THE AYURVEDIC PHARMACOPOEIA OF INDIA

PART - II (FORMULATIONS)
VOLUME - I

First Edition

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
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CONTENTS

KṢĀRA/ LAVAṆA:

TAILA:

LEPA:

LEGAL NOTICES

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

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

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

Under the Drugs & Cosmetics Act, the Ayurvedic Pharmacopoeia of India (A.P.I.), Part-II, Vol. I, is the book of standards for compound formulations included therein and the standards prescribed in the Ayurvedic Pharmacopoeia of India, Part-II, (Formulation) Vol. I, would be official. If considered necessary these standards can be amended and the Chairman of the Ayurvedic Pharmacopoeia Committee's authorised to issue such amendements. Whenever such amendments are issued the Ayurvedic Pharmacopoeia of India, Part-II (Formulation), Vol. I, 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-I. Wherever the abbreviation "API, Pt.-II, Vol.-I" is used, it may be presumed to stand for the same and the supplements or amendments thereto.

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

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

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

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

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

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

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

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

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

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

The requirements given in the monographs are not framed to provide against all impurities, contaminants or adulterants; they provide appropriate limits only for possible

impurities that may be permitted to a certain extent. Material found to contain an impurity, contaminant or adulterant which is not detectable by means of the prescribed tests are also to be considered as impurity should rational consideration require its absence.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Where it is directed in the assay for Tablet formulation to "weigh and powder not less than" a given number, usually 20, of the tablets, it is intended that a counted number of tablets shall be weighed and reduced to a fine powder. Likewise, where it is directed in the assay for Capsules to remove, as completely as possible, the contents of not less than a given

number, usually 20, of the capsules, it is intended that a counted number of capsules should be carefully opened and the contents quantitatively removed, combined, mixed, and weighed accurately. The portion of the powdered tablets or the mixed contents of the capsules taken for assay is representative of the whole tablets or capsules, respectively, and is, in turn, weighed accurately. The result of the assay is then related to the amount of active ingredients per tablet in the case of tablets and per capsule in the case of capsules from the weight of contents of each tablet/capsule.

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

Thin Layer Chromatography (TLC): Under this title, wherever given, the R_f values given in the monographs are not absolute but only indicative. The analyst may use any other solvent system and detecting reagent to establish the identity of any particular chemical constituent reported to be present in the formulation. However in case of dispute the pharmacopoeial method would prevail. Unless specified in the individual monograph all TLC have been carried out on pre-coated Silica 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 measurement are made at 25^0.

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

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

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

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

Descriptive Terms	**Relative quantities of solvent**
Very soluble	less than 1 part
Freely soluble	from 1 to 10 parts
Soluble	from 10 to 30 parts
Sparingly soluble	from 30 to 100 parts
Slightly soluble	from 100 to 1000 parts
Very slightly soluble	from 1000 to 10,000 parts
Practically insoluble	more than 10,000 parts

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

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

Doses: The doses mentioned in each monograph are in metric system which are the approximate conversions from classical weights mentioned in Ayurvedic texts. A conversion table is appended giving classical weights with their metric equivalents.(Appendix 7) Doses mentioned in the Ayurvedic Pharmacopoeia of India (API) are intended merely for general guidance and represent, unless otherwise stated, the average range of quantities per dose which is generally regarded suitable by clinicians for adults only when administered orally. They are not to be regarded as binding upon the prescribers.

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

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

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

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

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

Room temperature - The temperature prevailing in a working area.

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

Excessive heat - Any temperature above 40^0.

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

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

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

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

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

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

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

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

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

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

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

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

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

ABBREVIATIONS FOR TECHNICAL TERMS

gram(s)	-	-	g
milligram(s)	-	-	mg
kilogram(s)	-	-	kg
milliliter(s)	-	-	ml
litre(s)	-	-	l
hour(s)	-	-	h
minute(s)	-	-	min
second(s)	-	-	sec
^{0}C	-	-	^{0}
Micron	-	-	µ
ortho	-	-	*o*
meta	-	-	*m*
para	-	-	*p*
parts per million	-	-	ppm
parts per billion	-	-	ppb
volume	-	-	vol
weight	-	-	wt
weight in weight	-	-	w/w
weight in volume	-	-	w/v
volume in volume	-	-	v/v
quantity sufficient	-	-	Q.S.

ABBREVIATIONS FOR PARTS OF PLANTS

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

PREFACE

1. Ayurveda is the most ancient science of life having a holistic health approach. The preparation of medicines i.e. pharmacy is an integral part of this science, and evolved from a very rudimentary form. In ancient times, the preparation of medicine was part of the practicing physician's functions. The preparation of medicine was limited, selective and at personal level only. Hence the methodology of preparation and quality parameters more or less differed from Vaidya to Vaidya. In Vedic times the practice of medicine was a personal mission without any monetary motive, and exclusively for the recovery of ailing people. Later on, this attitude changed and the profession was followed with a profit motive. The manufacture of Ayurvedic medicines also began on a larger scale. Since the last 40 years Ayurvedic practice has assumed business proportions and the manufacture of Ayurvedic drugs are on a commercial scale.

2. Ayurvedic science is dynamic and progressive. It gives importance to therapeutic strategy. The four pillars of treatment are said to be the Physician, the Medicine, the Auxiliary Staff and the Patient. In the classics, it is clearly explained that an ideal medicine should have multiple actions, should be available in different dosage forms, should possess all the required attributes suited to a patient to rid him of the disease and be devoid of any adverse effects.

3. In ancient texts the quality parameters for raw drugs and finished products including compound formulations are well described and moreover this is in practices. It is mentioned how to collect the plant material, auspicious day and specific time with offering prayer to the plant that the material to be procured will be used for the welfare of the humanity.
   Procurement of plant material in a particular time has a strong scientific base, like for collection of latex; it is advised to collect latex before sunrise to get good quality and quantity of material. Similarly after procurement of the material, use of plant material after a specific period of storage is described. For example *Vidanga* (*Embilia ribes*, seeds) are advise are to be used after one year of its procurement as the percentage of embelin (active phyto-constituents) will be stable and quantity will be more compared to freshly procured sample. This reflects the quality assurance parameters.

4. The Ayurvedic pharmaceutical preparations were evolved gradually from a simpler form to more complex forms based on plants and plant-mineral combinations. During early period, particularly in Charakacharya's time, the pharmaceutical preparations were primarily in five simple forms, which were collectively termed as ''*Pañcavidha Kaṣāya Kalpanās''*. Apart from this, a

number of other dosage forms were described in *Caraka Samhitā* such as *Āsava, Ārista, Cūrṇa, Avaleha, Kṣīrapāka, Vaṭaka, Varti, Taila, Ghṛta, Lepa, Mantha, Ayaskṛiti* etc. for various purposes.

5. During the period of Susruta also, a few new pharmaceutical preparations and aids were introduced, as for example *Kṣāra, Kṣārodaka, Kṣārasutra, Masi, Vikesika* etc. In *Aṣṭaṅga Saṅgraha* and *Hṛdaya* more or less similar pharmaceutical preparations were mentioned as described in the earlier texts like *Caraka* and *Susruta Saṁhitā.* During the time of 11th AD, *Cakradatta,* added a few more preparations like *Khaṇḍa, Parpaṭī* etc. The significant contribution of *Cakradatta* is an elaborate description of *Kṣārasūtra.*

6. *Śarṅgadhara Saṁhitā*, which was written during 14th AD, gave new dimensions to Ayurvedic pharmacy. This book is considered as an authoritative text for Ayurvedic pharmacy. Many new pharmaceutical preparations like *Malahara, Sukta, Phala Varti* etc were defined with explanations. The concept of Phala Varti, though available in Caraka Saṁhitā, its use was extended to urethral and vaginal disorders by *Āḍhamalla.*

7. Later, *Yoga Ratnākara* introduced a few innovative drug delivery systems and pharmaceutical preparations like *Sūcikabharana Rasa*, which were to be administered in micro quantities into the blood through scratch made by the tip of a needle. A detailed description of *Satva,* extraction with reference to *Guḍūcī Satva* was explained, which is a reductionist approach to dosage forms.

8. During 18th A.D., *Bhaisajya Ratnāvalī*, listed a few more pharmaceutical preparations like Mūrchita Taila. Such concepts can also be observed in the commentaries on *Śārṅgādhara Saṁhitā,* but the purpose of both the *Mūrchana* processes is different. Commentators on *Śārṅgādhara Saṁhitā* advised the process of *Mūrchana* for removing excess water content and other unwanted residues if any from the formulated oil, while in *Bhaiṣajya Ratnāvalī* the process was advised to be followed in the expressed oil prior to use in the formulation.

9. The numbers of compound formulations are very huge, even more than 75,000, and of varied nature, using plant, mineral and animal sources. Another important characteristic feature of Ayurvedic compound formulations is that of their availability in different dosage forms such as *cūrṇa, guṭī, vaṭī, taila, ghṛta, kv ātha, āsava, avaleha, bhasma, parpaṭī, poṭṭalī, malahara, lepa, pānaka* etc.

10. In recent times, even encapsulating an Ayurvedic drug in capsules is prevalent, in harmony with advancement of science and technology. Though this seems to be

new to Ayurvedic sciences, the concept of encapsulating has been in tradition since centuries. For example, metallic preparations were embedded in Jaggery or banana, and such other palatable materials.

11. Ayurvedic Compound Formulations are complex in nature. The pharmaceutical processes involve any one or more of the following steps:

1. *Ansuobhedana*	Fine cutting
2. *Apakarṣaṇa*	Elimination
3. *Abhiśavana*	Fermentation
4. *Avaśiñcana*	Sprinkling
5. *Ādityapāka*	Sun-cooking
6. *Āloḍana*	Mixing a liquid
7. *Upakodana*	Baking of Cakrikas
8. *Kledana*	Moistening
9. *Kṣodana/Cūrnana*	Pulverization
10. *Khaṇḍasaḥ chedana*	Cutting into pieces
11. *Jarjarikarna*	Disintegration
12. *Tāpana*	Heating
13. *Dahana*	Burning
14. *Dhūpana*	Fumigation
15. *Nirvāpaṇa*	Dipping in liquid
16. *Niśkulīkarana*	Elimination of seeds
17. *Niśkvathaṇa*	Boiling
18. *Niśpavana*	Winnowing
19. *Paripavana/Gālana*	Filtration
20. *Paripāna*	Soaking
21. *Parisrāvaṇa*	Decantation
22. *Pīḍana*	Compression
23. *Peṣaṇa*	Grinding
24. *Puṭapāka*	Heating in a closed vessel
25. *Praksālan*a	Washing
26. *Pratīvāpana*	Addition
27. *Bharjana*	Roasting
28. *Bhāvānā*	Impregnation
29. *Manthana*	Churning
30. *Rasagrahana*	Extraction
31. *Vipācana*	Cooking
32. *Śodhana*	Purification
33. *Śoṣaṇa*	Desiccation
34. *Ātapaśoṣaṇa*	Sun-drying
35. *Chāyāsoṣaṇa*	Drying in shade

36. *Sadhana*	Preparation and
37. *Śvedana*	Steaming etc.

12. Any one or more of the above said processes will be integral part of Ayurvedic drug manufacturing. It is a challenging exercise to define and standardize the above processes, and establish quality parameters for different ingredients before and during the manufacturing process as well as for the final product.

13. At present in the industry, very few generalized quality parameters are adopted. Some pharmaceutical firms may be having their in-house standard method of operations, and quality parameters for finished compound formulations. But there is no uniformity in the operating procedures i.e. in the method of preparations. This is sometimes responsible for one and the same formulation by name having different qualities in the finished products, and not having reproducibility. An effort has been made now to optimize the method of preparation, so that such differences between manufacturer□s products in the market are not beyond reasonable limits.

14. It was again during the last 100 years of colonial rule that economic conditions in India changed, a process of urbanization began and it was during this period that the Ayurvedic physicians took to cities and lost their contact with forests and drug sources. It was during this period that as a consequence of better transport facilities, the crude drug supplying agencies came up and commercial manufacture of Ayurvedic Medicines on mass scale in factories started. These were the inevitable consequences of the socio-economic changes in the country. The new economic set up was such that the Ayurvedic practitioner could no longer process and prepare his own medicines but had to depend on commercial sources for supply of crude drugs to whatever extent he needed them. There was, in a way, a forced division of professional responsibilities where the *vaidya* had no choice but to purchase his drugs. Nor had he any means to ascertain the authenticity of the medicines and formulations supplied to him. There was no Governmental control on manufacturers to ensure the quality of the marketed medicines prescribed by *vaidyas* and administered to their patients.

15. The conditions prevailing in India prior to Independence were quite discouraging for indigenous medicines to make any progress. But, during the post-independence era, many scientists took active interest in preserving the legacy of Ayurveda and other indigenous systems.

16. As an outcome of the first Health Minister's Conference of 1946, a Committee under the Chairmanship of Lt. Col. R. N. Chopra was appointed in 1946 by the

Government of India. It was the Chopra Committee that had first gone into the question of need for proper identification of Ayurvedic medicinal plants as available in the bazaar, control over collection and distribution of crude drugs and made positive recommendations for compilation of an Ayurvedic Pharmacopoeia. Thereafter, the Dave's Committee [1955] reiterated the recommendations for compilation of an Ayurvedic Pharmacopoeia.

17. The Government of Bombay, was especially interested in the survey of resources of Ayurvedic Drugs, their collection, cultivation, farming, distribution and standardization. They, therefore had appointed a Committee for Standard and Genuine Ayurvedic Herbs and Drugs in 1955 and subsequently after receiving its report, appointed a second committee with fresh set of terms of reference, called the Committee for Standard Ayurvedic Herbs and Drugs in 1957 both under the Chairmanship of Vaidya Bapalal Shah, of which Professor A. N. Namjoshi was the Member Secretary. The Bapalal Committee had very elaborately recommended the compilation of the Ayurvedic Pharmacopoeia as an urgent prerequisite for effective control of Ayurvedic Drugs to ensure quality assurance. Finally Government of India appointed the ''Ayurvedic Research Evaluation Committee'', under the Chairmanship of Dr. K. N. Udupa (1958) which had strongly highlighted the urgency of the compilation of an Ayurvedic Pharmacopoeia.

18. In compliance with some of these recommendations, the Union Government as also some of the State Governments had started taking positive steps. The Government of Bombay State established its Board of Research in Ayurveda, Bombay in 1951, which was subsequently reconstituted in 1955 and 1958. The Government of India established CCRIMH in 1969 for research in all aspects including drug standardization in Indian Medicine & Homeopathy. This Council was divided into 4 research councils in 1978 and the research work in Ayurveda & Siddha was entrusted to the Central Council for Research in Ayurveda & Siddha. The PLIM at Ghaziabad was established in 1970 for testing and standardization of single drugs and compound formulations. Under the auspices of the Central Council for Research in Ayurveda and Siddha, several survey units in different States were established and work of standardization of single drugs and compound medicines as also composite research work was initiated. The first Ayurvedic Pharmacopoeia Committee was constituted in 1962 under the Chairmanship of Col. Sir Ram Nath Chopra. The Committee was reconstituted in 1972 under the Chairmanship of Prof. A.N.Namjoshi to continue the work of compilation of the Ayurvedic Formulary of India as a pre-requisite for undertaking the work of Ayurvedic Pharmacopoeia of India. The first part of the

Ayurvedic Formulary was published in 1978 and the second part in 2000. A revised edition of the first part also brought out in 2003.

19. After publication of the First and the Second part of the Ayurvedic Formulary of India Part-III of the Formulary is under preparation.

20. The First and Second Part of the Ayurvedic Formulary of India comprising of some 444 and 191 formulations respectively cover more than 351 single drugs of plant origin. This covers about 500 priority drugs of plant origin for which monographs have been evolved and included in several volumes of Ayurvedic Pharmacopoeia of India.

21. As a fallout of the growing interest in the renaissance of Ayurveda and the systematic efforts to investigate into the merits of this ancient science during the post-independence period, it is of significance that the western or modern system of medicine, with its formidable armoury of synthetic drugs, chemo-therapeutic agents and antibiotics, has slowly come to terms with the adverse side effects and toxicity of synthetic drugs. The western world has now turned its attention to traditional medicines based on drugs of natural origin. An appreciation of the basic tenets of Ayurvedic therapeutics, which initially appeared to be rather abstract and difficult to interpret in terms of modern medical sciences, has now emerged, resulting in new branches of pharmacology such as pharmacogenomics.

22. With the introduction of a uniform system of Ayurvedic education all over the country, a process initiated some 50 years ago, there would be some uniformity in the education in pharmacy, pharmaceutical technology, pharmaceutical chemistry, pharmacognosy and research. With the physician and the patient needing to be assured of the quality of the medicine through research, such an advance in Ayurvedic education would have a positive effect.

23. In the absence of official standards published by Government for statutory purposes, Ayurvedic Pharmaceutical Industry in particular has been experiencing several handicaps in implementing in house standards, as in any case, they need to comply with official standards.

24. The publication of the Ayurvedic Formulary of India and the Ayurvedic Pharmacopoeia of India would now enable the Government to implement the Drugs and Cosmetic Act, 1940 in respect of quality control for the Ayurvedic, Siddha, Unani drug manufacturers, distributed and sold in India, under a license granted by it.

25. The Ayurvedic Pharmacopoeia Committee has laid down standards for single drugs based on experimental data worked out at the PLIM, Ghaziabad and in some of the units of the Central Council for Research in Ayurveda and Siddha. Published scientific literature on the subject, although scanty, has also been collected and included after due verification.

26. The western countries did pass through the same phase over 150 years ago for their medicines, their characteristics, methods of preparation and identity, purity and strength. Research towards this end was vigorous and out of the scientific data contributed by the scientists in research institutes and industry, the pharmacopoeial monographs of drugs were drafted. As a result pharmacopeiae of the western world show considerable uniformity in principles, approach and information. Thus, while for compilation of the British Pharmacopoeia, information and scientific data was available, for the compilation of the Ayurvedic Pharmacopoeia little information and published data existed and the Ayurvedic Pharmacopoeia Committee had to do a lot of spade work.

27. The Part I of Ayurvedic pharmacopoeia of India consists of Vol-I, II, III, IV and V comprising respectively 80, 78, 100, 68 and 92 monographs prescribing standards for Ayurvedic *single drugs* of plant origin, which go into one or more formulations admitted to the Ayurvedic Formularies of India, Part-I and Part-II. The Part-II of the Ayurvedic Pharmacopoeia consists of official standards for 50 *compound formulations* present in the Ayurvedic Formulary of India Part-I and Part-II.

28. The title of the monograph for each compound formulation is given in Samskrit, as in the Ayurvedic Formulary of India. This is followed by the Definition, Formulation Composition, Method of Preparation, a brief Description of the compound formulation, standards for Identity and Purity in so far as they are reflected by microscopy and physico chemical parameters. Other requirements such as tests for heavy metals, microbial content have also been prescribed. Information on therapeutic uses, dose, administration and storage is included. The raw material which complies with the standards of API were selected for developing standards for compound formulations. In a few cases, where such standards were not available, the collaborator developed them and used them as standards for that raw material.

29. The monograph gives limits under Assay, for any one constituent or group of constituents like total alkaloids or total volatile oils. In the case of water soluble or alcohol soluble extractives a minimum lower limit has been given. For

impurities like Ash, Acid insoluble Ash etc, a maximum upper limit has been given. It is a well known fact that there is wide variation in such values for crude drugs of plant origin in respect of their chemical contents. Therefore, such variations had to be taken into consideration in laying down minimum and maximum standards for the compound formulations.

30. The General Notices provide guidance for the manufacturers and analysts. Official details of Apparatus, Reagents and solutions, Methods of tests, preparation of sample for microscopical examination have all been given the Appendices.

31. The Committee hopes that with the publication of Ayurvedic Pharmacopoeia of India Part-II (Formulations) Vol.-I, comprising of 50 compound formulations, would serve to exercise quality control and help in the implementation of the Drugs and Cosmetics Act. It is also expected that such implementation would create a feedback data, which is essential for improving the standards given in the pharmacopoeia.

32. The Committee urges the Government of India to recommend the adoption of these monographs for the purpose of defining Method of Preparation, Developing Standards for compound formulations for use in their Government, Semi-Government and Government aided institutions and voluntary public organizations. The Ayurvedic Pharmacopoeia of India, 2007, Part-II (Formulations), Vol.-I may also be notified by Government as a book of standards for implementation of the Drugs and Cosmetics Act, 1940 all over India, just as the Ayurvedic Pharmacopoeia of India part I, Vol. I, II, III, IV and V have been included in the First Schedule of Drugs & Cosmetics Act 1940.

33. The Ayurvedic Pharmacopoeia Committee records with deep appreciation the contributions made by the Directors, Officer In-charges, Project Officers and scientific staff of all the collaborating laboratories and Institutions who were associated with the project work on developing Pharmacopoeial Standards for formulations allotted to them.

34. I am indebted to secretary Department of AYUSH, Ms. Anita Das for her constant inspiration and motivation for this unique work. My sincere thanks and credit to Joint Secretary, Department of AYUSH, Sh. Shiv Basant for providing constant support and strategic plan for completion of this first phase of task and momentum to on going work.

35. It is my duty to place on records our sincere thanks and appreciation to Dept. of AYUSH, Ministry of Health & Family Welfare, Govt. of India; State Governments, Institutions, Councils, Scientists and Ayurvedic Scholars, for their whole hearted co-operation in preparing the monographs on compound formulations. I sincerely thank all members of Ayurvedic Pharmacopoeia Committee for their dedicated efforts and hard work in finalizing the monographs. My thanks to Prof. S.S. Handa, Chairman; Dr. S.K. Sharma, Vice-Chairman; Miss. S. S Satakopan, Member; Prof. S.K. Dixit, Member; Prof. Ved Vrat Sharma, Member; Prof. V.K. Kapoor, Member; Dr.(Ms.) Shanta Mehrotra, Member; Dr. P.D. Sethi, Member; Dr. D.R. Lohar, Member; Prof. M.A. Iyengar, Member; Sh. J. K. Dhing, Member; Dr. J. Mohansundaram, Member; Dr. B. L. Gaur, Member; Prof. Siddhinandan Mishra, Member; Dr. P. K. Prajapati, Member; Dr. Narendra Bhatt, Member; Sh. Ranjit Puranik, Member; Prof. V. K. Joshi, Member; Prof. K.C. Chunekar, Member; Vd. Devender Triguna, Member; Dr. M.R. Uniyal, Member; Prof. V.V. Prasad, Member and Dr. Karan Vashisth, Expert member for their constant efforts in bringing out this volume. My thanks are also to Dr. MM Padhi, Deputy Director [Tech.]; Shri. Vasantha Kumar, Asst. Director [Chem.] Dr. Pramila Pant, Research Officer [Chem.], Dr. Rajiv Sharma, Senior Scientific Officer [Pharmacognosy], Sri. Ravinder Singh, Research Officer [Chem.], Dr. Jai Prakash, Research Officer [Chem.], Dr. Chhote Lal, Dr. AKS Bhadoria and Dr. MN Rangne, Dr. Bishnu Priya Dhar, Research Officer [Phar], Dr. Galib, Research Officer [Ayu.], Dr. K. Sandhya Rani, S.R.F. [Ayu.] and other associated officers, who contributed a lot in finalizing the volume. I am also thankful to Mr. Sandeep Kumar, D.E.O., who took pains in typing and arranging all the technical data into a final shape.

Dr. G.S. Lavekar
Director CCRAS & Member Secretary, APC

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 came up for the manufacture of Ayurvedic drugs and formulations on commercial scale.

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

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

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

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

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

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

Having regard to all these considerations, the Central Council of Ayurvedic Research recommended the constitution of Ayurvedic Pharmacopoeia Committee consisting of experts on Ayurveda and other sciences. The Government of India accepted the recommendations of the Central Council of Ayurvedic Research and constituted the First Ayurvedic Pharmacopoeia Committee, vide their letter No. 14-8/62-ISM, dated the 20th September,

1962 for a period of three years with effect from the date of its first meeting under the Chairmanship of Col. Sir R.N. Chopra with the following member :-

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15. Shri Bapalal G.Vaidya, Principal, O.H. Nazar Ayurveda Mahavidyalaya, 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 MedicalServices, (Ayurveda), Govt. of U.P. *Member*

20. Dr.Y. Kondal Rao,Secretary, Indian Medical Practitioner□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*) were Chairman of reconstituted Ayurvedic Pharmacopoeia Committee during the specified periods.

The Ayurvedic Pharmacopoeia Committee (APC) was reconstituted under the Deptt. of ISM&H consisting of following members vide letter No.X-19011/6/94-APC dated 21st June, 2001.

1.	Dr. P.D. Sethi, M. Pharma, Ph.D., B-140, Shivalik Enclave, New Delhi-110 017.	Chairman
	OFFICIAL MEMBERS	
2.	Drugs Controller General (I), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi.	Member (Ex-officio)
3.	Director, Pharmacopoeial Laboratory of Indian Medicine, Central Govt. Offices Complex, Kamla Nehru Nagar, Ghaziabad-201 002.	Member (Ex-officio)
4.	Director, Central Council for Research in Ayurveda & Siddha, 61-65, Institutional Area, D-Block, Janakpuri, New Delhi.	Member (Ex-officio)
5.	Managing Director, Indian Medicines and Pharmaceuticals Ltd., Mohan, Uttaranchal (U.P.).	Member (Ex-officio)
6.	Advisor (Ayurveda), Deptt. of ISM & H, Red Cross Building, New Delhi.	Member Secretary
	NON-OFFICIAL MEMBERS	
7.	Prof. S.S. Handa, M.Pharma, Ph.D., F-7, 3rd Floor, Lajpat Nagar-III, New Delhi-110 024.	Member

8.	Ms. S. Satakopan, M.Sc., 40-A, Ist Main Road, (Opp. Pillayar Koil) Nanganallur, Chennai-600 061.	Member
9.	Vaidya Devendra Triguna, Ayurvedacharya, 143-Sarai Kale Khan, Nizamuddin East, New Delhi.	Member
10.	Dr. I. Sanjiva Rao, D. Ay. M., Sri Sai Krupa, 5-8-293/A-Mahesh Nagar, Chirag Ali Lane, Hyderabad-500 001.	Member
11.	Dr. Madhavan Kutti Warrier, M.D. (Ay.), Arya Vaidya Sala, Malappuram Distt., Kottakkal-676 503 (Kerala).	Member
12.	Dr. G.N. Tiwari, M.D. (Ay.), Ph.D., Shri Ayurveda Mahavidyalaya, Nagpur.	Member
13.	Dr. V.V. Prasad, M.D. (Ay.), Ph.D., Director, Rashtriya Ayurveda Vidyapeeth, Dhanvantri Bhavan, Road No.66, Punjabi Bagh (West), New Delhi – 110 026.	Member
14.	Dr. M.R. Uniyal, Former Director, CRIA (CCRAS, Patiala) and presently – Director (Drugs), Maharishi Ayurved Products, 17/18, Noida Export Processing Zone, NOIDA – 201 305 (U.P.).	Member
15.	Dr. (Prof.) S.K. Dixit, Ph.D., Head of the Department of Rasa Shastra, Institute of Medical Sciences, Banaras Hindu University, Varanasi – 221 005.	Member
16.	Vaidya D.R. Acharya, GAMS, Ph.D., Former Principal, Govt. Ayurvedic College, Paprola, P.O. Paprola, Himachal Pradesh – 176 115.	Member
17.	Vaidya Sidhinandan Mishra, GAMS, Ph.D., Former Director, Ayurvedic Pharmacy, G.A.U., Jamnagar (Presently at Varanasi).	Member

18.	Dr. M.A. Iyengar, M.Pharma, Ph.D., Prof. of Pharmacognosy, College of Pharmaceutical Sciences, Kasturba Medical College, Manipal – 576 119.	Member
19.	Dr. M.K. Raina, M.Sc., Ph.D., 203, Rainbow Apartments, Raheja Vihar, Powai, Mumbai – 400 012.	Member
20.	Dr. K.K. Sharma, M.Sc., Ph.D., Scientist F, Wadia Himalaya Institute of Geology, Dehradun.	Member
21.	Dr. Narender Nath Mehrotra, M.Sc. Ph.D., Sr. Scientist (E II), National Information Centre for Drugs & Pharmaceuticals, Central Drug Research Institute,Lucknow.	Member
22.	Dr. M.S. Ansari, M.Sc., Ph.D., 454-E, Kaila, Behind Masjid, Ghaziabad (U.P.).	Member
23.	Dr. (Mrs.) Shanta Mehrota, M.Sc., Ph.D., Incharge of the Drug Standardization Unit, National Botanical Research Institute (CSIR), Rana Pratap Marg, P.B. No.-436, Lucknow-226 001.	Member
24.	Dr. C.K. Katiyar, M.D. (Ayu.), Ph.D., Medical Advisor, Dabur India Limited, 22, Site IV, Sahibad, Ghaziabad – 201 010.	Member
25.	Dr. G.G. Parikh, M. Pharma, Ph.D., Managing Director, Zandu Pharmaceutical Works Ltd., 70, Gokhale Road South, Dadar, Mumbai – 400025.	Member
26.	Dr. K.C. Chunekar, Ph.D., 18/7, Ratan Phatak, Varanasi.	Member

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

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

Panjab University, Chandigarh)
1473, Pushpac Complex, 49B,
Chandigarh - 160 047.

2. Prof. S.S. Handa, M. Pharm., Ph.D., Member
(Former Director, RRL),
522-A, Block 'C', Sushant Lok, Phase-I,
Gurgaon, Haryana – 122 001.

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

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

Pharmacognosy Sub-Committee

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

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

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

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

Formulary Sub-Committee

(Rasa Shastra / Bhaishajya Kalpana – Ayurvedic Pharmacy)

1.	Prof. S.K. Dixit, A.B.M.S.; D.Ay.M; Ph.D. (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.	Prof. Siddhinandan Mishra, G.B.M.S.; Ph.D. Pharmacy In-charge, SDM Ayurvedic College, P.O. Kuthpady, Udupi – 574 118, (South Karnataka).	Member
4.	Prof. Ved Vrat Sharma, H.P.A. (Former Principal, DAV Ayurvedic College), House No. 65, Sector-8, Panchkula, Haryana.	Member
5.	Dr. P.K. Prajapati, M.D. (Ay.), Ph. D., Reader & Head, Deptt. of Ras Shastra, IPGT & RA, Gujarat Ayurved University, Jamnagar, Gujarat – 361 008.	Member
6.	Dr. Narendra Bhatt, M.D. (Ay.), Chief Executive Officer, Zandu Pharmaceutical Works Ltd., 70, Ghokhle Road (South), Dadar, Mumbai – 400 025.	Member
7.	Shri Ranjit Puranik, General Manager, Shree Dhootapapeshwar Ltd., 135, Nanubhai Desai Road, Khetwadi, Mumbai.	Member

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

1.	Prof. V.K. Joshi, M.D. (Ay.), Ph.D. Deptt. Dravyaguna, Institute of Medical Sciences, Banaras Hindu University (BHU), Varanasi – 221 005 (U.P.).	Chairman
2.	Prof. K.C. Chunekar, Ph.D. (Former Reader, Deptt. of Dravyaguna, BHU), 18/7, Ratan Phatak, Varanasi, (U.P.).	Member
3.	Vaidya Devender Triguna, Ayurvedacharya,	Member

"PADAM SHREE", 143-Sarai Kale Khan,
Nizamuddin East, New Delhi.

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

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

CO-OPTED MEMBERS

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

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

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

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

(vi) To develop quality standards, safety, efficacy profile of intermediates likes extracts of Ayurvedic raw drugs.

(vii) To develop the quality standards, safety, efficacy profile of different parts of the plants; as well as to include new plants as Ayurvedic drugs.

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

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

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

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

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

CONTRIBUTING LABORATORIES & INSTITUTIONS

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

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

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

National Botanical Research Institute,
(Council of Scientific & Industrial Research),
Rana Pratap Marg,
P. B. No. 436, Lucknow 226 00.
(P.I. -Dr. A. K. S. Rawat)

Indian Institute of Chemical Technology,
(Council of Scientific & Industrial Research),
Hyderabad 500 007.
(P.I. - Dr. Vijaya Kumar)

Institute of Minerals & Materials Technology
(Formerly know as Regional Research Laboratory)
Council of Scientific & Industrial Research,
Bhubneshwar. 751 013, Orissa.
(P.I. - Dr. U. V. Mallavadhani)

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