Assay:

Not less than 0.15 per cent of piperine when assayed by the following method.

Dissolve 1.0 mg of piperine in a mixture of *methanol*: *chloroform* (1: 1) and make up the volume to 10 ml in another volumetric flask. Apply 1, 2, 6, 10, 14, 18 µl of solution on TLC plate and develop the plate to 5.5 cm using *n-hexane*: *acetone* (7: 3) as mobile phase. After development, dry the plate in a current of hot air and scan in the TLC scanner at a wavelength of 338 nm. Note the peak area and prepare the calibration curve by plotting peak area vs concentration of piperine.

Extract accurately weighed 2 g powder of *Vaṭīs* in 75 ml of alcohol in Soxhlet apparatus for 6 h. Filter the extract while hot and dry completely and weigh. Take 100 mg in volumetric flask and dissolve in a mixture of methanol-chloroform (1:1) and make up the volume to 25 ml. Apply 20 µl of the test solutions on TLC plate. Develop, dry and scan the plate as described in the preceeding paragraph for calibration curve of piperine. Record the area under the curve for a peak corresponding to piperine in the test solution. Calculate the amount of piperine in the test solution from the calibration curve of piperine.

Mercury:	0.6-1.10 per cent w/w,	Appendix 5.8

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflatoxins:	Complies with Appendix 2.6

Storage:

Store in a cool place in tightly closed containers, protected from light and moisture.

Therapeutic uses:

Agnimāndya (digestive impairment); Grahaṇī (malabsorption syndrome); Arocaka (tastelessness); Paktiśūla (duodenal ulcers); Kṣaya (pthisis)

Dose:

500 mg - 1 g per day in divided doses with Honey/Warm water/Butter milk

PUNARNAVĀDI MAṆḌŪRA

(AFI Part I, 19:1)

Definition:

Punarnavādi Maṇḍūra is a compressed tablet preparation made with the ingredients in the Formulation Composition given below.

Formulation Composition:

1	Punarnavā (Rakta Punarnavā API)	*Boerhaavia diffusa*	Rt.	48 g
2	Trivṛt API	*Ipomea turpethum*	Rt.	48 g
3	Vyoṣa			
	a. Śuṇṭhī API	*Zingiber officinale*	Rz.	48 g
	b. Marica API	*Piper nigrum*	Fr.	48 g
	c. Pippalī API	*Piper longum*	Fr.	48 g
4	Viḍaṅga API	*Embelia ribes*	Fr.	48 g
5	Dāru (Devadāru API)	*Cedrus deodara*	Ht. Wd.	48 g
6	Citraka API	*Plumbago zeylanica*	Rt.	48 g
7	Kuṣṭha API	*Saussurea lappa*	Rt.	48 g
8	Haridrādvaya			
	a. Haridrā API	*Curcuma longa*	Rz.	48 g
	b. Dāruharidrā API	*Berberis aristata*	St.	48 g
9	Triphalā			
	a. Harītakī API	*Terminalia chebula*	P.	48 g
	b. Āmalakī API	*Emblica officinalis*	P.	48 g
	c. Bibhītaka API	*Terminalia bellirica*	P.	48 g
10	Dantī API	*Baliospermum montanum*	Rt.	48 g
11	Cavya API	*Piper chaba*	St.	48 g
12	Kaliṅgaka (Indrayava API)	*Holarrhena antidysenterica*	Sd.	48 g
13	Pippalī API	*Piper longum*	Fr.	48 g
14	Pippalīmūla API	*Piper longum*	St.	48 g
15	Musta (Mustā API)	*Cyperus rotundus*	Rz.	48 g
16	Maṇḍūra (Maṇḍūra Bhasma (API))	Calcined Maṇḍūra		1.920 kg
17	Gomūtra (API)	Cow urine		6.144 l

Method of preparation:

- Take all the ingredients of pharmacopoeial quality.
- Treat *Maṇḍūra* to prepare *Maṇḍūra bhasma*.
- Wash, clean, dry the ingredients numbered 1 to 15 of the formulation composition, powder separately and pass through 180 μm IS Sieve (sieve number 85) to obtain fine powder and mix them all to a homogeneous mixture.
- Strain *Gomūtra* through *muslin cloth.*

- Add *Gomūtra* to *Maṇḍūra bhasma,* heat in a stainless steel container stirring continuously and observe the mixture for formation of a thick paste.
- Stop the heating and allow to cool to 50^0.
- Add mixture of fine powders and mix thoroughly to prepare a homogeneous lumpy mass (dough). Allow to cool.
- Pass the dough through a granulator to obtain granules and add 0.5 per cent of talc powder as lubricant. Subject the granules to compression in a tablet punching machine.
- Store tablets in containers and pack them air-tight to protect from light and moisture.

Description:

Reddish brown coloured tablet with the characteristic odour of *Gomūtra*

Identification:

Thin layer chromatography:

Extract 2 g of formulation with 20 ml of *alcohol* for 40^0 for about 3 h. Filter and concentrate the extract to 5 ml and carry out thin layer chromatography. Apply 10 µl of extract on TLC plate and develop the plate to a distance of 8 cm using *toluene*: *ethyl acetate*: *acetic acid* (5: 4.5: 0.5) as mobile phase. After development, allow the plate to dry in air. Spray the plate with *anisaldehyde sulphuric acide reagent* followed by heating at 105^0 for about 10 min. The plate shows spots at R_f 0.30 (light blue), 0.66 (yellow), 0.70 (green) and 0.76, 0.85 (both blue).

Physico-chemical parameters:

Total ash:	Not more than 60 per cent,	Appendix 2.2.3
Acid-insoluble ash:	Not more than 28 per cent,	Appendix 2.2.4
Alcohol-soluble extractive:	Not less than 15 per cent,	Appendix 2.2.5
Water-soluble extractive:	Not less than 24 per cent,	Appendix 2.2.6
Loss on drying:	Not more than 8 per cent,	Appendix 2.2.8
*p*H (10% aqueous solution):	6 to 7,	Appendix 3.3
Disintegration time	Not more than 30 min.,	Appendix 3.14
Average weight	250 (±5) mg,	Appendix 3.15

Assay:

Total Iron:	Not less than 14 per cent w/w	Appendix 5.6

Other requirements:

Microbial limits:	Complies with Appendix 2.4
Aflotoxins :	Complies with Appendix 2.6

Storage:

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

Therapeutic uses:

Pāṇḍu roga (anaemia), Grahaṇī (malabsorption syndrome), Śotha (inflammation), Plīhā roga (splenic disease), Viṣamajvara (intermittent fever), Arśa (haemorrhoids), Kuṣṭha (diseases of skin), Kṛmi (helminthiasis/worm infestation)

Dose:

1 to 2 g per day in divided doses

Anupāna:

Buttermilk, water

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, phosphor bronze or stainless steel. 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 specifications as given in IS 460 (Pt I) 1985 (Reaffirmed 1998) – in terms of aperture size of the sieve, and for the convenience of the users the earlier IS 460-1978 – in terms of Sieve/Mesh Number has also been given in the following table:

Table 1

IS 460 (Pt I) 1985 (Reaffirmed 1998)	IS 460-1978
mm	--
4.0	4
2.8	6
2.0	8
1.7	10
1.4	12
1.0	16
μm	--
710	22
600	25
500	30

425	36
355	44
250	60
180	85
150	100
125	120
106	150
90	170
75	200
63	240
53	300
45	350

Designation

Test sieves of metal wire cloth are designated by the nominal size of aperture of the wire cloth, followed by the inscription 'IS Sieve'.

Examples:

a. 5.60-mm IS Sieve

b. 425 μm IS Sieve

Nominal aperture sizes of 1 mm and above, as well as their associated tolerances and wire diameters, are expressed in millimetres (mm) and for aperture sizes smaller than 1 mm, these are expressed in micrometres (μm).

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 of plain weave where warp is 22 per cm $\pm$1 and weft is 18 $\pm$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 are added *'in situ'* in powder form as *'Prakṣepa Dravyas'*. 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 dry and wet sieving, washing, sedimentation, density separation or by floatation etc. are the preliminary steps. This is followed by clearing the isolated 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 *'Prakṣepa Dravyas'*, 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 interfere. 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. If for some reason the reagents suggested for preparation of material for microscopy in the monographs itself, does not yield expected result for any sample under test, the relevant reagent given here may be substituted for better results.

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 lightening 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 tannins.*

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 *potassium chromate* dissolved in 90 ml of dilute sulphuric acid: *A 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 5 per cent solution of *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 in Potassium iodide solution: Dissolve 1 g of *potassium iodide* in 200 ml of distilled water, add 2 g of iodine to the solution and dissolved it; *stains lignified walls yellow and cellulosic walls blue.*

Lactophenol (Amman's Fluid): *Phenol* 20 g, *Lactic acid* 20 g, *Glycerin* 40 g, dissolved in *distilled water* 20 ml; *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 of 0.1 g of Methylene blue 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.*

Phloroglucinol: 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,* for which Alcoholic solution of safranin is more effective (See Safranin).

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*.

Sehweitzer's reagent: Same as Ammoniacal Copper Oxide Solution (Cuoxam).

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. *sulphuric 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 2 - Refractive Indices of Certain Mountants

Alcohol	1.36
Benzene	1.50
Bromoform	1.59
Canada balsam	1.54
Cassia oil	1.60
Castor oil	1.48
Cedar Oil	1.51
Chloral Hydrate solution	1.44 to 1.48
Chloroform	1.44
Clove oil	1.53
Cresol	1.53
Glycerol	1.473
Kerosene	1.448
Lactophenol	1.444

Methylene iodide	1.74
α-Monobromonaphthalene	1.66
Monobromo benzol	1.56
Olive oil	1.46 to 1.47
Water	1.333
Xylol	1.49

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 mould 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 600^0 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 600^0. 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 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. For determination of methanol soluble extractive, use methanol in place of alcohol.

2.2.6. Determination of Water Soluble Extractive:

Proceed as directed for the determination of alcohol-soluble extractive, using *chloroform-water* instead of ethanol.

2.2.7. 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.

2.2.8. 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.

2.2.9. 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.

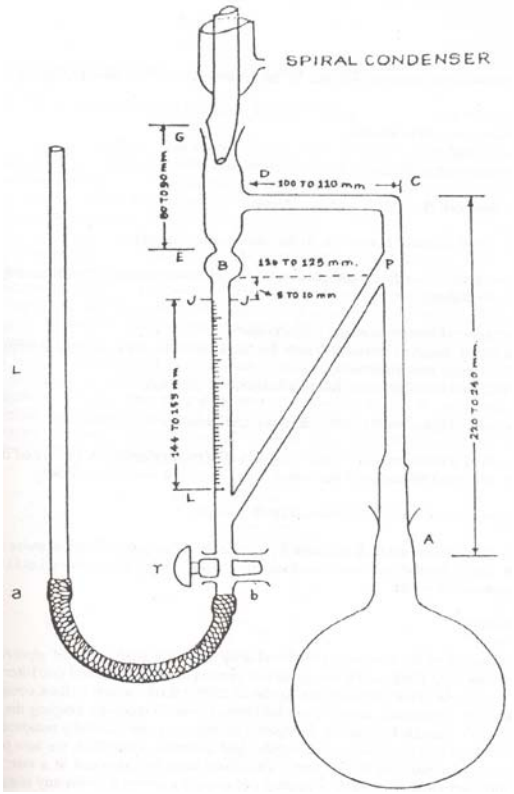

Fig. 1 Apparatus for volatile oil determination

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.

2.2.10. 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.

2.2.11. Fatty oil estimation:

To estimate fatty oils, extract accurately weighed air-dried powdered plant material with *petroleum ether* (40-60^0) 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.

2.3. Limit Tests:

Table 3- Permissible Limits of Heavy Metals and Arsenic

S.No.	Heavy Metal contents and Arsenic	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.

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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.*

Sodium Salicylate: Of the Indian Pharmacopoeia.

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 *barium chloride*.

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 115n 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 $\pm$ 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 $\pm$ 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$\pm$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$\pm$0.2.

MacConkey Agar Medium

Pancreatic digest of gelatin	17.0g
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 $\pm$ 0.2.

MacConkey Broth Medium

Pancreatic digest of gelatin	20.0g
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$\pm$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 $\pm$ 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$\pm$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 100^0 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$\pm$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$\pm$0.2.

Triple Sugar-Iron Agar Medium

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 $\pm$ 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 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 4, indicate the most probable number of micro-organisms per g or per ml of the test specimen.

Table 4 – 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

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 5, the sample meets the requirements of the test for the absence of the genus *Salmonella*.

If any colonies conforming to the description in Table 5 are produced, carry out the secondary test.

Secondary test: Subculture any colonies showing the characteristics given in Table 5 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 5 – 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 6 for the media used, the sample meets the requirement for freedom from *Pseudomonas aeruginosa*. If any colonies conforming to the description in Table 6 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 6 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.*

Table 6 – 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

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 7 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 7 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*.

Table 7 – 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)

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.

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 8- 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 - 9, The limits applying to pesticides that are not listed in Table - 9 and

whose presence is suspected for any reason comply with the limits calculated using the following expression:

$$\frac{\text{ADI x M}}{\text{MDD x 100}}$$

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:

$$\frac{\text{ADI x M x E}}{\text{MDD x 100}}$$

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*.

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 10
- 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 -9

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 -10

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

2.5.1. 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).

2.5.2. 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 11. Calculate the content of each insecticide from the peak areas and the concentrations of the solutions.

Table 11- 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

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.

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 12. Calculate the content of each insecticide from the peak areas and the concentrations of the solutions.

Table 12- 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. 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 B_2 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.*

Table13 - Permissible Limit of Aflatoxins*

S.No.	Aflatoxins	Permissible Limit
1.	B_1	0.5 ppb
2.	G_1	0.5 ppb
3.	B_2	0.1 ppb
4.	G_2	0.1 ppb

*For Domestic use only

2.7. 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.

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 ($\pm$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 14

Reference Liquid	$\eta_D 20^0$	Temperature Co-efficient $\Delta n/\Delta t$
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 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 phases 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 Ṅ 25 mm) placed inside another test-tube (about 160 mm Ṅ 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. 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).

3.7. 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:-

$$\text{Saponification Value} = \frac{(b-a) \times 0.02805 \times 1000}{W}$$

Where 'W' is the weight in g of the substance taken.

3.8. 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.

3.9. 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.

3.10. 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

$$\text{Peroxide Value} = \frac{10\,(a - b)}{W}$$

Where W = weight, in g, of the substance.

3.11. 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.

3.12. 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.

3.13. 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.

3.14. Disintegration test for tablets:

This test determines whether tablets disintegrate within a prescribed time when placed in a liquid medium under the prescribed experimental conditions.

Disintegration is defined as that state in which no residue of the tablet remains on the screen of the apparatus or, if a residue remains, it consists of fragments of insoluble coating of the tablets. If discs have been used with tablets, any residue remaining on the lower surfaces of the discs consists only of fragments of shells.

Apparatus:

a) A rigid basket-rack assembly supporting six cylindrical glass tubes, 77.5 $\pm$ 2.5 mm long, 21.5 mm in internal diameter and with a wall thickness of about 2 mm.

b) The tubes are held vertically by two superimposed transparent plastic plates, 90 mm in diameter and 6 mm thick, perforated by six holes having the same diameter as the tubes. The holes are equidistant from the centre of the plate and are equally spaced from one another. Attached to the under side of the lower plate is a piece of woven gauze made from stainless steel wire 635 μm in diameter and having nominal mesh apertures of 2.00 mm. The upper plate is covered with a stainless steel disc perforated by six holes, each about 22 mm in diameter, which fits over the tubes and holds them between the plastic plates. The holes coincide with those of the upper plastic plate and the upper open ends of the glass tubes.

c) The plates held rigidly in position and 77.5 mm apart by vertical metal rods at the periphery and a metal rod is also fixed to the centre of the upper plate to enable the assembly to be attached to a mechanical device capable of raising and lowering it smoothly at a constant frequency of between 28 and 32 cycles per minutes through a distance of 50 to 60 mm. The design of the basket rack assembly may be somewhat different provided specification for the glass tubes and the screen mesh size are unchanged.

d) A cylindrical disc for each tube, each 20.7 $\pm$ 0.15 mm in a diameter and 9.5 $\pm$ 0.15 mm thick, made of transparent plastic with a relative density of 1.18 to 1.20 and pierced with five holes each 2 mm in diameter, one in the centre and the other four spaced equally on a circle of radius 6 mm from the centre of the disc. Four equally spaced grooves are cut in the lateral surface of the disc in such a way that at the upper surface of the disc they are 9.5 mm wide and 2.55 mm deep and at the lower surface 1.6 mm square.

e) The assembly is suspended in the liquid medium in a suitable vessel, preferably a 1000 ml beaker. The volume of liquid is such that the wire mesh at its highest point is at least 25 mm below the surface of the liquid, and at its lower point is at least 25 mm above the bottom of the beaker.

f) A thermostatic arrangement for heating the liquid and maintaining the temperature at $37^0 \pm 2^0$.

Method:

Introduce one tablet into each tube and add a disc to each tube. Suspend the assembly in the beaker containing the specified liquid and operate the apparatus for the specified liquid and operate the apparatus for the specified time. Remove the assembly from the liquid. The tablets pass the test if all of them have disintegrated.

If 1 or 2 tablets fail to disintegrate, repeat the test on 12 additional tablets; not less than 16 of the total of 18 tablets tested disintegrate.

If the tablets adhere to the disc and the preparation being examined fails to comply, repeat the test omitting the discs. The preparation complies with the test if all the tablets in the repeat test disintegrate.

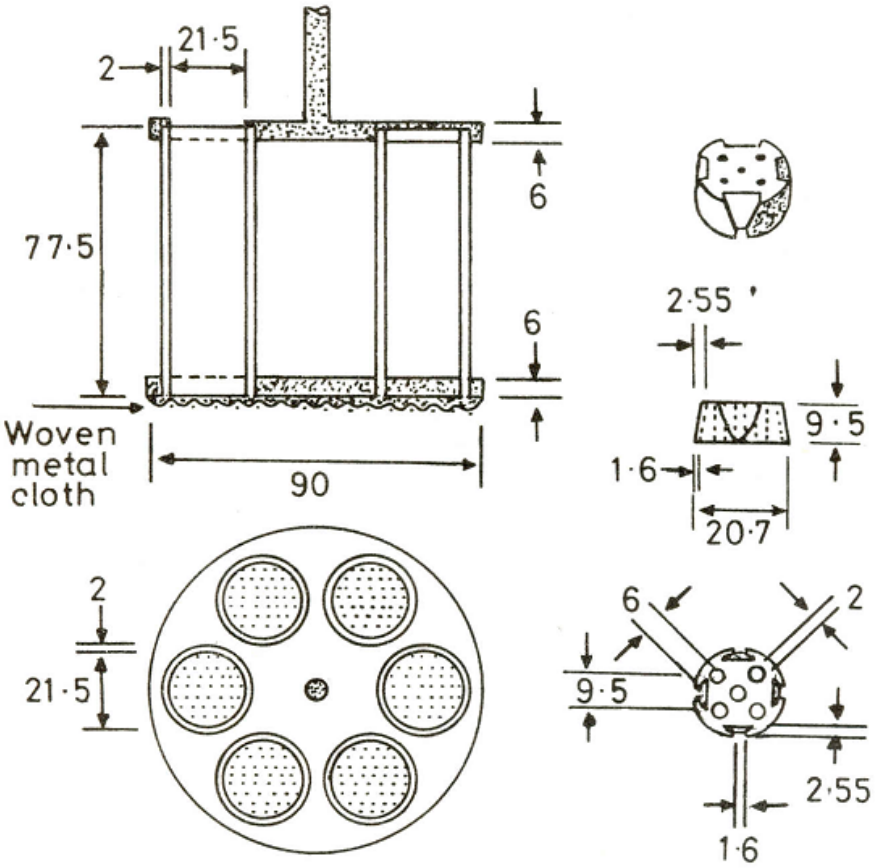


Fig.4. APPARATUS FOR DISINTEGRATION OF TABLETS

3.15. Uniformity of Weight of Single Dose Preparations

Weigh individually 20 units selected at random or, for single dose preparations in individual containers, the contents of 20 units, and calculate the average weight. Not more than two of the individual weights deviate from the average weight by more than the percentage shown in the Table - 15 and none deviates by more than twice that percentage.

Table-15

Dosage form	Average weight	Percentage deviation
Uncoated and film-coated tablets	80 mg or less	10
	More than 80 mg but less than 250 mg	7.5
	250 mg or more	5

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 105n 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.

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*.

The reagent has only limited stability and is no longer usable when the colour has turned to redviolet.

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.

Dragendorff 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.

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.

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

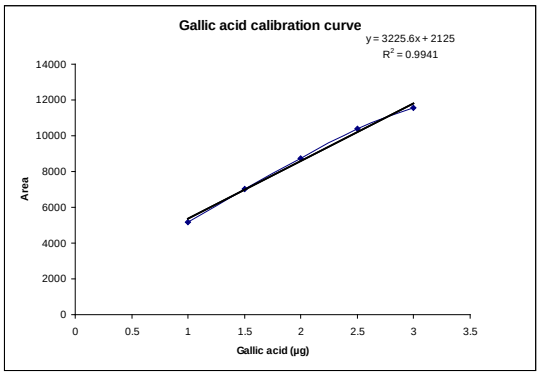
*Category***:** Astringent, styptic

*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, 13^{th} 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

Liebermann Burchard reagent —Add carefully 5 ml *acetic anhydride* and 5 ml *conc sulphuric acid* to 50 ml *absolute ethanol*, while cooling in ice. Spray the plate and heat at 105^0 C for about 10 min. Use freshly prepared reagent.

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 105n, 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).

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.

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.

Acidity or alkalinity – To 10 ml, freshly boiled and cooled in a borosilicate glass flask, add 0.05 ml of *methyl red solution*; the resulting solution is not red. To 10 ml add 0.1 ml of *bromothymol blue solution*; the resulting solution is not blue.

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.

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 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.*

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.

Sulphuric acid, methanolic- 10 per cent v/v solution of Sulphuric acid in ice cooled methanol

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 $C_2H_4O_2S$.

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

ASSAYS AND CHEMICAL TESTS

5.1. Estimation of Sugars

The method of Lane and Eyonon by reduction of Fehling's solution is the most generally applied volumetric method, the use of methylene blue as an internal indicator increasing the accuracy of the process. If strict attention be given to the details of the procedure and Table-16 are used to calculate the results, a high degree of accuracy can be obtained.

Prepare a solution of the sugar of such concentration that more than 15 ml and less than 50 ml. will be required to reduce all the copper in 10 ml. or 25 ml. of Fehling's solution (0.1 to 0.8 g per 100 ml of dextrose and 0.13 to 1.1 g per 100 ml. of lactose). For preliminary titration, measure accurately 10 ml. or 25 ml. of Fehling's solution into a conical flask of about 300 ml. capacity. From a burette add 15 ml. of the sugar solution and heat to boiling over asbestos covered wire gauze. Continue adding the sugar solution in fairly large portions at fifteen second intervals, until from the colour of the mixture, the copper appears to be nearly reduced; then boil for a minute or two, add 3 to 5 drops of 1 percent methylene blue solution and continue the titration until the blue colour is discharged. Repeat the titration, adding before heating, almost the full amount of sugar solution required to reduce all the copper. After boiling has commenced maintain a moderate degree of ebullition for two minutes and without removing the flame, add 3 to 5 drops of indicator and continue the titration so that it is just complete in a total boiling time of exactly three minutes. The end point is clearly indicated by the disappearance of the blue colour, the solution becoming orange. The flask must not be removed from the gauze at any stage of the titration.The proportion of the various sugars, equivalent to 10 ml of Fehling's solution are given in the Table-16.

Fehling's solution No. 1 contains 34.64 g of $CuSO_4$, $5H_2O$ and 0.5 ml of H_2SO_4 in water to 500 ml. No. 2 contains 176 g. of sodium potassium tartrate and 77 g of sodium hydroxide in water to 500 ml. Mix equal volumes of No. 1 and No. 2 solutions immediately before use.

Clarifying agents may be required for dark or turbid solutions, the general reagents being a slight excess of basic or neutral lead acetate or alumina cream, added before adjusting the volume . Alumina cream is prepared by adding a slight excess of ammonia to a saturated solution of alum and washing the precipitate by decantation until almost free from sulphates. Special reagents are used for definite processes and should always be employed where directed. Excess of lead may be removed by addition of anhydrous sodium carbonate to the filtered solution.

Table No. 16

Total reducing sugar required for complete reduction of 10 ml Soxhlet soln to be used in connection with Lane-Eynon general volumetric method

	Solution containing besides invert sugar:-									
	no sucrose		1 g sucrose per 100 ml		5 g sucrose per 100 ml		10 g sucrose per 100 ml		25 g sucrose per 100 ml	
ml of sugar solution required	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

5.2. 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 *zinc 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.

5.3. 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 $Na_2B_4O_7.10H_2O$.

5.4. 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.

5.5. 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

5.6. Determination of Iron :

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 500-550^0 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 + ortho phosphoric 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 10 percent 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

5.7. 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.

5.8. 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.

5.9. 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 $900\text{-}950^0$ 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 $900\text{-}950^0$ for 2-3 min. Allow to cool and weigh as SiO_2.

5.10. 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 600n. 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.

5.11. Determination of Sodium Chloride:

Dissolve about 2-3 g accurately weighed drug in 25 ml of *purified water,* leave for 30 minutes and 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.

5.12. 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.

5.13. Qualitative Reactions :

5.13.1 Sodium

5.13.1.a. 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.

5.13.1.b. Solutions of sodium salts yield, with solution of uranyl zinc acetate, a yellow crystalline precipitate.

5.13.2. Potassium

5.13.2.a. 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.

5.13.2.b. Moderately strong solutions of potassium salts, which have been previously ignited to remove ammonium salts, give a white, crystalline precipitate with perchloric acid.

5.13.2.c. 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.

5.13.3. Magnesium

5.13.3.a. Solutions 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.

5.13.3.b. Solutions of magnesium salts yield a white crystalline precipitate with solution of sodium phosphate in the presence of ammonium salts and dilute ammonia solution.

5.13.3.c. Solutions 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.

5.13.3.d. Solutions of magnesium salts in 1N hydrochloric acid, yield blue precipitate with solutions of 1drop of magneson II reagent and 3 ml 1N sodium hydroxide solution.

5.13.4. Carbonates and Bicarbonates

5.13.4.a. Carbonates and bicarbonates effervesce with dilute acids, liberating carbon doxide; the gas is colourless and produces a wihte precipitate in solution of calcium hydroxide.

5.13.4.b. Solutions of carbonates produce a brownish-red precipitate with solution of mercuric chloride; Solutions of bicarbonates produce a white precipitate.

5.13.4.c. 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.

5.13.4.d. 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.

5.13.4.e. Solutions of bicarbonates, on boiling, liberate carbon dioxide which produces a white precipitate in solution of calcium hydroxide.

5.13.5. Sulphates

5.13.5.a. Solutions of sulphates yield, with solution of barium chloride, a white precipitate insoluble in hydrochloric acid.

5.13.5.b. Solutions of sulphates yield, with solution of lead acetate, a white precipitate soluble in solution of ammonium acetate and in solution of sodium hydroxide.

5.13.6. Chlorides

5.13.6.a. 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.

5.13.6.b. Solutions of chlorides yield, on acidification with dilute nitric acid, a curdy white precipitate with few drops of 5 per cent w/v silver nitrate solution.

5.13.7. 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.

5.13.8. Sulphides

Solutions of sulphides yield, with solution of 5 per cent w/v silver nitrate solution, a black precipitate.

Dissolve 1 g of sample in 10 ml of deionised water and filter. Add 4 ml of 5 per cent w/v silver nitrate solution to the filtrate. A black precipitate appears.

5.13.9. Test for Mercury :

Weight about 0.1 g of the formulation, dissolve in hydrochloric acid and filter. Pass hydrogen sulphide gas to the filtrate, a precipitate appears. Filter the solution and wash the precipitate with water and redissolve in dilute hydrochloric acid/nitric acid. The presence of Mercury is indicated by appearance of violet colour when added to dithizone solution.

5.13.10. Test for Boron :

Dissolve 0.1 g of formulation in 10 ml of water and filter. Add 1 ml. of carminic acid (0.5 percent in concentrate sulphuric acid) to 1 ml. of filtrate. Blue colour indicates the presence of Boron.

5.13.11. Test for Sulphur:

Extract 1.0 g of the sample with 10 ml of *carbon disulphide*. Filter the carbon disulphide solution and evaporate the solvent. To the residue add 10 ml of 10 % *alcoholic potash* and boil until the sulphur is dissolved. Dilute with water, oxidize by adding *hydrogen peroxide solution* (~6 per cent w/v of H_2O_2) in excess and heat on a water bath for 30 min. Acidify with *hydrochloric acid*, filter and to the filtrate add *barium chloride solution* (10 % w/v in water). A White precipitate indicates the presence of sulphur.

5.13.12. Test for anthraquinones :

Add 0.5 g of formulation in 50 ml of water, boil until nearly dissolved & cool the solution. Add 0.5 g of Kieslguhr and filter. Apply following test to the filterate.

5.13.13. Test for Hiṅgu:

Boil 0.2 g of formulation with 2 ml *hydrochloric acid* for about 1 minute, cool, dilute with an equal volume of water and filter into 3 ml of dilute solution of *Ammonia*, if fluorescence is produced.

Heat 5 ml of filtrate with 0.2 g of *borax*, add few drops of this solution to a test tube nearly filled with water a light green fluoresces produced.

APPENDIX-6

AYURVEDIC DEFINITIONS AND METHODS

6.1.Kalpanā Paribhāṣā:

6.1.1. Kalka:

Kalka is the fine paste of macerated fresh plant material.

(*Paribhāṣā Prabandha*)

6.1.2. Kvātha / Kaṣāya:

Kvātha or *Kaṣāya* is the filtered liquid obtained by boiling coarse powder of drug(s) in proportion of 4, 8 or 16 [*Mṛdu Dravya* - 4, *Madhyama Dravya* - 8 and *Kaṭhina Dravya* - 16 respectively] times of water and reduced to one-fourth.

(*Śārṅgadhara saṃhitā* - II - 9/3)

6.1.3. Cūrṇa:

The fine sieved powder of well dried drug(s) is called *Cūrṇa.*

(*Śārṅgadhara saṃhitā* - II - 6/1)

6.1.4. Puṭapāka Svarasa:

It is a kind of procedure, where juice of fresh green herb will be obtained by the process of *Puṭapāka*. Bundle the *Kalka* of green plant material in leaves of *Kāśmarī, Vaṭa, Jambū* 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.*

(*Śārṅgadhara saṃhitā* - 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.*

(*Śārṅgadhara saṃhitā* - II - 1/2)

6.1.6. Hima Kaṣāya:

Hima Kaṣāya is the extractive obtained by straining of 48 g [1 part] of powdered drug(s) soaked in 288 ml [6 parts] of water overnight.

(*Śārṅgadhara saṃhitā* - II - 4/1)

6.1.7. Phāṇṭa

Phāṇṭa is the extractive obtained by pouring four times of boiling water on the powdered drug(s) and strained when cooled.

(*Paribhāṣāpradīpa* 2/26)

6.2. Sāmānya paribhāṣā:

6.2.1. Kajjalī:

Kajjalī is the fine black colored powder obtained by triturating *Gandhaka* (Sulphur) and *Pārada* (Mercury) without adding any liquid.

(*Rasataraṅgiṇī* - 2/27)

6.2.2. Kāñjika:

Sour liquid prepared with of rice grain etc. is called as *Kāñjika.* Take *ṣaṣṭika śāli* 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 a period of two to three weeks at regulated temperature during which the liquid becomes sour.

(*Paribhāṣā Prabandha*)

6.2.3. Kṣāra Preparation:

Cut the drug into small pieces, wash, clean and dry well.
Put few pieces in an earthen pot or iron vessel and ignite. As they burn, add more and more pieces till all the pieces burn completely and reduce to ash. Allow the ash to cool.
Add *water* to the ash in the ratio of 6: 1, mix well and allow to stand overnight.
Next day decant the supernatant liquid, strain repeatedly through *muslin cloth* till a clear filtrate is obtained.
Take the filtrate in a stainless steel vessel and heat it over moderate flame to evaporate the water to obtain a solid salty white residue (*Kṣāra*), at the bottom of the vessel. Allow to cool completely.
Store it in amber coloured glass containers and pack them air-tight to protect from light and moisture.

6.2.4. Cūrṇodaka:

1	Cūrṇa (Lime powder)	250 mg
2	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 *Cūrṇodaka*.

(*Rasataraṅgiṇī* – 11)

6.2.5. Mastu Preparation:

Tie *Godadhi* in a *muslin cloth* and allow the liquid part of it to get separated to obtain the *Mastu.*

6.2.6. Prakṣepa:

Fine powder form of the drug(s), which is added to a *kalpa* such as *Leha, Āsava Ariṣṭa* etc. before administration is known as *Prakṣepa*.

6.2.7. Bhāvanā:

Bhāvanā is the process by which powders of drugs are levigated to a soft mass with specified liquids and allowed to dry.

(*Rasataraṅgiṇī* - 2/49)

6.2.8. Śodhana:

Śodhana is the process which removes the impurities to some extent and helps in increasing the therapeutic values of the drugs.

6.2.8.1. Godantī Śodhana:

1	Godantī		1 part
2	Nimbu Svarasa	Fr.	QS
	or		
3	Droṇapuṣpī Svarasa	Pl.	QS

Bundle small pieces of *Godantī* in a cloth, suspend in *Nimbu* or *Droṇapuṣpī svarasa* in a *Dolāyantra*, and boil for 3 h

(*Rasataraṅgiṇī* - 11/239)

6.2.8.2. Gairika Śodhana:

1	Gairika	1 part
2	Godugdha	QS

Fine powder of *Gairika* is to be levigated with Cow's milk.

(*Rasaratnasamuccaya* - 3/49)

or

1	Gairika	1 part
2	Goghṛta	QS

Fry the fine powder of *Gairika* in little amount of *Ghṛta.*

(*Āyurveda prakāśa* - 2/272)

6.2.8.3. Gandhaka Śodhana:

1	Gandhaka		1 part
2	Godugdha		QS
	or		
3	Bhṛṅgarāja Svarasa	Pl.	QS

Melt small pieces of *Gandhaka* in an iron pan smeared with *Ghṛta* and pour in to a pot containing *Godugdha* or *Bhṛṅgarāja svarasa*. Collect after cooling. Repeat the process for seven times. At the end of the seventh process, wash and dry the material.

(*Rasāmṛtam* - 2/3)

6.2.8.4. 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 *Dolāyantra* containing any one of the following liquids.

Gomūtra
Godugdha
Triphalā kaṣāya
Vāsā kaṣāya / svarasa or
Nirguṇḍī svarasa with Haridrā cūrṇa

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.

6.2.8.5. Ṭaṅkaṇa Śodhana:

Take small pieces of *Ṭaṅkaṇa* in an iron pan, fry till complete dehydration.

(*Āyurveda prakāśa* - 2/244)

6.2.8.6. Tuttha Śodhana:

1	Tuttha		1 part
2	Raktacandana kvātha	Ht. Wd.	QS
3	Mañjiṣṭhā kvātha	Rt.	QS
4	Triphalā kvātha	P.	QS

Prepare fine powder of *Tuttha* and levigate with the individual liquid medias number (ii) to (iv) mentioned above seven times each.

(*Rasāmṛtam* - 3/74)

6.2.8.7. Bhallātaka Śodhana:

1	Bhallātaka	Fr.	1 part
2	Gomūtra		QS
3	Godugdha		QS
4	Iṣṭikā cūrṇa		QS
5	Water		QS

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 seeds with water and dry.

(*Rasāmṛtam- Pariśiṣṭa*)

6.2.8.8. Manaḥśilā Śodhana:

1	Manaḥśilā		1 part
2	Agastya patra svarasa	Lf.	QS
	or		
3	Śṛṅgavera (Ārdraka) Svarasa	Rz.	QS

Prepare fine powder of *Manaḥśilā* and levigate with any one of the above specified liquid media for seven times.

(*Rasaratnasamuccaya* - 3/93)

6.2.8.9. Vatsanābha Śodhana:

1	Viṣa (Vatsanābha)	Rt. Tr.	1 part
2	Gomūtra		QS

Take small pieces of *Vatsanābha*, bundle in *muslin cloth*, and soak in *Gomūtra* for three days, replacing the later every day. Wash the processed material and dry.

(*Rasāmṛtam- Pariśiṣṭa*)

6.2.8.10. Karavīra Śodhana:

1	Karavīraka (Karavīra)	Rt.	1 part
2	Godugdha		QS

Take small pieces of *Karavīra*, bundle in *muslin cloth*, and perform *Svedana* in *Dolāyantra* with *Godugdha* for 2 h. Wash the processed material and dry.

(*Śārṅgadhara Saṃhitā, Madhyamakhaṇḍa Adhyāya* 12:300)

6.2.8.11. Citraka Śodhana:

1	Rakta Citraka (Citraka)	Rt.	1 part
2	Cūrṇodaka		QS

Take small pieces of *Karavīra*, soak in *Cūrṇodaka*. Wash the processed material and dry.

(*Rasataraṅgiṇī* 24:575)

6.2.8.12. Lāṅgalī Śodhana:

1	Lāṅgalī	Rt.	1 part
2	Gomūtra		QS

Take small pieces of *Karavīra*, soak in *Gomūtra* for 24 h. Wash the processed material and dry.

(*Āyurvedaprakāśa* 6)

6.2.8.13. Śilājatu Śodhana:

1	Śilājatu		2 parts
2	Hot water		4 parts
3	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.

(*Rasataraṅgiṇī* 22/69-78)

6.2.8.14. Haritāla Śodhana:

1	Haritāla		1 part
2	Kūṣmāṇḍa Toya or	Fr.	QS
3	Tila Kṣāra Jala or	Pl.	QS
4	Cūrṇodaka		QS

Take small pieces of *Haratāla*, bundle in clean muslin cloth, suspend in a *Dolāyantra* containing any one of the above liquid media. Boil for three hours, dry in sun rays and preserve for further purpose.

(*Rasaratnasamuccaya* - 3/70)

6.2.8.15. Hiṅgu Śodhana:

1	Rāmaṭha (Hiṅgu)	Exd.	1 part
2	Ājya (Goghṛta)		QS

Prepare fine powder of *Hiṅgu* and fry it in sufficient amounts of *Goghṛta,* till it becomes crisp.

(*Rasataraṅgiṇī*, 24/578)

6.2.8.16. Vijayā Śodhana:

1	Vijayā	Lf.	1 part
2	Jala		QS

Put *Vijayā* in a *muslin cloth bag* and wash in water till free from terbdity and dry.

(*Rasāmṛtam, Pariśiṣṭa* 8/147)

6.2.8.17. Kāśīśa Śodhana:

1	Kāśīśa		1 part
2	Bhṛṅga nīra (Bhṛṅgarāja)	Pl.	QS

Bhāvanā is given with *Bhṛṅgarāja rasa*, 3 times.

(*Rasāmṛtam, Adhyāya* 3/158)

6.2.8.18. Sauvīrāñjana Śodhana:

1	Sauvīrāñjana API	Lead sulphide		1 part
2	Bhṛṅgarājadrava (Bhṛṅgarāja)	*Eclipta alba*	Pl. juice	QS

Method

Powder *Sauvīrāñjana* and give *Bhāvanā* with *Bhṛṅgarāja svarasa* for 7 days.

(Rasaratnasamuccaya, Adhyāya 3; 107)

6.2.8.19. Narasāra Śodhana:

1	Narasāra	Sal ammoniac	1 part
2	Jala	Potable water	3 parts

Method

Add 3 times Jala to *Narasāra*, make a solution and filter. Boil the solution till water is evaporated.

(Rasataraṅgiṇī, Taraṅga 14; 3-4.)

6.2.8.20. Pārada Sāmānya Śodhana:

1	Pārada (Mercury)		2 parts
2	Sudhāraja (Lime powder)		2 parts
3	Rasona (Laśuna)	Bl.	2 parts
4	Saindhava Lavaṇa (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 lavaṇa* to the *Pārada,* triturate till the paste of *Rasona* becomes black. Wash with warm water and separate the *Pārada* with caution.

(Rasataraṅgiṇī - 5/ 27-30)

6.2.8.21. Aṣṭasaṃskāra of Pārada

Aṣṭasaṃskāra of *Pārada* have been prescribed in Ayurvedic classics for purification and to increase the therapeutic activities.

6.2.8.21.a. Svedana:

(*Rasahṛdayatantra* - 2/3)

1	Pārada (Mercury)		1 part
2	Āsurī (Rājikā)	Sd.	1/16th part
3	Paṭu (Saindhava Lavaṇa)		1/16th part
4	Śuṇṭhī	Rz.	1/16th part
5	Marica	Fr.	1/16th part
6	Pippalī	Fr	1/16th part
7	Citraka	Rt.	1/16th part
8	Ārdraka	Rz.	1/16th part
9	Mūlaka	Rt. Tr.	1/16th part
10	Kāñjika		QS

Method:

Take the ingredients numbered 2 to 9 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 paradisiacal*), 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 *poṭṭalī* in a *Dolāyantra* containing *Kāñjika*. Boil for three days. Remove *Pārada* and *Kalka,* wash carefully with warm water and collect *Pārada.*

6.2.8.21.b Mardana:

(*Rasahṛdayatantra* - 2/4)

1	Pārada (Mercury)		1 part
2	Guḍa		1/16th part
3	Dagdhorṇā		1/16th part
4	Lavaṇa (Saindhava Lavaṇa)		1/16th part
5	Mandira dhūma		1/16th part
6	Iṣṭikā cūrṇa		1/16th part
7	Āsurī (Rājikā)	Sd.	1/16th part
8	Kāñjika		QS

Method:

Take the ingredients numbered 1 to 7 in *Khalva*yantra, add with required amounts of *Kāñjika* and levigate for three days. Remove *Pārada* and *Kalka,* wash carefully with warm water and collect *Pārada.*

6.2.8.21.c. Mūrcchana:

(*Rasahṛdayatantra* - 2/6)

1	Pārada (Mercury)		1 part
2	Gṛhakanyā (Kumārī)	Lf.	1/16th part
3	Harītakī	P.	1/16th part
4	Bibhītaka	P.	1/16th part
5	Āmalakī	P.	1/16th part
6	Citraka	Rt.	1/16th part

Method:

Take the ingredients numbered 3 to 6, dry, powder and pass through 180 μm IS Sieve. Add ingredient number 2 and grind with sufficient quantity of water to prepare *Kalka*. Add *Pārada* to the *Kalka* and triturate for three days.

6.2.8.21.d. Utthāpana:

(*Rasahṛdayatantra* - 2/7)

1	Pārada (Mercury)	1 part
2	Kāñjika	QS

Method:

Collect the *Pārada* at the end of *Mūrcchana* process and subject it to *Utthāpana,* and wash with *Kāñjika* and collect the *Pārada* carefully.

6.2.8.21.e. Pātana:

The process of *Pātana* is again of three types, viz. *Ūrdhvapātana, Adhaḥpātana* and *Tiryakpātana.*

Ūrdhvapātana:

(*Āyurveda prakāśa* - 1/68-71)

1	Pārada (Mercury)		3 parts
2	Ravi (Tāmra)		1 part
3	Jambīra svarasa (Nimbu)	Fr. juice	QS

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 *Ḍamaru yantra* and apply heat for 12 h. Collect the *Pārada* settled at the upper pot gently.

Adhaḥpātana:

(*Āyurveda prakāśa* - 1/75-77)

1	Pārada (Mercury)		1 part
2	Harītakī	P.	1/16th part
3	Bibhītaka	P.	1/16th part
4	Āmalakī	P.	1/16th part
5	Śigru	St. Bk.	1/16th part
6	Citraka	Rt.	1/16th part
7	Saindhava Lavaṇa		1/16th part
8	Āsurī (Rājikā)	Sd.	1/16th part
9	Nimbu rasa		QS

Method:

Take the ingredients numbered 2 to 6, dry, powder and pass through 180 μm I. S. sieve. Add the powders to *Pārada* and levigate by adding ingredients numbered 7 to 9 to prepare fine paste. Apply the paste in the *Adhaḥpātana yantra*, subject to heat and collect *Pārada.*

Tiryakpātana:

(*Āyurveda prakāśa* - 1/79-81)

1	Pārada (Mercury)	3 parts
2	Ravi (Tāmra)	1 part
3	Jambīra svarasa (Nimbu)	QS

Method:

Take *Pārada* obtained at the end of *Adhaḥpātana* 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.*

6.2.8.21.f. Rodhana / Bodhana:

(*Rasendracūḍāmaṇi* - 4/88)

1	Pārada (Mercury)	3 parts
2	Saindhava Lavaṇa jala	QS

Method:

Place the *Pārada* in a pot containing *Saindhava lavaṇa 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.*

6.2.8.21.g. Niyāmana:

(*Rasahṛdayatantra* - 2/10)

1	Pārada (Mercury)		1 part
2	Phaṇi (Nāgavallī)	Lf.	1/16th part

3	Laśuna	Bl.	1/16th part
4	Ambujā		1/16th part
5	Karkoṭī		1/16th part
6	Mārkava (Bhṛṅgarāja)	Pl.	1/16th part
7	Ciñcikā (Ciñcā)	Lf.	1/16th part
8	Kāñjī		QS

Method:

Prepare *Kalka* of the ingredients numbered 2to 7, add with *Pārada* and prepare a *poṭṭalī*. Suspend the *poṭṭalī* in a *Dolāyantra* containing *Kāñjika* and boil. Remove *Pārada* and *Kalka,* wash carefully with warm water and collect *Pārada.*

6.2.8.21. h. Dīpana / Sandīpana:

(*Rasahṛdayatantra* - 2/11)

1	Pārada (Mercury)		1 part
2	Bhū (Sphaṭikā)		1/16th part
3	Khaga (Kāśīśa)		1/16th part
4	Ṭaṅkaṇa		1/16th part
5	Marica	Fr.	1/16th part
6	Lavaṇa (Saindhava Lavaṇa)		1/16th part
7	Āsurī (Rājikā)	Sd.	1/16th part
8	Śigru	Sd.	1/16th part
9	Kāñjika		QS

Method:

Prepare *Kalka* of the ingredients numbered 2 to 8, add with *Pārada* and prepare a *poṭṭalī*. Suspend the *poṭṭalī* in a *Dolāyantra* containing *Kāñjka* and boil for three days. Remove *Pārada* and *kalka,* wash carefully with warm water and collect *Pārada.*

6.2.9. Mūrchanā:

Mūrcchana is the process which removes *Āma doṣa* of *Taila / Ghṛta* and provides good color and fragrance. *Mūrcchana* process is to be followed before any *Sneha* preparation.

6.2.9.1. Mūrcchanā of Eraṇḍa Taila:

(*Bhaiṣajyaratnāvalī, Jvarādhikāra*)

Ingredients:

1	Mañjiṣṭhā 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* *	Rt.	12 g
8	Hrīvera API	*Coleus vettiveroides*	Rt.	12 g
9	Kharjūra API	*Phoenix sylvestris*	Fr.	12 g
10	Vaṭa 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	Śuṇṭhī API	*Zingiber officinale*		12 g.
15	Ketakī API	*Pandanus odoratissimus*	Rt.	12 g.
16	Dadhi (API)	Curd		1.536 l
17	Kāñjika API			1.536 l
18	Eraṇḍa taila (API)	Castor oil	Oil	768 ml

Method of preparation:

Take all ingredients of pharmacopoeial quality.

Wash, clean, dry the ingredients numbered 1 to 15 of the formulation composition powder separately and pass through 180 μm I. S. sieve (*Kalka dravyas).*

Transfer the powdered ingredients to wet grinder, grind with sufficient quantity of water to prepare *Kalka* (homogeneous blend).

Take *Eraṇḍa taila* in a stainless steel vessel and heat it mildly.

Add increments of *Kalka*. Stir thoroughly while adding *Dadhi* and Kāñjika.

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 appearance of froth (*phenodgama*) and constantly check the *Kalka* for formation of *varti (madhyama pāka lakṣaṇa).*

Expose the *varti* and oil 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.

* Official substitute

6.2.9.2. Mūrcchanā of Ghṛta:

(*Bhaiṣajyaratnāvalī, Jvarādhikāra*)

Ingredients:

1	Pathyā (Harītakī API)	*Terminalia chebula*	P.	48 g
2	Dhātrī (Āmalakī API)	*Emblica officinalis*	P.	48 g
3	Bibhītа (Bibhītaka API)	*Terminalia belerica*	P.	48 g
4	Jaladhara (Mustā API)	*Cyperus rotundus*	Rz.	48 g
5	Rajanī (Haridrā API)	*Curcuma longa*	Rz.	48 g
6	Mātuluṅga API - drava	*Citrus medica*	Fr.	48 g
7	Ghṛta (Goghṛta 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 180 μm I. S. sieve (*Kalka dravyas).*

Wash, clean the *Mātuluṅga* 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 *Ghṛta* 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 *(phenaśānti)* and constantly check the *Kalka* for formation of *varti (madhyama pāka lakṣaṇa).*

Expose the *varti* and *Ghṛta* 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 yellow-coloured, soft, low melting medicated fat, unctuous to touch with odour and taste of *Haridrā*

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

6.2.9.3. Mūrcchana of Sarṣapa Taila:

(*Bhaiṣajyaratnāvalī, Jvarādhikāra*)

Ingredients:

1	Vayaḥsthā (Harītakī API)	*Terminalia chebula*	P.	12 g
2	Rajanī (Haridrā API)	*Curcuma longa*	Rz.	12 g
3	Musta (Mustā API)	*Cyperus rotundus*	Rz.	12 g
4	Bilva API	*Aegle marmelos*	Fr. Pp.	12 g
5	Dāḍima API	*Punica granatum*	Dr. Sd.	12 g
6	Keśara (Nāgakeśara API)	*Mesua ferrea*	Stmn.	12 g
7	Kṛśṇājīraka API	*Carum carvi*	Fr.	12 g
8	Hrīvera API	*Coleus vettiveroides*	Rt.	12 g
9	Nalikā (Tvak API)	*Cinnamomum tamala*	St. Bk.	12 g
10	Bibhītaka API	*Terminalia belerica*	P.	12 g
11	Aruṇā (Mañjiṣṭhā API)	*Rubia cordifolia*	Rt.	96 g
12	Toya (Jala API)	Water		3.072 l
13	Kaṭutaila (Sarṣapa Taila (API))	Mustard oil		768 ml

Method of Preparation:

Take all ingredients of pharmacopoeial quality.

Wash, clean, dry the ingredients numbered 1 to 10 of the formulation composition powder separately and pass through 180 μm I. S. sieve (*Kalka dravyas).*

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

Take *Sarṣapa taila* in a stainless steel vessel and heat mildly.

Add increments of *Kalka*. 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 appearance of froth (*phenodgama*) and constantly check the *Kalka* for formation of *varti (madhyama pāka lakṣaṇa).*

Expose the *varti* and oil 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.

Physico-chemical parameters:

Refractive index at 40^0:	1.471,	Appendix 3.1
Saponification value:	159,	Appendix 3.10
Iodine value:	70,	Appendix 3.11
Acid value:	Not more than 0.40,	Appendix 3.12
Peroxide value:	Not more than 3.5,	Appendix 3.13

6.2.9.4. Mūrcchana of Tila Taila:

(*Bhaiṣajyaratnāvalī, Jvarādhikāra*)

Ingredients:

1	Mañjiṣṭhā 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	Hrīvera 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	Sūcīpuṣpa (Ketakī API)	*Pandanus odoratissimus*	Rt.	24 g
10	Vaṭāṅkura (Nyagrodha API)	*Ficus bengalensis*	Lf. Bd.	24 g
11	Nalikā (Tvak API)	*Cinnamomum tamala*	St. Bk.	24 g
12	Taila (Tila tailaAPI)	Sesame oil		1.536 l
13	Jala API	Water		6.144 l

Method of preparation:

Take all ingredients of pharmacopoeial quality.

Wash, clean, dry the ingredients numbered 1 to 11 of the formulation composition powder separately and pass through 180 μm I. S. sieve (*Kalka dravyas).*

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

Take *Sarṣapa taila* in a stainless steel vessel and heat mildly.

Add increments of *Kalka*. 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 appearance of froth (*phenodgama*) and constantly check the *Kalka* for formation of *varti (madhyama pāka lakṣaṇa).*

Expose the *varti* and oil 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.

6.3. Yantra Paribhāṣā:

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.

(*Rasataraṅgiṇī* - 4/53)

6.3.2. Tiryak pātana yantra:

Tiryak pātana yantra is an instrument prepared for distillation of *Pārada* with the delivery tank weld approximately at an angle of 45^0.

(*Āurveda prakāśa* - 1/79)

6.3.3. Ḍamaru yantra:

Ḍamaruyantra is a contravenes of shape resembling *Ḍamaru* for sublimation prepared by sealing two pots with their mouths one telescoping the other sealing joint securely.

(*Rasataraṅgiṇī* - 4/41)

6.3.4. Dolāyantra:

Dolāyantra 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.

(*Rasaratnasamuccaya* - 9/3-4)

APPENDIX – 7

WEIGHTS AND MEASURES

7.1. Metric Equivalents of Classical Weights and Measures

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 Rattī or Guñjā		= 125 mg
8 Rattī or Guñjā	= 1 Māṣa	= 1 g
12 Maṣas	= 1 Karṣa (Tolā)	= 12 g
2 Karṣas	= 1 Śukti	= 24 g
2 Śukti	= 1 Palam	= 48 g
2 Palas	= 1 Prasṛti	= 96 g
2 Prasṛtis	= 1 Kuḍava	= 192 g
2 Kuḍavas	= 1 Mānikā	= 384 g
2 Mānikās	= 1 Prastha	= 768 g
4 Prasthas	= 1 Āḍhaka	= 3 kg 72 g
4 Āḍhakas	= 1 Droṇa	= 12 kg 288 g
2 Droṇas	= 1 Śūrpa	= 24 kg 576 g
2 Śūrpas	=1 Droṇī (Vāhī)	= 49 kg 152 g
4 Droṇīs	= 1 Khārī	= 196 kg 608 g
100 Palas	= 1 Tulā	= 4 kg 800 g
20 Tulās	= 1 Bhāra	= 96 kg

In case of liquids, the metric equivalents would be the corresponding litre and milliliter.

II. LINEAR MEASURES

Classical Unit	Inches	Metric Equivalent
Yavodara	1/8 of 3/4"	0.24 cm
Aṅgula	3/4"	1.95 cm
Vitasti	9"	22.86 cm
Aratni	10 1/2"	41.91 cm
Hasta	18"	45.72 cm
Nṛpahasta (Rājahasta)	22"	55.88 cm
Vyāma	72"	182.88 cm

III. MEASUREMENT OF TIME

Unit		Equivalent (in hours, minutes & seconds)
2 Kṣaṇas	= 1 Lava	
2 Lavas	= 1 Nimeṣa	
3 Nimeṣas	= 1 Kāṣṭhā	= 4.66 seconds
1 Ghaṭīs		= 24 minutes
30 Kāṣṭhās	= 1 Kalā	= 2 minutes 20 seconds
20 Kalās + 3 Kāṣṭhās	= 1 Muhūrta	= 48 minutes
30 Muhūrtas	= 1 Ahorātra	= 24 hours
15 Ahorātras	= 1 Pakṣa	= 15 days
2 Pakṣas	= 1 Māsa	= 30 days/1 month
2 Māsas	= 1 Ṛtu	= 60 days/ Two Months
3 Ṛtus	= 1 Ayana	= 6 Months
2 Ayanas	= 1 Saṃvatsara	= 12 months/1 Year
5 Saṃvatsara	= 1Yuga	= 5 Years
1 Ahorātra of Devas		= 1 Year
1 Ahorātra of Pitaras		= 1 Month

7.2. 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) is 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 - 8

CLASSICAL AYURVEDIC REFERENCES

JAṬĀMĀṂSYARKA (जटामांस्यर्क) (AFI, Part-I; 2:3)

(Arkaprakāśa, Śataka 4 : 22 1/2)

सुगन्धवीरणं बाला जटामांसी मुराघनः ।
सटीकर्चूरएकाङ्गी सुगन्धोऽयं गुणोत्तमः ।।२२।।
विधिनिष्कासितो योऽर्को रुच्यः पाचनदीपनः ।
(अर्कप्रकाश, शतक ४; २२१/२)

YAVĀNYARKA (यवान्यर्क) (AFI, Part-II; 2:2)

(Arkaprakāśa, śataka : 3:7)

यवान्याः पाचनो रुच्यो दीपनस्त्रिकशूलहृत्।।
अजमोदोद्भवो वातकफहा बस्तिशोधनः।।७।।
(अर्कप्रकाश, शतक ३; ७)

HARIDRĀ KHAṆḌA (हरिद्रा खण्ड) (AFI, Part-I; 3:31)

(Bhiṣajyaratnāvalī, Śītapittodardakoṭhādhikāra : 12-16)

हरिद्रायाः पलान्यष्टौ षट्पलं हविषस्तथा ।
क्षीराढकेन संयुक्तं खण्डस्यार्द्धशतं तथा ।।१२।।
पचेन्मृद्वग्निना वैद्यो भाजने मृण्मये दृढे ।
त्रिकटुश्च त्रिजातञ्च कृमिघ्नं त्रिवृता तथा ।।१३।।
त्रिफला केशरं मुस्तं लौहं प्रति पलं पलम् ।
सञ्चूर्ण्य प्रक्षिपेत्तत्र तोलकार्द्धन्तु भक्षयेत् ।।१४।।
कण्डूविस्फोटदद्रूणां नाशनं परमौषधम्।
प्रतप्तकाञ्चनाभासो देहो भवति नान्यथा।।१५।।
शीतपित्तोदर्दकोठान् सप्ताहादेव नाशयेत्।

हरिद्रानामतः खण्डः कण्डूनां परमौषधम्।।१६।।
(भैषज्यरत्नावली, शीतपित्तोदर्दकोठाधिकार; १२-१६)

NĀRIKELA KHAṆḌA (नारिकेल खण्ड) (AFI, Part-I; 3:16)

(Bhaiṣajyaratnāvalī, Śularogādhikāra : 168-169)

कुडवमितमिह स्यान्नारिकेलं सुपिष्टं पलपरिमितसर्पिः पाचितं खण्डतुल्यम् ।
निजपयसि तदेतत् प्रस्थमात्रे विपक्वं गुडवदथ सुशीते शाणभागान् क्षिपेच्च ।।१६८।।
धन्याकपिप्पलिपयोदतुगाद्विजीरान् शाणं त्रिजातमिभकेशरवद्विचूर्ण्य।
हन्त्यम्लपित्तमरुचिं क्षतमस्रपित्तं शूलं वमिं सकलपौरुषकारि हारि।।१६९।।
(भैषज्यरत्नावली, शूलरोगाधिकार; १६८-१६९)

CITRAKĀDI CŪRṆA (चित्रकादि चूर्ण) (AFI, Part-I; 7:11)

(Śārṅgadharasaṃhitā, Madhyamakhaṇḍa, Adhyāya 6 : 108-110)

चित्रकं नागरं हिङ्गु पिप्पली पिप्पलीजटा ।
चव्याजमोदा मरिचं प्रत्येकं कर्षसम्मितम् ।।१०८।।
स्वर्जिका च यवक्षारः सिन्धुः सौवर्चलं विडम् ।
सामुद्रकं रोमकं च कोलमात्राणि कारयेत् ।।१०९।।
एकीकृत्याखिलं चूर्णं भावयेन्मातुलुङ्गजैः ।
रसैर्दाडिमजैर्वापि शोषयेदातपेन च ।।११०।।
एतच्चूर्णं जयेद् गुल्मं ग्रहणीमामजां रुजम्।
अग्निं च कुरुते दीप्तं रुचिकृत् कफनाशनम्।।१११।।
(शाङ्र्गधरसंहिता, मध्यमखण्ड, अध्याय ६; १०८-११०)

SAPTĀṄGA GUGGULU (सप्ताङ्ग गुग्गुलु) (AFI, Part-III; 5:3)

(Cakradatta, Bhagandaracikitsāprakaraṇa; 15)

गुग्गुलुस्त्रिफलाव्योषैः समांशैराज्ययोजितः ।
नाडीदुष्टव्रणशूलभगन्दरविनाशनः ।।
(चक्रदत्त, भगन्दरचिकित्साप्रकरण; १५)

VARĀDI GUGGULU (वरादि गुग्गुलु) (AFI, Part-III; 5:1)

(Bhaiṣajyaratnāvalī, Upadaṃśarōgacikitsāprakaraṇa; 65)

वरानिम्बार्जुनाश्वत्थखदिरासनवासकैः ।
चूर्णितैर्गुग्गुलुसमैर्वटका अक्षसम्मिताः ।
उपदंशानसृग्दोषान् तथा दुष्टव्रणानपि।।
(भैषज्यरत्नावली, उपदंशरोगचिकित्साप्रकरण; ६५)

VIḌAṄGĀDI GUGGULU (विडङ्गादि गुग्गुलु) (AFI, Part-III; 5:2)

(Yōgaratnākara, Vraṇaśōdhanarōpaṇavidhi; 1)

विडङ्गत्रिफलाव्योषचूर्णं गुग्गुलुना समम्।
सर्पिषा वटकान् कुर्यात् खादेद्वा हितभोजनः।
दुष्टव्रणापचीमेहकुष्ठनाडीविशोधनम्।
(योगरत्नाकर, व्रणशोधनरोपणविधि; १)

SUKUMĀRA GHṚTA (सुकुमार घृत) (AFI, Part-I; 6:44)

(Sahasrayoga, Ghṛtaprakaraṇa: 4)

पचेत् पुनर्नवतुलां तथा दशपलाः पृथक् ।
दशमूलपयस्याश्वगन्धैरण्डशतावरीः ।।
द्विदर्भशरकाशेक्षुमूलपोटगलान्विताः ।
वहेऽपामष्टभागस्थे तत्र त्रिंशत्पलाद् गुडात् ।।
प्रस्थमेरण्डतैलस्य द्वौ घृतात्पयसस्तथा ।
आवपेद्द्विपलांशाश्च कृष्णातन्मूलसैन्धवम् ।।
यष्टीमधुकमृद्वीकायवानीनागराणि च ।
तत्सिद्धं सुकुमाराख्यं सुकुमारं रसायनम् ।।
वातातपाध्वभाष्यस्त्रीपरिहार्येष्वयन्त्रणम्।
प्रयोज्यं सुकुमाराणामीश्वराणां सुखात्मनाम्।।
नृणां स्त्रीवृन्दभर्तॄणामलक्ष्मीकलिनाशनम्।
सर्वकालोपयोगेन कान्तिलावण्यपुष्टिदम्।।

वर्ध्मविद्रधिगुल्मार्शोयोनिशूलानिलार्तिषु।
शोफोदरखुडप्लीहविड्विबन्धेषु चोत्तमम्।।
(सहस्रयोग, घृतप्रकरण; ४)

AṆU TAILA (अणु तैल) (AFI, Part-I; 8:1)

(Aṣṭāṅgahṛdaya, Sūtrasthāna, Adhyāya 20: 37-38)

जीवन्तीजलदेवदारुजलदत्वक्सेव्यगोपीहिमं
दार्वीत्वङ्मधुकप्लवागुरुवरीपुण्ड्राह्वबिल्वोत्पलम् ।
धावन्यौ सुरभिः स्थिरे कृमिहरं पत्रं त्रुटिं रेणुकां
किञ्जल्कं कमलाह्वयं शतगुणे दिव्येऽम्भसि क्वाथयेत् ।।३७।।
तैलाद्रसं दशगुणं परिशेष्य तेन तैलं पचेच्च सलिलेन दशैव वारान् ।
पाके क्षिपेच्च दशमे सममाजदुग्धं नस्यं महागुणमुशन्त्यणुतैलमेतत् ।।३८।।
(अष्टाङ्गहृदय, सूत्रस्थान, अध्याय २०; ३७-३८)

APĀMĀRGA KṢĀRA TAILA (अपामार्गक्षार तैल) (AFI, Part-II; 8:1)

(Bhaiṣajyaratnāvalī, Karṇarogādhikāra: 26)

मार्गक्षारजलेन च तत्कृतकल्केन साधितं तैलम्।
अपहरति कर्णनादं बाधिर्यञ्चापि पूरणतः।।२६।।
(भैषज्यरत्नावली, कर्णरोगाधिकार : २६)

ARIMEDĀDI TAILA (अरिमेदादि तैल) (AFI, Part-I; 8:2)

(Aṣṭāṅgahṛdaya, Uttarasthāna, Adhyāya 22: 90 - 96)

खदिरसाराद् द्वे तुले पचेद्बल्कात्तुलां चारिमेदसः ।
घटचतुष्के पादशेषेऽस्मिन् पूते पुनः क्वथनाद् घने ।।९०।।
आक्षिकं क्षिपेत्सुसूक्ष्मं रजः सेव्याम्बुपत्तङ्गगैरिकम् ।
चन्दनद्वयरोध्रपुण्ड्राह्वयष्ट्याह्वलाक्षाञ्जनद्वयम् ।।९१।।
धातकीकट्फलद्विनिशात्रिफलाचतुर्जातजोङ्गकम् ।
मुस्तमञ्जिष्ठान्यग्रोधप्ररोहमांसीयवासकम् ।।९२।।

पद्मकैलेयसमङ्गाश्च शीते तस्मिंस्तथा पालिकां पृथक् ।
जातिपत्रिकां सजातीफलां सहलवङ्गकङ्कोलिकाम् ।।९३।।
स्फटिकशुभ्रसुरभिकर्पूरकुडवं च तत्रावपेत्ततः ।
कारयेद् गुटिकाः सदा चैता धार्या मुखे तद् गदापहाः।।९४।।
क्वाथौषधव्यत्यययोजनेन तैलं पचेत्कल्पनयाऽनयैव।
सर्वास्यरोगोद्धृतये तदाहुर्दन्तस्थिरत्वे त्विदमेव मुख्यम् ।।९५।।
खदिरेणैता गुटिकास्तैलमिदं चारिमेदसा प्रथितम् ।
अनुशीलयन् प्रतिदिनं स्वस्थोऽपि दृढद्विजो भवति।।९६।।
(अष्टाङ्गहृदय, उत्तरस्थान, अध्याय २२; ९०-९६)

ASANABILVĀDI TAILA (असनबिल्वादि तैल) (AFI, Part-I; 8:3)

(Sahasrayoga, Tailaprakaraṇa: 45)

असनबिल्वबलामृतपाचिते मधुकनागरकत्रिफलान्विते ।
पयसि तैलमिदं पयसा पचेन्नयनकर्णशिरोहितमुत्तमम् ।।
(सहस्रयोग, तैलप्रकरण, ४५)

BALĀ TAILA (बला तैल) (AFI, Part-I; 8:33)

(Aṣṭāṅgahṛdaya, Cikitsāsthāna, Adhyāya 21 : 72-80)

बलाशतं छिन्नरुहापादं रास्नाऽष्टभागिकम् ।।७२।।
जलाढकशते पक्त्वा शतभागस्थिते रसे।
दधिमस्त्विक्षुनिर्यासशुक्तैस्तैलाढकं समैः ।।७३।।
पचेत्साजपयोऽर्धांशैः कल्कैरेभिः पलोन्मितैः ।
शठीसरलदार्वेलामञ्जिष्ठागुरुचन्दनैः ।।७४।।
पद्मकातिबलामुस्ताशूर्पपर्णीहरेणुभिः ।
यष्ट्याह्वसुरसव्याघ्रनखर्षभकजीवकैः ।।७५।।
पलाशरसकस्तूरीनीलिकाजातिकोशकैः ।
स्पृक्काकुङ्कुमशैलेयजातिकाकट्फलाम्बुभिः ।।७६।।
त्वक्कुन्दरुककर्पूरतुरुष्कश्रीनिवासकैः ।
लवङ्गनखकङ्कोलकुष्ठमांसीप्रियङ्गुभिः ।।७७।।

स्थौणेयतगरध्यामवचामदनकप्लवैः ।
सनागकेसरैः सिद्धे दद्याच्चाऽत्रावतारिते ।।७८।।
पत्रकल्कं ततः पूतं विधिना तत्प्रयोजितम् ।
कासश्वासज्वरच्छर्दिमूर्च्छागुल्मक्षतक्षयान्।।७९।।
प्लीहशोषमपस्मारमलक्ष्मीं च प्रणाशयेत्।
बलातैलमिदं श्रेष्ठं वातव्याधिविनाशनम्।।८०।।
(अष्टाङ्गहृदय, चिकित्सास्थान, अध्याय २१; ७२-८०)

BALĀHAṬHĀDI TAILA (बलाहठादि तैल) (AFI, Part-I; 8:37)

(Sahasrayoga, Tailaprakaraṇa : 54)

बलाहठामृतामुद्गमाषक्वाथे तिलोद्भवम् ।
पक्वं शिरोरुजं हन्ति चन्दनामययष्टिभिः ।।
(सहस्रयोग, तैलप्रकरण; ५४)

BHṚṄGARĀJA TAILA (भृङ्गराज तैल) (AFI, Part-I; 8:42)

(Bhaiṣajyaranāvalī, Kṣudrarogādhikāra: 91-96)

अनूपदेशसम्भूतं गृहीत्वा मार्कवं शुभम् ।
सुधौतं जर्जरीकृत्य स्वरसं तस्य चाहरेत् ।।९१।।
चतुर्गुणेन तेनैव तैलप्रस्थं विपाचयेत् ।
क्षीरपिष्टैरिमैर्द्रव्यैः संयोज्य मतिमान् भिषक् ।।९२।।
मञ्जिष्ठा पद्मकं लोध्रं चन्दनं गैरिकं बला ।
रजन्यौ केशरञ्चैव प्रियङ्गु मधुयष्टिका ।।९३।।
प्रपौण्डरीकं गोपी च पलिकान्यत्र दापयेत् ।
सम्यक् पक्वं ततो नीत्वा शुभे भाण्डे निधापयेत्।।९४।।
केशपाते शिरोदुष्टे मन्यास्तम्भे गलग्रहे।
शिरःकर्णाक्षिरोगेषु नस्येऽभ्यङ्गे च योजयेत्।।९५।।
कुञ्चिताग्रानतिस्निग्धान् कचान् कुर्याद् बहूंस्तथा।
खालित्यमिन्द्रलुप्तञ्च तैलमेतद् व्यपोहति।।८६।।
(भैषज्यरत्नावली, क्षुद्ररोगाधिकार; ९१-९६)

BṚHAT SAINDHAVĀDYA TAILA (बृहत् सैन्धवाद्य तैल) (AFI, Part-I; 8:40)

(Bhaiṣajyaratnāvalī, Amavātādhikāra : 157-162.)

सैन्धवं श्रेयसी रास्ना शतपुष्पा यमानिका ।
सर्जिका मरिचं कुष्ठं शुण्ठी सौवर्चलं विडम् ।।१५७।।
वचाजमोदा मधुकं जीरकं पौष्करं कणा ।
एतान्यर्द्धपलांशानि श्लक्ष्णपिष्टानि कारयेत् ।।१५८।।
प्रस्थमेरण्डतैलस्य प्रस्थाम्बु शतपुष्पजम् ।
काञ्जिकं द्विगुणं दत्त्वा तथा मस्तुः शनैः पचेत् ।।१५९।।
सिद्धमेतत्प्रयोक्तव्यमामवातहरं परम्।
पानाभ्यञ्जनवस्तौ च कुरुतेऽग्निबलं शुभम्।।१६०।।
वातार्त्तरक्षणे शस्तं कटीजानूरुसन्धिजे।
शूले हृत्पार्श्वपृष्ठेषु कृच्छ्राश्मरिनिपीडिते।।१६१।।
बाह्यायामार्दितानाहे अन्त्रवृद्धिनिपीडिते।
अन्यांश्चानिलजान् रोगान् नाशयत्याशु देहिनाम्।।१६२।।
(भैषज्यरत्नावली, आमवाताधिकार; १५७-१६२)

CITRAKĀDI TAILA (चित्रकादि तैल) (AFI, Part-I; 8:16)

(Suśrutasaṃhitā, Bhagandara Cikitsā : 50-50 1/2)

चित्रकार्कौ त्रिवृत्पाठे मलपूं हयमारकम् ।
सुधां वचां लाङ्गलकीं सप्तपर्णं सुवर्चिकाम् ।।५०।।
ज्योतिष्मतीं च सम्भृत्य तैलं धीरो विपाचयेत् ।
(सुश्रुतसंहिता, चिकित्सास्थान, अध्याय ८; ५०-५०१/२)

HIṄGVĀDI TAILA (हिङ्ग्वादि तैल) (AFI, Part-II; 8:18)

(Cakradatta, Karṇarogacikitsā: 16)

हिङ्गुतुम्बुरुशुण्ठीभिः साध्यं तैलन्तु सार्षपम्।
कर्णशूले प्रधानन्तु पूरणं हितमुच्यते।।१६।।
(चक्रदत्त कर्णरोगचिकित्सा, १६)

JYOTIṢMATĪ TAILA (ज्योतिष्मती तैल) (AFI, Part-I; 8:18)

(Yogaratnākara, Kuṣṭhacikitsā: Page 696)

मयूरकक्षारजले सप्तकृत्वः परिशृतम् ।
सिद्धं ज्योतिष्मतीतैलमभ्यङ्गाच्छ्वित्रनाशनम् ।।
(योगरत्नाकर, कुष्ठश्वित्रचिकित्सा; ६९६)

KANAKA TAILA (कनक तैल) (AFI, Part-I; 8:4)

(Bhaiṣajyaratnāvalī, Kṣudrarogādhikāra: 59 - 60)

मधुकस्य कषायेण तैलस्य कुडवं पचेत् ।
कल्कैः प्रियङ्गुमञ्जिष्ठाचन्दनोत्पलकेशरैः ।।५९।।
कनकं नाम तत्तैलं मुखकान्तिकरं परम्।
अभीरुनीलिकाव्यङ्गशोधनं परमार्च्चितम्।।६०।।
(भैषज्यरत्नावली, क्षुद्ररोगाधिकार; ५९-६०)

MAHĀ NĀRĀYAṆA TAILA (महानारायण तैल) (AFI, Part-I; 8:45)

(Bhaiṣajyaratnāvalī, Vatavyādhyadhikāra : 151-162.)

बिल्वाश्वगन्धाबृहतीश्वदंष्ट्राश्योनाकवाट्यालकपारिभद्रम् ।
क्षुद्राकठिल्लाग्निबलाग्निमन्थं मूलानि चैषां सरणीयुतानाम् ।।१५१।।
मूलं विदध्यादथ पाटलीनां प्रस्थं सपादं विधिनोद्धृतानाम् ।
द्रोणैरपामष्टभिरेव पक्त्वा पादावशेषेण रसेन तेन ।।१५२।।
तैलाढकाभ्यां सममेव दुग्धमाजं निदध्यादथवापि गव्यम् ।

एकत्र सम्यग्विपचेत्सुबुद्धिर्दद्याद्रसञ्चैव शतावरीणाम् ।।१५३।।
तैलेन तुल्यं पुनरेव तत्र रास्नाश्वगन्धामिषिदारुकुष्ठम् ।
पर्णीचतुष्कागरुकेशराणि सिन्धूत्थमांसीरजनीद्वयञ्च ।।१५४।।
शैलेयकं चन्दनपुष्कराणि एलास्रयष्टीतगराब्दपत्रम् ।
भृङ्गाष्टवर्गाम्बुवचापलाशं स्थौणेयवृश्चीरकचोरकाख्यम् ।।१५५।।
एतैः समस्तैर्द्विपलप्रमाणैरालोड्य सर्वं विधिना विपक्वम् ।
कर्पूरकाश्मीरमृगाण्डजानां चूर्णीकृतानां त्रिपलप्रमाणम् ।।१५६।।
प्रस्वेददौर्गन्ध्यनिवारणाय दद्यात् सुगन्धाय वदन्ति केचित्।
नारायणं नाम महच्च तैलं सर्वप्रकारैर्विधिवत्प्रयोज्यम् ।।१५७।।
आश्वेव पुंसां पवनार्दितानामेकाङ्गहीनार्दितवेपनानाम्।
ये पङ्गवः पीठविसर्पिणश्च बाधिर्यशुक्रक्षयपीडिताश्च।।१५८।।
मन्याहनुस्तम्भशिरोरुजार्ता मुक्तामयास्ते बलवर्णयुक्ताः।
संसेव्य तैलं सहसा भवन्ति वन्ध्या च नारी लभते च पुत्रम्।।१५९।।
वीरोपमं सर्वगुणोपपन्नं सुमेधसं श्रीविनयान्वितञ्च।
शाखाश्रिते कोष्ठगते च वाते वृद्धौ विधेयं पवनार्दितानाम्।।१६०।।
जिह्वानिले दन्तगते च शूले उन्मादकौब्ज्यज्वरकर्षितानाम्।
प्राप्नोति लक्ष्मीं प्रमदाप्रियत्वं वपुःप्रकर्षं विजयञ्च नित्यम्।।१६१।।
तैलोपसेवी जरयाभिमुक्तो जीवेच्चिराच्चापि भवेद् युवेव।
देवासुरे युद्धपरे समीक्ष्य स्नाय्वस्थिभग्नानसुरैः सुरांश्च।
नारायणेनापि सुबृंहणार्थं स्वनामतैलं विहितञ्च तेषाम्।।१६२।।
(भैषज्यरत्नावली, वातव्याध्यधिकार; १५१-१६२)

NĀLPĀMARĀDI TAILA (नाल्पामरादि तैल) (AFI, Part-I; 8:24)

(Sahasrayoga, Tailaprakaraṇa, 26)

नाल्पामरं त्रिफलचन्दनसेव्यकुष्ठ-
चोवळ्ळ चोरमकिलेन्निव कल्कमाक्कि।
पैमञ्ञळ् पर्पटरसे परिपक्वमेण्ण
तेक्किल् केट्टुं चोरिचिरङ्ङु विसर्पकुष्ठम् ।।
(सहस्रयोग, तैलप्रकरण; २६)

NĪLĪBHṚṄGĀDI TAILA (नीलीभृङ्गादि तैल) (AFI, Part-I; 8:26)

(Sahasrayoga; Tailaprakaraṇa: 38)

नीलीभृङ्गरसशतक्रतुलताधात्रीफलानां रसे
क्षीरैराजकनालिकेरमहिषीधेनूद्भवैस्साधितम् ।
तैलं तत्पयसैव पिष्टलुलितैर्यष्ट्याह्वगुञ्जाञ्जनैः
केशान् सञ्जनयेत्तलेऽपि करयोरास्तामकेशं शिरः।।
(सहस्रयोग, तैलप्रकरण; ३८)

PRABHAÑJANA VIMARDANA TAILA(प्रभञ्जनविमर्दन तैल) (AFI, Part-I; 8:30)

(Sahasrayoga, Tailaprakaraṇa : 5)

बलाशतावरीशिग्रुवरुणार्ककरञ्जकाः ।
एरण्डं चापि कोरण्टो वाजिगन्धा प्रसारिणी ।।
पञ्चमूलं वरिष्ठं च तैस्सर्वैः क्वथिते जले ।
पादावशेषिते दद्यात्तैलस्यार्द्धाढकं भिषक् ।।
क्षीरं तद्विगुणं दद्यात्तत्समे दधिकाञ्जिके ।
तगरामरकाष्ठैलाशुण्ठीसर्षपचोरकाः ।।
शताह्वाकुष्ठसिन्धूत्थरास्नाकालानुसारिकाः ।
वचा सचित्रकं मांसी सरलं कटुरोहिणी ।।
प्रत्येकं कार्षिकोन्मानं प्रतीवापाय योजयेत्।
सर्वैरेभिस्तु मृद्वग्निसिद्धं तिलजमादरात् ।।
पानाभ्यञ्जननस्येषु विधेयं वस्तिकर्मणि।
अशीतिं वातजान् रोगान्हन्यादाशु सुदारुणान्।।
वातगुल्मार्दितं वृद्धिमान्त्रजं वातविद्रधिम्।
मूढगर्भं तथा शूलान्विविधांश्च विनाशयेत्।
एतत्तैलं महावीर्यमात्रेयप्रमुखैः पुरा।
निर्मितं नामतश्चापि प्रभञ्जनविमर्दनम्।।
(सहस्रयोग, तैलप्रकरण; ५)

PRASĀRIṆĪ TAILA (प्रसारिणी तैल) (AFI, Part-I; 8:32)

(Śārṅgadharasaṃhitā, Madhyamakhaṇḍa, Adhyāya 9: 119-123 1/2.)

प्रसारणीपलशतं जलद्रोणेन पाचयेत्।
पादशिष्टः शृतो ग्राह्यस्तैलं दधि च तत्समम् ।।११९।।
काञ्जिकं च समं तैलात् क्षीरं तैलाच्चतुर्गुणम्।
तैलात् तथाष्टमांशेन सर्वकल्कानि योजयेत् ।।१२०।।
मधुकं पिप्पलीमूलं चित्रकः सैन्धवं वचा।
प्रसारिणी देवदारु रास्ना च गजपिप्पली ।।१२१।।
भल्लातः शतपुष्पा च मांसी चैभिर्विपाचयेत्।
एतत् तैलवरं पक्वं वातश्लेष्मामयाञ्जयेत्।।१२२।।
कौब्ज्यं पङ्गुत्वखञ्जत्वे गृध्रसीमर्दितं तथा।
हनुपृष्ठशिरोग्रीवाकटिस्तम्भान् विनाशयेत्।।१२३।।
अन्यांश्च विषमान् वातान् सर्वानाशु व्यपोहति।
(शाङ्र्गधरसंहिता, मध्यमखण्ड, अध्याय ९; ११९-१२३ १/२)

TUVARAKA TAILA (तुवरक तैल) (AFI, Part-I; 8:20)

(Suśrutasaṃhitā, Cikitsāsthāna, Adhyāya 13: 20-23, 29)

वृक्षास्तुवरका ये स्युः पश्चिमार्णवभूमिषु ।।२०।।
वीचीतरङ्गविक्षेपमारुतोद्धूतपल्लवाः ।
तेषां फलानि गृह्णीयात् सुपक्वान्यम्बुदागमे ।।२१।।
मज्जां तेभ्योऽपि संहृत्य शोषयित्वा विचूर्ण्य च ।
तिलवत् पीडयेद् द्रोण्यां स्रावयेद्वा कुसुम्भवत् ।।२२।।
तत्तैलं संहृतं भूयः पचेदातोयसंक्षयात् ।
अवतार्य करीषे च पक्षमात्रं निधापयेत् ।।२३।।
तदेव खदिरक्वाथे त्रिगुणे साधु साधितम् ।।२९।।
(सुश्रुतसंहिता, चिकित्सास्थान, अध्याय १३; २०-२३,२९)

YAṢṬIMADHUKA TAILA (यष्टीमधुक तैल) (AFI, Part-I; 8:47)

(Śārṅgadharasaṃhitā, Madhyamakhaṇḍa, Adhyāya 9: 155 1/2)

यष्टीमधुकक्षीराभ्यां नवधात्रीफलैः शृतम् ।।१५५।।
तैलं नस्यकृतं कुर्यात् केशाञ्श्मश्रूणि सङ्घशः।
(शाङ्र्गधरसंहिता, मध्यमखण्ड, अध्याय ९; १५५ १/२)

ARKA VAṬĪ (अर्क वटी) (AFI, Part-II; 10:2)

(Siddhabheṣajamaṇiṃālā; Agnimāndyādicikitsā; 254)

सौवर्चलं सादरमर्कपुष्पं मरिचमेकत्र समं विमर्द्य।
गुञ्जाप्रमाणा गुटिका विधेयाः कर्षन्ति काश्र्यं क्रमशः कृशानोः।। २५४।।

CITRAKĀDI GUṬIKĀ (चित्रकादि गुटिका) (AFI, Part-I; 12:11)

(Carakasaṃhitā, Cikitsāsthāna, Adhyāya 15: 96-97)

चित्रकं पिप्पलीमूलं द्वौ क्षारौ लवणानि च ।
व्योषं हिङ्ग्वजमोदां च चव्यं चैकत्र चूर्णयेत् ।।९६।।
गुटिका मातुलुङ्गस्य दाडिमस्य रसेन वा।
कृता विपाचयत्यामं दीपयत्याशु चानलम्।।९७।।
(चरकसंहिता, चिकित्सास्थान, अध्याय १५; ९६-९७)

ELĀDI GUṬIKĀ (एलादि गुटिका) (AFI, Part-I; 12:3)

(Bhaiṣajyaratnāvalī, Raktapittādhikāra: 32-35)

एलापत्रत्वचोऽर्द्धाक्षाः पिप्पल्यर्द्धपलं तथा ।
सितामधुकखर्जूरमृद्वीकाश्च पलोन्मिताः ।।३२।।
सञ्चूर्ण्य मधुना युक्ता गुटिकाः कारयेद्भिषक् ।
तोलकार्द्धां ततश्चैकां भक्षयेन्ना दिने दिने ।।३३।।
श्वासं कासं ज्वरं हिक्कां छर्दिं मूर्च्छां मदं भ्रमम्।
रक्तनिष्ठीवनं तृष्णां पार्श्वशूलमरोचकम्।।३४।।

शोषप्लीहाढ्यवातांश्च स्वरभेदं क्षतक्षयम्।
गुटिका तर्पणी वृष्या रक्तपित्तं विनाशयेत्।।३५।।
(भैषज्यरत्नावली, रक्तपित्ताधिकार; ३२-३५)

LAŚUNĀDI VAṬĪ (लशुनादि वटी) (AFI, Part-I; 12:27)

(Vaidyajīvanam, Kṣayarogādicikitsā: 13)

लशुनजीरकसैन्धवगन्धक त्रिकटुरामठचूर्णमिदं समम् ।
सपदि निम्बुरसेन विषूचिकां हरति भो रतिभोगविचक्षणे ।।१३।।
(वैद्यजीवनम्, क्षयरोगादिचिकित्सा; १३)

LAVAṄGĀDI VAṬĪ (लवङ्गादि वटी) (AFI, Part-I; 12:26)

(Vaidyajīvanam, Kāsaśvāsacikitsā: 7)

तुल्या लवङ्गमरिचाक्षफलत्वचः स्युः।
सर्वैः समो निगदितः खदिरस्य सारः ।।
बब्बूलवृक्षजकषाययुतञ्च चूर्णम् ।
कासान्निहन्ति गुटिका घटिकाऽष्टकान्ते ।।७।।
(वैद्यजीवनम्, कासश्वासचिकित्सा, ७)

PLĪHĀRI VAṬIKĀ (प्लीहारि वटिका) (AFI, Part-I; 12:17)

(Bhaiṣajyaratnāvalī, Plīhāyakṛdrogādhikāra: 59)

सहासाराभ्रकासीसलशुनानि समानि च ।
द्रोणपुष्पीरसेनैव मर्दयेत्प्रहरत्रयम् ।।५९।।
वल्लद्वयं प्रदातव्यं प्रदोषे सलिलं ह्यनु।
प्लीहानं यकृतं गुल्ममग्निमान्द्यं सशोथकम्।।६०।।
कासं श्वासं तृषां कम्पं दाहं शीतं वमिं भ्रमम्।
प्लीहारिवटिका ह्येषा नाशयेन्नात्र संशयः।।६१।।
(भैषज्यरत्नावली, प्लीहयकृद्रोगाधिकार; ५९-६१)

PRABHĀKARA VAṬĪ (प्रभाकर वटी) (AFI, Part-I; 12:15)

(Bhaiṣajyaratnāvalī, Hṛdrogādhikāra : 67)

माक्षिकं लोहमभ्रञ्च तुगाक्षीरी शिलाजतु ।
क्षिप्त्वा खल्लोदरे पश्चाद् भावयेत् पार्थवारिणा ।।६६।।
गुञ्जाद्वयमितां कुर्याद् वटीं छायाविशोषिताम्।
प्रभाकरवटी सेयं हृद्रोगान् निखिलान् जयेत्।।६७।।
(भैषज्यरत्नावली, हृद्रोगाधिकार; ६६-६७)

RAJAḤPRAVARTINĪ VAṬĪ(रजःप्रवर्तिनी वटी)(AFI, Part-I; 12:25)

(Bhaiṣajyaratnāvalī, (Strīrogādhikāra) : 233-235)

कन्यासारं च कासीसं रामठं टङ्कणं तथा ।
समादाय समं सर्वं पेषयेत्कन्यकाद्रवैः ।।२३३।।
निर्मापयेद्भिषग्वर्यो रक्तिद्वयमिता वटीः।
शीलितेयं तु वटिका विनिहन्ति सुदारुणाम्।।२३४।।
रजोरोधव्यथां कष्टरजःस्रावव्यथां तथा।
रजःप्रवर्त्तिनी ह्येषा नीलकण्ठेन भाषिता।।२३५।।
(भैषज्यरत्नावली, स्त्रीरोगाधिकार; २३३-२३५)

SAÑJĪVANĪ VAṬĪ (सञ्जीवनी वटी) (AFI, Part-I; 12:35)

(Śarṅgadharasaṃhitā, Madhyamakhaṇḍa. Adhyāya 7: 18-21)

विडङ्गं नागरं कृष्णा पथ्यामलबिभीतकम् ।।१८।।
वचा गुडूची भल्लातं सविषं चात्र योजयेत् ।
एतानि समभागानि गोमूत्रेणैव पेषयेत् ।।१९।।
गुञ्जाभा गुटिका कार्या दद्यादार्द्रकजै रसैः।
एकामजीर्णगुल्मेषु द्वे विषूच्यां प्रदापयेत्।।२०।।
तिस्रश्च सर्पदष्टे तु चतस्रः सान्निपातके।
वटी सञ्जीवनी नाम्ना सञ्जीवयति मानवम्।।२१।।
(शाङ्र्गधरसंहिता, मध्यमखण्ड, अध्याय ७; १८-२१)

ŚAṄKHA VAṬĪ (शङ्ख वटी) (AFI, Part-I; 12:32)

(Bhaiṣajyaratnāvalī, Agnimāndyādhikāra : 182-183)

चिञ्चाक्षारपलं पटुव्रजपलं निम्बूरसे कल्कितम् ।
तस्मिन् शङ्खपलं प्रतप्तमसकृत् संस्थाप्य शीर्णावधि ।।१८२।।
हिङ्गुव्योषपलं रसामृतवली निक्षिप्य निष्कांशिकाः ।
बद्ध्वा शङ्खवटी क्षयग्रहणिकारुक्पक्तिशूलादिषु।।१८३।।
(भैषज्यरत्नावली, अग्निमान्द्यादिरोगाधिकार; १८२-१८३)

PUNARNAVĀDI MAṆḌŪRA (पुनर्नवा मण्डूर) (AFI, Part-I; 19:1)

(Carakasaṃhitā, Cikitsāsthāna, Adhyāya 16: 93-95)

पुनर्नवा त्रिवृद् व्योषं विडङ्गं दारु चित्रकम् ।।९३।।
कुष्ठं हरिद्रे त्रिफला दन्ती चव्यं कलिङ्गकाः ।
पिप्पली पिप्पलीमूलं मुस्तं चेति पलोन्मितम् ।।९४।।
मण्डूरं द्विगुणं चूर्णाद् गोमूत्रे द्व्याढके पचेत् ।
कोलवद् गुटिकाः कृत्वा तक्रेणालोड्य ना पिबेत् ।।९५।।
ताः पाण्डुरोगान् प्लीहानमर्शांसि विषमज्वरम्।
श्वयथुं ग्रहणीदोषं हन्युः कुष्ठं क्रिमींस्तथा।।९६।।
(चरकसंहिता, चिकित्सास्थान, अध्याय १६, ९३-९६)

APPENDIX - 9

LIST OF SINGLE DRUGS USED IN FORMULATIONS

9.1 List of Single Drugs of Animal Origin mentioned in Formulation compositon with equivalent English Names:

Official Name	English Equivalent	Ref. to A.P.I. Pt. I (Vol. No.)
Ajādugdha	Goat milk	
Godadhi	Curd from cow milk	
Godugdha	Cow milk	
Goghṛta	Clarified butter from cow milk	Vol-VI
Gomūtra	Cow urine	
Lākṣā	Secretion of Lac insect *(Lacca laccifera)*	
Madhu	Honey	Vol-VI
Madhūcchiṣṭa	Bees wax	
Mahiṣīdugdha	Buffalo milk	
Śaṅkha bhasma	Calcined Conch	

9.2 List of Single Drugs of Mineral and Metal Origin mentioned in Formulation composition with equivalent Scientific Names:

Official Name	Scientific Equivalent	Ref. to A.P.I. Pt. I (Vol. No.)
Abhraka Bhasma		
Audbhida Lavaṇa		
Gairika	Red ochre	Vol-VII
Gandhaka	Sulphur	Vol-VII
Kāśīśa	Green vitreol	Vol-VII
Lauha		Vol-VII
Maṇḍūra	Iron slag	Vol-VII
Narasāra	Sal ammoniac	Vol-VII
Pārada	Mercury	
Romaka Lavaṇa		
Saindhava Lavaṇa	Rock salt	
Sauvarcala Lavaṇa	Black salt	
Sauvīrāñjana	*Lead sulphide*	Vol-VII
Sāmudra Lavaṇa	Sea salt	Vol-VII
Svarjīkṣāra	Crude alkaline earth	Vol-VII
Svarṇamākṣika	Chalcopyrite	Vol-VII
Śilājatu		
Taṅkaṇa	Borax	Vol-VII
Viḍa Lavaṇa		

9.3 List of Single Drugs of Plant origin, mentioned in Formulation composition with Botanical Nomenclature:

Official Name	Botanical name	Ref. to A.P.I. Pt. I (Vol. No.)
Agaru	*Aquilaria agallocha* Roxb.	Vol. IV
Agnimantha	*Clerodendrum phlomidis* L.f. *(= C. multiflorum* (Burm.f.) O. Kuntze*.)*	Vol. III
Ajamodā	*Apium leptophyllum* (Pers.) F.V.M. ex Benth.	Vol. I
Apāmārga	*Achyranthes aspera* L.	Vol. II, III
Arimeda	*Acacia leucophloea* Willd.	Vol. II
Arjuna	*Terminalia arjuna* (Roxb.) W. & A.	Vol. II
Arka	*Calotropis procera* (Ait.) R. Br.	Vol. I, III
Asana	*Pterocarpus marsupium* Roxb.	Vol. I, III
Aśvagandhā	*Withania somnifera* (L.) Dunal	Vol. I
Aśvattha	*Ficus religiosa* L.	Vol. I
Atibalā	*Abutilon indicum* (L.) Sweet	Vol. I
Āmalakī	*Emblica officinalis* Gaertn. *(= Phyllanthus emblica* L.*)*	Vol. I
Babbūla	*Acacia nilotica* (L.) Willd. ex Del. ssp. *indica* (Benth.) Brenan (=*A. arabica* Willd.)	Vol. I
Balā	*Sida cordifolia* L.	
Bhṛṅgarāja	*Eclipta alba* (L.) Hassk.	Vol. II
Bhallātaka	*Semecarpus anacardium* L.f	Vol. II
Bibhītaka	*Terminalia belerica* (Gaertn.) Roxb.	Vol. I
Bilva	*Aegle marmelos* (L.) Corr.	Vol. I, III, IV
Brāhmī	*Bacopa monnieri* (L.) Wettst.	Vol. II
Bṛhatī	*Solanum indicum* L.	Vol. II
Cavya	*Piper chaba* Hunter	Vol. II
Ciñcā	*Tamarindus indica* L.	Vol. IV
Citraka	*Plumbago zeylanica* L.	Vol. I
Coraka	*Angelica glauca* Edgew.	Vol. V

Official Name	Botanical name	Ref. to A.P.I. Pt. I (Vol. No.)
Coram	*Kaempferia galanga* L.	
Darbha	*Imperata cylindrica* (L.) Beauv.	Vol. V
Dāruharidrā	*Berberis aristata* DC.	Vol. II, VI
Devadāru	*Cedrus deodara* (Roxb. ex D. Don) G. Don	Vol. IV
Dhānyaka	*Coriandrum sativum* L.	Vol. I
Dhātakī	*Woodfordia fruticosa* (L.) Kurz	Vol. I
Drākṣā	*Vitis vinifera* L.	Vol. III
Droṇapuṣpī	*Leucas cephalotus* (Roth) Spreng.	Vol. II
Elavāluka	*Prunus avium* L.f.	Vol. VI, V
Eraṇḍa	*Ricinus communis* L.	Vol. I, III
Gajapippalī	*Scindapsus officinalis* (Roxb.) Schott.	Vol. II
Gambhārī	*Gmelina arborea* Roxb.	Vol. I, II, III, IV
Gokṣura	*Tribulus terrestris* L.	Vol. I, VI
Guḍūcī	*Tinospora cordifolia* (Willd.) Miers. ex Hook.f. & Thoms.	Vol. I
Guggulu	*Commiphora wightii* (Arn.) Bhand.	Vol. I
Gulāba	*Rosa damascena* Mill.	
Guñjā	*Abrus precatorius* L.	Vol. I, Vol. II
Harītakī	*Terminalia chebula* (Gaertn.) Retz.	Vol. I
Haridrā	*Curcuma longa* L.	Vol. I
Hiṅgu	*Ferula foetida* Regel. (= *F. assa-foetida* L.)	Vol. I
Hrīvera	*Coleus vettiveroides* K.C. Jacob	
Ikṣu	*Saccharum officinarum* L.	Vol. IV
Jaṭāmaṃsī	*Nardostachys jatamansi* (D. Don) DC.	Vol. I
Jātīphalā	*Myristica fragrans* Houtt.	Vol. I
Jīvaka	*Malaxis acuminata* D. Don	Vol. V
Jīvantī	*Leptadenia reticulata* (Retz.) W.& A.	Vol. VI
Jyotiṣmatī	*Celastrus paniculatus* Willd.	Vol. II

Official Name	Botanical name	Ref. to A.P.I. Pt. I (Vol. No.)
Kamala	*Nelumbo nucifera* Gaertn.	Vol. II, III
Kaṅkola	*Piper cubeba* L. f.	Vol. I
Kaṇṭakārī	*Solanum surratense* Burm.f.	Vol. I
Karañja	*Pongamia pinnata* (L.) Merr. (= *Derris indica* (Lam.) Bennet)	Vol. I, II
Karavīra	*Nerium indicum* Mill.	Vol. I, Vol. III
Karpūra	*Cinnamomum camphora* (L.) Nees & Eberm.	Vol. VI
Kaṭphala	*Myrica esculenta* Buch.- Ham. ex D. Don	Vol. III
Kaṭukā	*Picrorhiza kurroa* Royle ex Benth.	Vol. II
Kāśa	*Saccharum spontaneum* L.	Vol. III
Kākamācī	*Solanum nigrum* L.	Vol. II
Kākatiktā	*Cardiospermum halicacabum* L.	Vol. V
Kākolī	*Lilium polyphyllum* D. Don	Vol. III
Kejoputī	*Melaleuca leucadendron* L.	
Khadira	*Acacia catechu* (L.f.) Willd.	Vol. I
Kharjūra	*Phoenix sylvestris* Roxb.	Vol. IV
Kṛṣṇa jīraka	*Carum carvi* L.	Vol. I
Kṣīrakākolī	*Fritillaria roylei* Hook.	Vol. V
Kulañjana	*Alpinia galanga* Willd.	Vol. V
Kumārī	*Aloe barbadensis* Mill. (= *A. vera* (L.) Burm.f.)	Vol. I
Kunduru	*Boswellia serrata* Roxb. ex Coleb.	Vol. IV
Kuṅkuma	*Crocus sativus* L.	Vol. IV
Kuśa	*Desmostachya bipinnata* Stapf	Vol. III
Kuṣṭha	*Saussurea lappa* (Decne) Sch.-Bip.	Vol. I
Lajjālu	*Mimosa pudica* L.	Vol. II
Laśuna	*Allium sativum* L.	Vol. III
Lavaṅga	*Syzygium aromaticum* (L.) Merr. & Perr.	Vol. I
Lāṅgalī	*Gloriosa superba* L.	Vol. III

Official Name	Botanical name	Ref. to A.P.I. Pt. I (Vol. No.)
Lodhra	*Symplocos racemosa* Wall. ex DC.	Vol. I
Madana	*Xeromphis spinosa* (Thunb.) Keay	Vol. I
Madhusnuhī	*Smilax china* L.	Vol. V
Madhūka	*Madhuca indica* J.F. Gmel. (= *M. butyracea* (Roxb.) Macbride)	Vol. II
Mahāmedā/ Medā	*Polygonatum cirrhifolium* (Wall.) Royle	Vol. V
Mañjiṣṭhā	*Rubia cordifolia* L.	Vol. III
Marica	*Piper nigrum* L.	Vol. III
Māṣaparṇī	*Teramnus labialis* Spreng.	Vol. III
Mātuluṅga	*Citrus aurantifolia* (Christm.) Swingle	
Methī	*Trigonella foenum-graecum* L.	Vol. II
Miśreyā	*Foeniculum vulgare* Mill.	Vol. I
Mudga	*Phaseolus radiatus* L. (= *P. vulgaris* L.)	Vol. III
Mudgaparṇī	*Vigna trilobata* (L.) Verde.	Vol. IV
Muṇḍītikā	*Sphaeranthus indicus* L.	Vol. III, IV
Mustā	*Cyperus rotundus* L.	Vol. III
Nāgakeśara	*Mesua ferrea* L.	Vol. II
Nārikela	*Cocos nucifera* L.	Vol. III
Nimba	*Azadirachta indica* (L.) A. Juss.	Vol. II, V
Nimbu	*Citrus limon* (L.) Burm.f.	Vol. IV
Nīlī	*Indigofera tinctoria* L.	Vol. II, III
Nyagrodhajaṭā	*Ficus bengalensis* L.	Vol. I, IV
Padmaka	*Prunus cerasoides* D. Don	Vol. III
Palāśa	*Butea monosperma* (Lam.) Taub.	Vol. II, IV, V
Parpaṭa	*Fumaria parviflora* Lam. (= *F. vaillantii* Loisel)	Vol. IV
Pattaṅga	*Caesalpinia sappan* L.	Vol. IV
Pāribhadra	*Erythrina indica* Lam. (= *E. superba* Roxb.)	Vol. II

Official Name	Botanical name	Ref. to A.P.I. Pt. I (Vol. No.)
Pāṭalā	*Stereospermum suaveolens* (Roxb.) DC. (= *S. chelonoides* (L.f.) DC.)	Vol. III
Pāṭhā	*Cissampelos pareira* L.	Vol. I
Phalgu	*Ficus hispida* L.f.	Vol. III
Pippalī	*Piper longum* L.	Vol. IV
Pippalīmūla	*Piper longum* L.	Vol. II
Plakṣa	*Ficus lacor* Buch.-Ham. (= *F. virens* Ait.)	Vol. II, IV
Poṭagala	*Typha elephantina* Roxb.	Vol. V
Prasāriṇī	*Paederia foetida* L. (= *P. scandens* (Lour.) Merr.)	Vol. II
Priyaṅgu	*Callicarpa marcophylla* Vahl	Vol. II, IV
Pṛśniparṇī	*Uraria picta* Desv.	Vol. IV
Pudīnā	*Mentha viridis* L. (= *M. spicata* L.)	Vol. V
Puṣkara	*Inula racemosa* Hook. f.	Vol. IV
Rakta Candana	*Pterocarpus santalinus* L.f.	Vol. III
Rakta Punarnavā	*Boerhaavia diffusa* L.	Vol. I, III
Rāsnā	*Pluchea lanceolata* (DC.) Clarke	Vol. III
Reṇukā	*Vitex negundo* L. – Seed	Vol. V
Rohiṣa	*Cymbopogon martinii* (Roxb.) Wats.	Vol. V
Ṛṣabhaka	*Microstylis muscifera* Ridley.	
Ṛddhi / Vṛddhi	*Habenaria intermedia* D. Don	Vol. V
Sahacara	*Barleria prionitis* L.	Vol. III
Saptaparṇa	*Alstonia scholaris* R.Br.	Vol. I
Sarala	*Pinus roxburghii* Sargent.	Vol. III
Sarṣapa	*Brassica campestris* L.	Vol. III
Snuhī	*Euphorbia neriifolia* L.	Vol. I
Spṛkkā	*Anisomeles malabarica* (L.) R.Br. ex Sims.	Vol. VI
Sthauṇeya	*Taxus baccata* L. (= *T. officinale* Weber ex Wigg.)	Vol. III
Sūkṣmailā	*Elettaria cardamomum* (L.) Maton	Vol. I

Official Name	Botanical name	Ref. to A.P.I. Pt. I (Vol. No.)
Śaileya	*Parmelia perlata* (Huds.) Ach.	Vol. III
Śara	*Saccharum bengalense* Retz. (= *S. munja* Roxb.)	Vol. III
Śatāhvā	*Anethum sowa* Roxb. ex Flem. (= *A. graveolens* L.)	Vol. II
Śatāvarī	*Asparagus racemosus* Willd.	Vol. IV
Śaṭī	*Hedychium spicatum* Ham. ex Smith	Vol. I
Śāla	*Shorea robusta* Gaertn. f.	Vol. VI
Śālaparṇī	*Desmodium gangeticum* (L.) DC.	Vol. III, VI
Śigru	*Moringa oleifera* Lam.	Vol. II, IV
Śuṇṭhī	*Zingiber officinale* Rosc.	Vol. I
Śveta Candana	*Santalum album* L.	Vol. III
Śveta Jīraka	*Cuminum cyminum* L.	Vol. I
Śveta Punarnavā	*Boerhaavia verticillata* Poir.	Vol. V
Śveta Sārivā	*Hemidesmus indicus* (L.) R.Br.	Vol. I
Śyonāka	*Oroxylum indicum* (L.) Vent.	Vol. III
Tagara	*Valeriana wallichii* DC. (= *V. jatamansi* Jones)	Vol. I
Tailaparna Taila	*Eucalyptus globulus* Labill.	Vol. VI
Tumburu	*Zanthoxylum armatum* DC.	Vol. IV
Tila Taila	*Sesamum indicum* L.	Vol. VI
Trivṛt	*Operculina turpethum* (L.) Silva Manso (=*Ipomoea turpethum* R. Br.)	Vol. III
Tulasī	*Ocimum sanctum* L.	Vol. II, IV
Turuṣka	*Liquidambar orientalis* Mill.	
Tuvaraka	*Hydnocarpus pentandra* (Buch.-Ham.) Oken (=*Hydnocarpus laurifolia* (Dennst.) Sleum.)	Vol. VI
Tvak	*Cinnamomum zeylanicum* Blume (= *C. verum* J.S. Presl)	Vol. I, VI
Tvakpatra	*Cinnamomum tamala* (Buch.-Ham.) Nees & Eberm.	Vol. I
Udumbara	*Ficus racemosa* L.	Vol. I
Uśīra	*Vetiveria zizanioides* (L.) Nash	Vol. III

Official Name	Botanical name	Ref. to A.P.I. Pt. I (Vol. No.)
Utpala	*Nymphaea stellata* Willd.	Vol. III
Vacā	*Acorus calamus* L.	Vol. II
Vaṃśalocana	Bamboo manna	
Vanya Ajamodā	*Trachyspermum roxburghianum* (DC.) Wolff	
Varuṇa	*Crataeva nurvala* Buch.-Ham.	Vol. I
Vatsanābha	*Aconitum chasmanthum* Holmes ex Stapf	Vol. II
Vāsā	*Adhatoda zeylanica* Medik.	Vol. IV
Vārāhī	*Dioscorea bulbifera* L.	Vol. IV
Vidārīkanda	*Pueraria tuberosa* (Roxb. ex Willd.) DC.	Vol. V
Vyāghranakha	*Capparis sepiaria* L.	Vol. V
Yaṣṭī	*Glycyrrhiza glabra* L.	Vol. I
Yavakṣāra	*Hordeum vulgare* L. – Water soluble ash of Pl.	Part II Vol. II
Yavānī	*Trachyspermum ammi* (L.) Sprague	Vol. I
Yavāsaka	*Alhagi pseudalhagi* (Bieb.) Desv.	Vol. II

APPENDIX-10

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Avaleha:

1. Aṣṭāṅgāvaleha
2. Bhallātakādi Modaka
3. Bilvādi Leha
4. Citraka Harītakī
5. Cyavanaprāśa
6. Kalyāṇaka Leha
7. Kūṣmāṇḍaka Rasāyana
8. Mṛdvīkādi Lehya
9. Pūga Khaṇḍa
10. Sūraṇāvaleha
11. Vāsāvaleha
12. Vyāghrī Harītakī

Cūrṇa:

13. Āmalakyādi Cūrṇa
14. Avipattikara Cūrṇa
15. Bālacāturbhadrikā Cūrṇa
16. Elādi Cūrṇa
17. Hiṅgvaṣṭaka Cūrṇa
18. Navāyasa Cūrṇa
19. Nimbādi Cūrṇa
20. Pañcasama Cūrṇa
21. Puṣyānuga Cūrṇa
22. Tālīsādya Cūrṇa
23. Vaiśvānara Cūrṇa

Ghṛta:

24. Brāhmī Ghṛta
25. Daśamūla Ghṛta
26. Daśamūlaṣaṭpalaka Ghṛta
27. Dhātryādi Ghṛta
28. Jātyādi Ghṛta
29. Kalyāṇaka Ghṛta
30. Pañcagavya Ghṛta
31. Pañcatikta Ghṛta
32. Phala Ghṛta
33. Sārasvata Ghṛta
34. Traikaṇṭaka Ghṛta
35. Triphalā Ghṛta

Guggulu:

36. Kaiśora Guggulu

Gutika:

37. Maricādi Guṭikā

Kṣāra / Lavaṇa

38. Apāmārga Kṣāra
39. Arka Lavaṇa
40. Kalyāṇaka Kṣāra
41. Mūlaka Kṣāra
42. Palāśa Kṣāra
43. Yava Kṣāra

Taila:

44. Balāguḍūcyādi Taila
45. Dhānvantara Taila
46. Gandharvahasta Taila
47. Koṭṭamcukkādi Taila
48. Kṣīrabalā Taila
49. Saindhavādi Taila

Lepa:

50. Dārvī Malahara (Gel)

MONOGRAPHS PUBLISHED IN AYURVEDIC PHARMACOPOEIA OF INDIA PART – II (FORMULATIONS); VOL. – II

Āsava and Ariṣṭa

1. Abhayāriṣṭa
2. Amṛtāriṣṭa
3. Aravindāsava
4. Aśokāriṣṭa
5. Aśvagandhādyariṣṭa
6. Babbūlāriṣṭa
7. Balāriṣṭa
8. Daśamūlāriṣṭa
9. Drākṣāriṣṭa
10. Drākṣāsava
11. Jīrakādyariṣṭa
12. Kanakāsava
13. Khadirāriṣṭa
14. Kumāryāsava (B)
15. Kuṭajāriṣṭa
16. Lohāsava
17. Mustakāriṣṭa
18. Pārthādyāriṣṭa
19. Pippalyādyāsava
20. Punarnavādyāriṣṭa
21. Punarnavāsava
22. Rohītakāriṣṭa
23. Sārivādyāsava
24. Uśīrāsava

Avaleha:

25. Daśamūla Harītakī
26. Drākṣāvaleha
27. Elādya Modaka
28. Madhusnuhī Rasāyana

Cūrṇa:

29. Bhāskaralavaṇa Cūrṇa
30. Gomūtra Harītakī
31. Jātīphalādya Cūrṇa
32. Nārasiṃha Cūrṇa

Ghṛta:

33. Dāḍimādi Ghṛta
34. Indukānta Ghṛta
35. Mahā Triphalādya Ghṛta
36. Tiktaka Ghṛta

Guggulu:

37. Gokṣurādi Guggulu
38. Kāñcanāra Guggulu
39. Lākṣā Guggulu
40. Pañcāmṛta Loha Guggulu
41. Pañcatikta Guggulu Ghṛta
42. Punarnavā Guggulu
43. Saptaviṃśatika Guggulu
44. Siṃhanāda Guggulu
45. Trayodaśāṅga Guggulu
46. Triphalā Guggulu
47. Vātāri Guggulu
48. Vyoṣādi Guggulu
49. Yogarāja Guggulu

Taila:

50. Śambūkādya Taila

Device:

51. Kṣārasūtra

ADDENDUM

API, PART II, Vol.I

Page No.	Formulation	Parameter	Read as	In place of
17	Kalyāṇakāvaleha	Quantity of Sarpi	Q.S.	Q.S.(6 parts)
30	Sūraṇāvaleha	Total sugar	80 to 85	80 to 90
33	Vāsāvaleha	Total sugar	82 to 88	83 to 88
119	Dhānvantara Taila	Refractive Index	1.461 to 1.465	1.465 to 1.465
199	–	Saponification Value	$\frac{(b-a) \times 28.05}{W}$	$\frac{(b-a) \times 0.02805 \times 1.0}{W}$

ADDENDUM

API, PART II, Vol.II

Page No.	Formulation	Parameter	Read as	In place of
23	Daśamūlāriṣṭa	Specific gravity	1.09-1.1	1.09-1.1 g/ml
77	Madhusnuhī Rasāyana	Total sugar	29 to35	29.86 to35.14
77	Madhusnuhī Rasāyana	Non-reducing sugar	4 to 5	4.78 to 5.14
93	Dāḍimādi Ghṛta –A	Acid value	NMT 1	NMT 0.9
95	Dāḍimādi Ghṛta -B	Acid value	NMT 1	NMT 0.33
97	Indukānta Ghṛta -A	Acid value	NMT 2	NMT1.53
100	Indukānta Ghṛta –B	Acid value	NMT 2	NMT 1.44
103	Mahātriphalādya Ghṛta	Saponification value	210-214	0.2100-0.2147
103	Mahātriphalādya Ghṛta	Acid Value	NMT 3	NMT 2.9
106	Tiktaka Ghṛta -A	Acid value	NMT 2	NMT 1.9
108	Tiktaka Ghṛta -B	Acid value	NMT 1	NMT 0.56
222	–	Saponification Value	$\frac{(b-a) \times 28.05}{W}$	$\frac{(b-a) \times 0.02805 \times 1.000}{W}$