THE AYURVEDIC PHARMACOPOEIA OF INDIA

PART - II (FORMULATIONS)
VOLUME - II

First Edition

GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY,
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LEGAL NOTICES

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

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

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

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

GENERAL NOTICES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the performance of assay or test procedures, not less than the specified number of dosage units should be taken for analysis. Proportionately larger or smaller quantities than the specified weights and volumes of assay or test substances and Reference Standards or Standard

Preparations may be taken, provided the measurement is made with at least equivalent accuracy and provided that any subsequent steps, such as dilutions, are adjusted accordingly to yield concentrations equivalent to those specified and are made in such manner as to provide at least equivalent accuracy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Doses: The doses mentioned in each monograph are in metric system which are the approximate conversions from classical weights mentioned in Ayurvedic texts. A conversion table is appended giving classical weights with their metric equivalents.(Appendix 8) Doses mentioned

in the Ayurvedic Pharmacopoeia of India (API) are intended merely for general guidance and represent, unless otherwise stated, the average range of quantities per dose which is generally regarded suitable by clinicians for adults only when administered orally. They are not to be regarded as binding upon the prescribers.

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

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

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

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

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

Room temperature - The temperature prevailing in a working area

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

Excessive heat- Any temperature above 40^0

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

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

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

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

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

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

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

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

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

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

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

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

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

ABBREVIATIONS FOR TECHNICAL TERMS

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

ABBREVIATIONS FOR PARTS OF PLANTS

Aerial root	-	-	A. Rt.
Androecium	-	-	Adr.
Aril	-	-	Ar.
Bulb	-	-	Bl.
Exudate	-	-	Exd.
Flower	-	-	Fl.
Fruit	-	-	Fr.
Fruit rind	-	-	Fr. R.
Heart wood	-	-	Ht. Wd.
Inflorescence	-	-	Ifl.
Kernel	-	-	Kr.
Leaf	-	-	Lf.

Leaf rachis	-	-	Lf. R.
Latex	-	-	Lx.
Pericarp	-	-	P
Plant (whole)	-	-	Pl.
Rhizome	-	-	Rz.
Root	-	-	Rt.
Root bark	-	-	Rt. Bk.
Root tuber	-	-	Rt. Tr.
Seed	-	-	Sd.
Stamens	-	-	Stmn.
Stem	-	-	St.
Stem bark	-	-	St. Bk.
Stem tuber	-	-	St. Tr.
Style & stigma	-	-	Stl./Stg.
Ripe fruit Pulp	-	-	Rp. Fr. Pp.
Subterranean root tuber	-	-	Sub. Rt. Tub.
Subterranean root	-	-	Sub. Rt.
Dry			Dr.
Ext.	-	-	Extract
Bud	-	-	Bd.
Siliceous Concretion	-	-	S.C.
Resinous encrustation	-	-	Res. Enc.
Endosperm (Bija majja)	-	-	Enm.
Oleo-resin			O.R.

सचिव
भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
आयुर्वेद, योग व प्राकृतिक चिकित्सा,
यूनानी, सिद्ध एवं होम्योपैथी (आयुष) विभाग
रैड क्रॉस भवन, नई दिल्ली - 110001
SECRETARY
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
DEPTT. OF AYURVEDA, YOGA & NATUROPATHY,
UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)
RED CROSS BUILDING, NEW DELHI-110001
Tel. : 011-23715564, Telefax : 011-23327660
E-mail : secy-ayush@nic.in
Mailing No. 110 108

अनिता दास
ANITA DAS

जय हिन्द

Foreword

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

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

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

Anita Das

(Anita Das)

New Delhi,
1st August 2008.

INTRODUCTION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16. Kumari Savita Satakopan, Drugs Control Laboratory, — *Member*

Near Polytechnic, National Highway 8, Baroda.

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

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

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

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

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

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

The Committee was assigned the following functions:-

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

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

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

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

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

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

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

As a first step in this direction the Ayurvedic Pharmacopoeia Committee started preparing the official Formulary of Ayurveda in two parts as mentioned under the assigned functions of the Committee. Since the work of preparation of Ayurvedic Formulary could not be completed after

the expiry of first three years, the Government of India extended the term of the Committee by another three years vide their notification No. F. 20-1/66-RISM, dated 14th January, 1966 and a gain for a further period of three years vide their notification No. F. 1-1/69-APC, dated 9th January, 1969.

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

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

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

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

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

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

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

OFFICIAL MEMBERS

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

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

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

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

NON-OFFICIAL MEMBERS

Phytochemistry & Chemistry Sub-Committee

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

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

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

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

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.).

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

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)

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
Dr. B.L. Gaur, Ph.D.; Vice-Chancellor, Jodhpur Ayurvedic University, Jodhpur, Rajasthan,	Member
Prof. Siddhinandan Mishra, G.B.M.S.; Ph.D. Pharmacy In-charge, SDM Ayurvedic College, P.O. Kuthpady, Udupi – 574 118, (South Karnataka).	Member
Prof. Ved Vrat Sharma, H.P.A. (Former Principal, DAV Ayurvedic College), House No. 65, Sector-8, Panchkula, Haryana.	Member
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
Dr. Narendra Bhatt, M.D. (Ay.), Chief Executive Officer, Zandu Pharmaceutical Works Ltd., 70, Ghokhle Road (South), Dadar, Mumbai – 400 025.	Member
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)

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

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

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

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.

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

CO-OPTED MEMBERS

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

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

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

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

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

(i) To evolve standards of single drugs mentioned in the Ayurvedic Formularies of India.
(ii) To evolve standards for compound formulations mentioned in the Ayurvedic Formularies of India & other Ayurvedic formulations of National Priority.
(iii) To prepare drafts SOP of Ayurvedic Formularies of India from the classical texts and other authentic sources.

CONTRIBUTING LABORATORIES & INSTITUTIONS

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

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

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

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

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

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

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

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