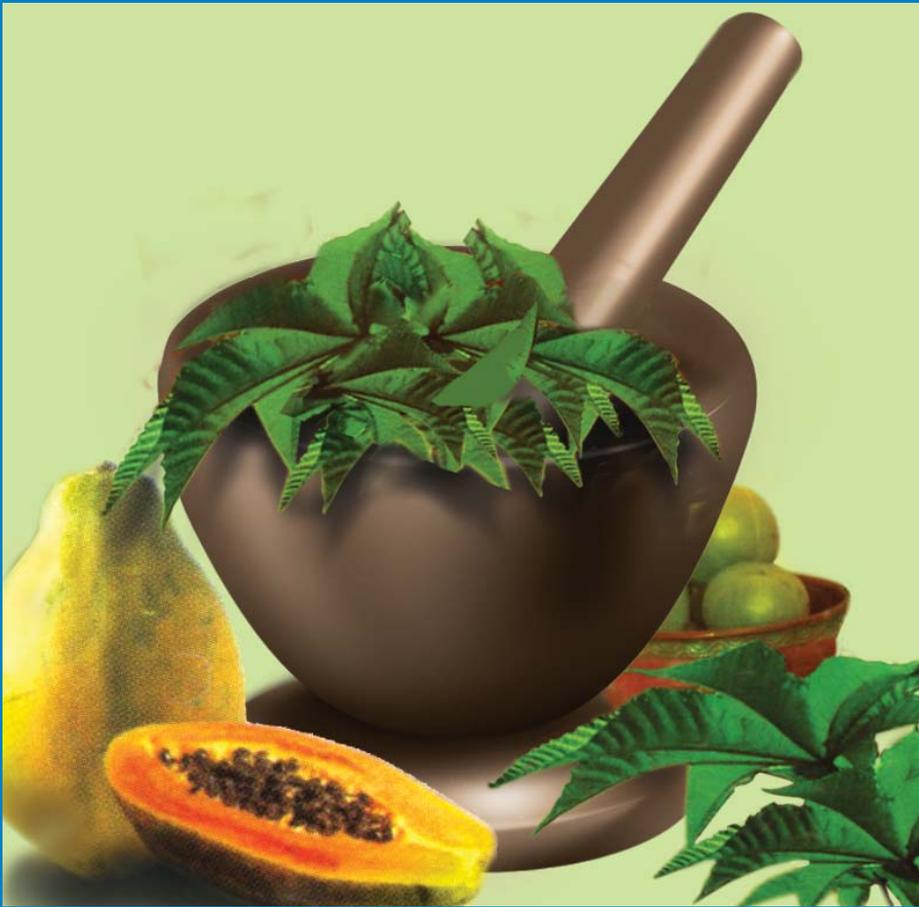




# LEGAL STATUS

## OF AYURVEDIC, SIDDHA & UNANI MEDICINES



**Govt. of India**  
**Department of AYUSH**  
**Ministry of Health and Family Welfare**  
**Pharmacopoeial Laboratory for Indian Medicines**  
**GHAZIABAD**

# LEGAL STATUS OF AYURVEDIC, SIDDHA & UNANI MEDICINES

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Department of AYUSH  
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## PREFACE



**D**uring the past five decades, the Ayurvedic, Siddha and Unani Pharmaceutical Industries have provided a vast range of drugs for human use and have evolved an increasing sophistication in the production of medicaments.

Manufacture and quality control of Ayurvedic, Siddha and Unani Medicines come under the purview of Drugs & Cosmetics Act. Regulatory and recommendatory standards for most of them have been released. There has been appreciable acceptance with considerable improvement in quality.

Information about manufacture, sale, import of Ayurvedic, Siddha and Unani medicines in relation to pharmacopoeia and legal provisions etc. are scattered. Attempts have been made to bring various aspects of manufacture of Ayurvedic, Siddha and Unani drugs, quality control measures, legal provisions relating to quality control and the penal actions at one place so that it may become handy for manufacturers, pharmacies, and the persons involved in quality control of Ayurvedic, Siddha and Unani medicines.

The need of compilation of different Ayurvedic, Siddha and Unani manufacturing processes, Good Manufacturing Practices and the related portion of Drugs & Cosmetics Act to create general awareness among the persons who are involved in this professions or who are keen in this profession was long felt. This laboratory has made an endeavor to compile such information. Besides the Legal provisions of ASU medicines, related provisions and proforma for import of medicines (which are directly or indirectly related to ASU medicines, marker compounds or materials for research or self use) have also been given for related products.

The primary responsibility for assuring quality control of medicines is that of manufacturer and it is hoped that this booklet will help them to achieve this target. Standards for Ayurvedic, Siddha and Unani medicines have been released in Ayurvedic Pharmacopoeia of India and Unani Pharmacopoeia of India which should be consulted for the details.

The information given in this document is compilation of related portions from API, UPI and Drugs & Cosmetics Act. For legal purposes or any controversy, the Ayurvedic Pharmacopoeia of India, Unani Pharmacopoeia of India and Drugs & Cosmetics Act may be consulted.

DR. D.R. LOHAR



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**LEGAL STATUS OF AYURVEDIC,  
SIDDHA AND UNANI DRUGS**

**DRUGS AND COSMETICS ACT, 1940**



# INTRODUCTORY

## CHAPTER I

### 1. Short title, extent and commencement.—

- (i) This Act may be called the Drugs [and Cosmetics] Act, 1940.
- (ii) It extends to the whole of India.
- (iii) It shall come into force at once; but Chapter III shall take effect only from such date as the Central Government may, by notification in the Official Gazette, appoint in this behalf, and Chapter IV-A shall take effect in a particular State only from such date as the State Government may, by like notification, appoint in this behalf:

Provided that in relation to the State of Jammu and Kashmir, Chapter III shall take effect only from such date after the commencement of the Drugs and Cosmetics (Amendment) Act, 1972 (19 of 1972), as the Central Government may, by notification in the Official Gazette, appointed in this behalf.

**2. Application of other laws not barred.—** The provision of this Act shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930 (2 of 1930), and any other law for the time being in force.

**Definitions:—** In this Act. Unless there is anything repugnant in the subject or context,—

- (a) “Ayurvedic, Siddha or Unani Drugs” includes all medicines intended for internal or external use for or in the

diagnosis, treatment, mitigation or prevention of [disease or disorder in human beings or animals, manufactured exclusively in accordance with the formulae prescribed in the authoritative books of [Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the First Schedule;]

- (aa) “the Board” means,— in relation to Ayurvedic, Siddha or Unani drug, the [Ayurvedic, Siddha and Unani Drugs Technical Advisory Board] constituted under Section 33-C; and

- [(aaa) “cosmetic” means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promotion of attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic,]

- [(b) “drug includes,—

- i) all medicines for internal or external use of human beings or animals and all substance intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of

- repelling insects like mosquitoes;]
- ii) Such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of [vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;
  - iii) all substances intended for use as components of a drug including empty gelatin capsules and
  - iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the central Government by notification in the official Gazette, after consultation with the Board;

**“Government Analyst” means,**– in relation to [Ayurvedic, Siddha or Unani] drug, a Government Analyst appointed by the Central Government or a State Government under Section 33-F; and

**“Inspector” means,**– in relation to [Ayurvedic, Siddha or Unani] drug, an Inspector appointed by the Central Government or a State Government under Section 33-G; and

**“Manufacture”** in relation to any drug [or cosmetic] includes any process or part of a process for making, altering, ornamenting, finishing, packing, labelling, breaking up or otherwise treating or adopting any drug [or cosmetic] with a view to its [sale or distribution] but does not include the

compounding or dispensing [of any drug, or the packing of any drug or cosmetic] in the ordinary course of retail business; and “to manufacture” shall be construed accordingly;]

**“to import”** means with its grammatical variations and cognate expressions means to bring into [India]

**“Patent or proprietary medicine” means,**– In relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a);

**“prescribed”** means prescribed by rules made under this Act.

#### COMMENTS

- i) It is not necessary that the article should be applied to the whole body. If it is applied to a part of the body and if it beautifies or promotes attractiveness or alters appearance then also it will be a cosmetic within the meaning of the Drugs and Cosmetics Act, 1940; *State of Bombay v. Zabid Hussain, 1975 Mah LJ 455*
- ii) ‘Gandh’ and nail polish’ are ‘cosmetics’ within the meaning of the Act; *State of Bombay v. Zabid Hussain, 1975 Mah LJ 455*
- i) The definition of ‘drug’ is an inclusive one. It includes all medicines for external or internal use of human beings or animals or any substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases

in human beings or animals; *Langamurti v. State of Orissa, (1973) 1 cwr 368.*

- ii) The appropriate meaning of the expression 'substances' in the section is things; *Chimanlal J. Sheth v. State of Maharashtra, AIR 1963 SC 665*
- i) Water meant to be used for dissolving other medicines for injection into human body is 'drug' *R.C. Sundarka v. State of West Bengal, 1971 Cr LJ 1369 77 CWN 437*

**3A. Construction of references to any law not in force or any functionary not in existence in the State of Jammu and Kashmir.**— Any reference in this Act to any law which

is not in force, or any functionary not in existence in the State of Jammu and Kashmir, shall, in relation to that State, be construed as a reference to the corresponding law in force, or to the corresponding functionary in existence, in that State.

**4. Presumption as to poisonous substances.**— Any substance specified as poisonous by rule made under Chapter III or Chapter IV [or Chapter IVA] shall be deemed to be a poisonous substance for the purpose of Chapter III or Chapter IV [or Chapter IVA] as the case may be.

## THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE

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### **6. The Central Drugs Laboratory.**–

(1) The Central Government shall, as soon as may be, establish a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter:

(2) The Central Government may, after consultation with the Board, make rules prescribing –

- a) the functions of the Central Drugs Laboratory;
- b) the procedure for the submission of the said Laboratory [under Chapter IV or Chapter IVA] of samples of drugs [or cosmetics] for analysis or

test, forms of the Laboratory's reports thereon and the fees payable in respect of such reports;

- c) such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions;
- d) the matter necessary to be prescribed for the purposes of the proviso to sub-section (1).

**7A. Section 6 and 7** not to apply to Ayurvedic, Siddha or Unani drugs.– Nothing contained in section 5 and 7 shall apply to [Ayurvedic, Siddha or Unani drugs.]

## IMPORT OF DRUGS AND COSMETICS

### 10A. Power of Central Government to Prohibit Import of Drugs and Cosmetics in Public Interest.–

Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the Official Gazette, prohibit the import of such drug or cosmetic.]

#### COMMENTS

The Central Government on the basis of the expert advice can indeed adopt an approved national policy and prescribe an adequate number of formulations which would on the whole meet the requirement of the people at large. While laying the guidelines on this score, injurious drugs should be totally eliminated from the market; *Vincent Panikurlangara v. Union of India*, AIR 1987 SC 990.

### 11. Application of Law Relating to Sea Customs and Powers of Customs Officers.–

(1) The law for the time being in force relating to sea customs and to goods the import of which is

prohibited by section 18 of the Sea Customs Act, 1878 (8 of 1878) shall, subject to the provisions of section 13 of this Act, apply in respect of drugs [and cosmetics] the import of which is prohibited under this Chapter, and officers of Customs and officers empowered under that Act to perform the duties imposed thereby on a [Commissioner of Customs] and other officers of Customs shall have the same powers in respect of such drugs [and cosmetics] as they have for the time being in respect of such goods as aforesaid.

(2) Without prejudice to the provisions of sub-section (1) the [Commissioner of Customs] or any officer of the Government authorized by the Central Government in this behalf, may detain any imported package which is prohibited under this Chapter and shall forthwith report such detention to the Drugs Controller, India and if necessary, forward the package or sample of any suspected drug [or cosmetic] found therein to the Central Drugs Laboratory]

#### COMMENTS

- i) The tainted goods may be confiscated without proceeding personally against any person and without coming to a finding as to who was the smuggler; *Shermal Jain v. Collector of Central Excise*, AIR 1956 Cal 621.

- ii) Mere unlawful possession of prohibited goods does not lead to conclusion that the goods had been imported unlawfully. Onus is on the custom authorities to prove the breach of prohibition order; *Kanungo & Co. v. Collector of Customs Air 1965 Cal 248 (1965) Cri LJ 547.*

**12. Power of Central Government to Make Rules.**– (1) The Central Government may, [after consultation with or on the recommendation of the Board] and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter:

[Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may –

- a) specify the drugs or classes of drugs [or cosmetics or classes of cosmetics] for the import of which a licence is required [and prescribe the form and conditions of such licences, the authority empowered to issue the same, the fees payable therefore and provide for the cancellation, or suspension of such licence in any case where any provision of this chapter or the rules made thereunder is contravened or any of the conditions subject to which the licence is issued is not complied with];
- b) prescribe the methods of test or analysis to be employed in determining whether a drug [or cosmetic] is of standard quality;
- c) prescribe in respect of biological and organometallic compounds, the units or methods of standardization;
- cc) prescribe under clause (d) of [section 9A] the colour or colours which a drug may bear or contain for purpose of colouring;
- d) specify the diseases or ailments which an imported drug may not purport or claim [to prevent, cure or mitigate] and such other effects which such drug may not purport or claim to have.
- e) specify the conditions subject to which small quantities of drugs, the import of which is otherwise prohibited under this Chapter, may be imported for the purpose of examination, test or analysis or for personal use;
- f) prescribe the places at which drugs [or cosmetics] may be imported, and prohibit their import at any other place;
- g) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any specified imported drug or class of such drug, and prohibit the import of the said drug or class or drug after the expiry of a specified period from the date of manufacture;
- h) regulate the submission by importers, and the securing, of samples of drugs [or cosmetics] for examination, test or analysis by the Central Drugs Laboratory, and prescribe the fees, if any, payable for such examination, test or analysis;

- i) prescribe the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of drugs [or cosmetics] sought to be imported, the procedure of officers of Customs in dealing with such evidence, and the manner of storage at places of import of drugs [or cosmetics] detained pending admission;
- j) provide for the examination, conditionally or otherwise, from all or any provision of this chapter and the rule made thereunder of drugs [or cosmetics] imported for the purpose only of transport through, and export from, [India];
- k) prescribe the conditions to be observed in the packing in bottles, packages or other containers, of imported drugs [or cosmetics] [including the use of packing material which comes into direct contact with the drugs];
- l) regulate the mode of labelling drugs [or cosmetics] imported for sale in packages, and prescribe the matters which shall or shall not be included in such labels;
- m) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any imported drug, prohibit the import of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;
- n) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any imported, patent or proprietary medicine containing such drug;
- o) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder of any specified drug or class of drugs [or cosmetics or class or cosmetics]

**22. Power of Inspectors.**– (1) Subject to the provisions of section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed,–

- a) inspect,–
  - i) any premises wherein any drug or cosmetic is being manufactured and the means employed for standardizing and testing the drug or cosmetic;
  - ii) any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed;
- b) take samples of any drug or cosmetic,–
  - i) which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;
  - ii) from any person who is in the course of conveying delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee;
- c) at all reasonable times, with such assistance, if any, as he considers necessary,–
  - i) search any person, who, he has reason to believe, has secreted about his person, any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed; or
  - ii) enter and search any place in

which he has reason to believe that an offence under this Chapter has been, or is being, committed or

- iii) stop and search any vehicle, vessel or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence under this Chapter has been or is being, committed,

and order in writing the person in possession of the drug or cosmetic in respect of which the offence has been, or is being, committed, not to dispose of any stock of such drug or cosmetic for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the drug or cosmetic seize the stock of such drug or cosmetic and any substance or article by means of which the offence has been, or is being, committed or which may be employed for the commission of such offence;]

- [cc) examine any record, register, document or any other material object found [with any person, or in any place, vehicle, vessel or other conveyance referred to in clause (c)], and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act

- or the Rules made thereunder;]  
 [cca) require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed  
 d) exercise such other powers as may be necessary for carrying out the purpose of this Chapter or any rules made thereunder.

(2) The provision of [the Code of Criminal Procedure, 1973 (2 of 1974)] shall, so far as may be, apply to any search or seizure under this Chapter as they apply to any search or seizure made under the authority of a warrant issued under of the said Code.

(2A) Every record, register or other document seized under clause (cc) or produced under clause (cca) shall be returned to the person, from whom they were seized or who produce the same, within a period of twenty days of the date of such seizure or production, as the case may be, after copies thereof or extracts there from certified by that person, in such manner as may be prescribed, have been taken.]

(3) If any person willfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter [or refuses to produce any record, register or other document when so required under clause (cca) of sub-section (1),] he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.]

### 23. Procedure of Inspectors.—

(1) Where an Inspector takes any sample of a drug [or cosmetic] under this Chapter, he shall tender the fair price

thereof and may require a written acknowledgement therefore.

(2) where the price tendered under sub-section (1) is refused or where the Inspector seizes the stock of any drug [or cosmetic] under clause (c) of section 22, he shall tender a receipt therefore in the prescribed form.

(3) Where an Inspector takes a sample of a drug [or cosmetic] for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he willfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked;

Provided that where the sample is taken from premises whereon the drug [or cosmetic] is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that where the drug [or cosmetic] is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug [or cosmetic] be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:-

- i) one portion or container he shall forthwith send to the Government Analyst for test or analysis.
- ii) the second, he shall produce to the

Court before which proceedings in respect of the drug [or cosmetic] and

iii) the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.

(5) Where an Inspector takes any action under clause (c) of section 22,—

a) he shall use all dispatch in ascertaining whether or not the drug [or ascertained that the drug [or cosmetic] does not so contravene forthwith revoke the order passed under the said clause or, as the case may be take such action as may be necessary for return of the stock seized;

b) if he seizes the stock of the drug [or cosmetic] he shall as soon as may be, inform [a judicial Magistrate] and take his orders as to the custody thereof;

c) without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug [or cosmetic], he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

[(6) Where an Inspector seizes any record, register, document or any other material object under clause (cc) of sub-section (1) of section 22, he shall, as soon as may be, inform [a judicial Magistrate] and take his orders as to the custody thereof.

#### **24. Persons Bound to Disclose Place where Drugs or Cosmetics are Manufactured or Kept.**—

Every person for the time being in charge of any premises whereon any drug [or cosmetic] is being manufactured or is kept for sale or distribution shall, on being required

by any Inspector so to do, be legally bound to disclose to the Inspector the place where the drug [or cosmetic] is being manufactured or is kept, as the case may be.

#### **25. Reports of Government Analysts.**—

(1) The Government Analyst to whom a sample of any drug [or cosmetic] has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken [and another copy to the person, if any whose name address and other particulars have been disclosed under section 18A] and shall retain the third copy for use in any prosecution in respect of the sample.

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein and such evidence shall be conclusive unless the person from whom the sample was taken [or the person whose name, address and other particulars have been disclosed under section 18A] has within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complaint or the

accused: cause the sample of the drug [or cosmetic] produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.

**26. Purchase of Drug or Cosmetic Enabled to Obtain Test or Analysis.**—

Any person [or any recognized consumer association, whether such person is a member of that association or not] shall, on application in the prescribed manner and on payment of the prescribed fee, be entitled to submit for test or analysis to a Government Analyst any drug [or cosmetic] [purchased by him or it] and to receive a report of such test or analysis signed

by the Government Analyst.

*[Explanation—* For the purposes of this section and section 32, “recognized consumer association” means a voluntary consumer association registered under the Companies Act, 1956 or any other law for the time being in force.]

**26a. Power of Central Government to Prohibit Manufacture, etc., of Drug and Cosmetic in Public Interest.**—

Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then that Government may, by notification in the Official Gazette, prohibit the manufacture, sale or distribution of such drug or cosmetic]

## PROVISION RELATING TO [AYURVEDIC, SIDDHA AND UNANI DRUGS]

### 33-C. [Ayurvedic, Siddha and Unani Drugs Technical Advisory Board.] –

(1) The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein, constitute a Board (to be called the [Ayurvedic, Siddha and Unani Drugs Technical Advisory Board]) to advise the Central Government and the State Governments on technical matters arising out of this Chapter and to carry out the other functions assigned to it by this Chapter.

(2) The Board shall consist of the following members, namely–

- i) The Director-General of Health Services, ex officio;
- ii) the Drugs Controller, India, ex officio;
- iii) The principal officer dealing with Indian systems of medicine in the Ministry of Health, ex officio;
- iv) the director of the Central Drugs laboratory, Calcutta, ex officio;
- v) one person holding the appointment of Government Analyst under Section 33-F to be nominated by the Central Government.
- vi) one Pharmacognocist to be nominated by the Central Government;
- vii) one Phyto-chemist to be nominated by the Central Government;
- viii) four persons to be nominated by the Central Government, two from amongst the members of the Ayurvedic Pharmacopoeia Committee, one from amongst the members of

the Siddha and Unani Pharmacopoeia Committee;

- ix) one teacher in Darvyaguna, and Bhaishajya kalpana, to be nominated by the Central Government;
- x) one teacher in Ilm-ul-Advia and Taklis-wa-Dawasazi, to be nominated by the Central Government.
- xi) one teacher in Gunapadam to be nominated by the Central Government;
- xii) three persons, one each to represent the Ayurvedic, Siddha and Unani drug industry, to be nominated by the Central Government;
- xiii) three persons, one each from among the practitioners of Ayurvedic, Siddha and Unani Tibb systems of medicine to be nominated by the Central Government.

(3) The Central Government shall appoint a member of the Board as its Chairman.

(4) The nominated members of the Board shall hold office for three years but shall be eligible for re-nomination.

(5) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and conduct of all business to be transacted by it.

(6) The functions of the board may be exercised notwithstanding any vacancy therein.

(7) The Central Government shall

appoint a person to be Secretary of the board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.

### **33-D. The Ayurvedic, Siddha and Unani Drugs Consultative Committee.**

(1) The Central Government may constitute an advisory Committee to be called the Ayurvedic, Siddha and Unani Drugs Consultative Committee to advise the Central Government, the State Government and the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board on any matter for the purpose of securing uniformity throughout India in the administration of this Act in so far as it relates by Ayurvedic, Siddha or Unani drugs.

(2) The Ayurvedic, Siddha and Unani Drugs Consultative Committee shall consist of two persons to be nominated by the Central Government as representatives of that Government and not more than one representative of each State to be nominated by the State Government concerned.

(3) The Ayurvedic, Siddha and Unani Drugs Consultative Committee shall meet when required to do so by the Central Government and shall regulate its own procedure.

**33-E. Misbranded Drugs.**— For the purpose of this Chapter an Ayurvedic, Siddha or Unani drug shall be deemed to be misbranded,—

- a) if it is so coloured, coated, powdered or polished that damage is concealed, or if it is made to appear of better or greater therapeutic value than it really is; or
- b) if it is not labelled in the prescribed manner; or
- c) if its label or container or anything accompanying the drug bears any

statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

### **COMMENT**

*Plea of no prohibition in other state not sustainable* – If the legality, constitutional or otherwise of the requirement of a licence for manufacturing the drugs envisaged under Section 33-D of the Drugs and Cosmetics Act, 1940, and of the prohibition to stock, sell and exhibit unlicensed drugs, is not in dispute, the enforcement of these provisions by a State, indeed, cannot be questioned either by manufacturer of such drugs being located, in such a state, or the dealer who stocks, sells and exhibits such drugs, on the ground that their counterparts in other states are not required to take a licence to manufacture, stock, sell and exhibits the drugs manufactured without a licence as the case may be. Say for example, if, in one State, the prohibition is enforced while in another prohibition is not enforced, can the affected person in the State, in which prohibition imposed, plead that the prohibition is unreasonable or violative of his right Article 304 (b) of the Constitution of India merely on the ground that his counterparts in the other State are not prohibited either from manufacturing the liquor or selling and consuming the same. Such a plea is not sustainable.

**33-EE. Adulterated Drugs.**— For the purpose of this Chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be adulterated:—

- a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or
- b) if it has been prepared, packed or stored under insanitary conditions

whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

- c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
- d) if it bears or contains for purpose of colouring only, a colour other than one which is prescribed; or
- e) if it contains any harmful or toxic substance which may render it injurious to health; or
- f) if any substance has been mixed therewith so as to reduce its quality or strength.

*Explanation:*— For the purpose of clause (a), a drug shall not be deemed to consist, in whole or in part, of any decomposed substance only by reason of the fact that such decomposed substance is the result of any natural decomposition of the drug:

Provided that such decomposition is not due to any negligence on the part of the manufacturer of the drug or the dealer thereof and that it does not render the drug injurious to health.

**33-EEA. Spurious Drugs.**— For the purpose of this Chapter, and Ayurvedic, Siddha or Unani drug shall be deemed to be spurious,—

- a) if it is sold, or offered or exhibited for sale, under a name which belongs to another drug; or
- b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

- c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious does not exist; or
- d) if it has been substituted wholly or in part by any other drug or substance; or
- e) if it purports to be the product of a manufacturer of whom it is not truly a product.

**33-EEB. Regulation of Manufacturer for Sale of Ayurvedic, Siddha and Unani Drugs.**— No person shall

manufacture for sale or for distribution any Ayurvedic, Siddha or Unani drug except in accordance with such standards, if any as may be prescribed in relation to that drug.

**33-EEC. Prohibition of Manufacture and Sale of Certain Ayurvedic, Siddha and Unani Drugs.**— From such

date as the State Government may, by notification in the Official Gazette, specify in this behalf, no person, either by himself or by any other person on his behalf shall,

- a) manufacture for sale or for distribution,—
  - i) any misbranded, adulterated or spurious Ayurvedic, Siddha or Unani drug;
  - ii) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true list of all the ingredients contained in it; and
  - iii) any Ayurvedic, Siddha or Unani drug in contravention of any of the provisions of this Chapter or any rule made thereunder;
- b) sell, stock or exhibit or offer for sale or distribute any Ayurvedic,

Siddha or Unani drug which has been manufactured in contravention of any of the provisions of this Act, or any rule made thereunder;

- c) manufacture for sale or for distribution, any Ayurvedic, Siddha or Unani drug, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter by the prescribed authority:

Provided that nothing in this section shall apply to Vaidyas and Hakims who manufacture Ayurvedic, Siddha or Unani drug for the use of their own patients:

Provided further that nothing in this section shall apply to the manufacturer, subject to the prescribed conditions, of small quantities of any Ayurvedic, Siddha or Unani drug for the purpose of examination, test or analysis.

**33-EED. Power of Central Government to Prohibit Manufacturer, etc., of Ayurvedic, Siddha or Unani Drugs in Public Interest.**— Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied on the basis of any evidence or other material available before it that the use of any Ayurvedic, Siddha or Unani drug is likely to involve any risk to human beings or animals or that any such drug does not have the therapeutic value claimed or purported to be claimed for it and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the Official Gazette, prohibit the manufacture, sale or distribution of such drug.

**33-F. Government Analysts.**— (1) The Central Government or a State Government may, by notification in the Official Gazette, appoint such person

as it thinks fit, having their prescribed qualifications, to be Government Analysts for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

(2) Notwithstanding anything contained in sub-section (1), neither the Central Government nor a State Government shall appoint as a Government Analysts, any official not serving under it, without the previous consent of the Government under which, he is serving.

(3) No person, who has any financial interest in the manufacture or sale of any drug shall be appointed to be a Government Analyst under this section.

**33-G. Inspectors.**— (1) The Central Government or a State Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualification, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

(2) The powers which may be exercised by an Inspector and the duties which may be performed by him and the conditions, limitations or restrictions subject to which such power and duties may be exercised or performed shall be such as may be prescribed.

(3) No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be an Inspector under this section.

(4) Every Inspector shall be deemed to be a public servant within the meaning of Section 21 of the Indian Penal Code (45 to 1860) and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

**33-H. Application of Provisions of Sections 22, 23, 24 and 25.**– The provisions of Sections 22,23,24 and 25 and the rules, if any made there under shall, so far as may be apply in relation to an Inspector and a Government Analyst appointed under this Chapter as they apply in relation to an Inspector and a Government Analyst appointed under Chapter IV, subject to the modification that the references to “drug” in the said sections, shall be constructed as references to “Ayurvedic, Siddha or Unani drug”.

**33-I. Penalty for Manufacture, Sale, etc., of Ayurvedic, Siddha or Unani Drug in Contravention of this Chapter.**– Whoever himself or by any other person on his behalf – (1) manufactures for sale or for distribution,–

- a) any Ayurvedic, Siddha or Unani drug-
  - i) deemed to be adulterated under Section 33-EE, or
  - ii) without a valid licence as required under clause © of Section 33-EEC, shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than two thousand rupees;
- b) any Ayurvedic, Siddha or Unani drug deemed to be spurious under Section 33EEA, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than five thousand rupees.

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than one year and of fine of less

than five thousand rupees: or

(2) Contravenes any other provisions of this Chapter or of Section 24 as applied by Section 33-H or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to three months and with fine which shall not be less than five hundred rupees.

**33-J. Penalty for Subsequent Offences.**– Whoever having been convicted of an offence,

- a) under clause (a) of sub-section 33-1 is again convicted of an offence under that, clause, shall be punishable with imprisonment for a term which may extend to two years and with fine which shall not be less than two thousand rupees;
- b) under clause (b) of sub-section (1) of Section 33-I is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to six years and with fine which shall not be less than five thousand rupees:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and of fine of less than five thousand rupees:

- c) under sub-section (2) of Section 33-I is again convicted of an offence under that sub-section, shall be punishable with imprisonment for a term which may extent to six months and with fine which shall not be less than one thousand rupees.

**33-K. Confiscation.**– Where any person has been convicted under this Chapter, the stock of the Ayurvedic,

Siddha or Unani drug, in respect of which the contravention has been made, shall be liable to confiscation.

**33-L. Application of Provisions to Government Departments.**— The provisions of this Chapter except those contained in Section 33-K shall apply in relation to the manufacture for sale, sale or distribution of any Ayurvedic, Siddha or Unani drug by any department of Government as they apply in relation to the manufacture for sale, sale or distribution of such drug by any other person.

**33-M. Cognizance of Offences.**— (1) No prosecution under this Chapter shall be instituted except by an Inspector [with the previous sanction of the authority specified under sub-section (4) of Section 33-G.

(2) No Court inferior to that [or a Metropolitan Magistrate or of a judicial Magistrate of the first class] shall try an offence punishable under this Chapter.

**33-N. Power of Central Government to make Rules.**— (1) The Central Government may, [after consultation with, or on the recommendation of, the Board] and after previous publication by notification in the Official Gazette, make rules for the first purpose of giving effect to the provisions of this Chapter:

Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case, the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the

amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may,—

- a) provide for the establishment of laboratories for testing and analyzing Ayurvedic, Siddha or Unani drugs;
- b) prescribe the qualification and duties of Government Analysts and the qualification of Inspectors;
- c) prescribe the methods of test or analysis to be employed in determining whether any Ayurvedic, Siddha or Unani drug is labelled with the true list of the ingredients which it is purported to contain;
- d) specify any substance as a poisonous substance;
- e) prescribe the forms of licences for the manufacture for sale of Ayurvedic, Siddha or Unani drugs, [and for sale of processed Ayurvedic, Siddha or unani drugs,] the form application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefore [and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or rules made there under is contravened or any of the conditions subject to which they are issued is not complied with];
- [(f) prescribe the conditions to be observed in the packing of Ayurvedic, Siddha or Unani drugs including the use of packing material which comes into contact with the drugs, regulate the mode of labelling packed drugs and prescribe the matters which shall not be included in such labels;]
- g) prescribe the conditions subject to which small quantities of Ayurvedic, Siddha or Unani drugs may be

- manufactured for the purpose of examination, test or analysis;
- [(gg) prescribe under clause (a) of Section 33-EE the colour or colours which an Ayurvedic, Siddha or Unani drug may bear or contain for purpose of colouring;
- (gga) prescribe the standards for Ayurvedic, Siddha or Unani drugs under Section 33-EEB;] and
- h) any other matter which is to be or may be prescribed under this Chapter.

#### STATE AMENDMENTS

**Maharashtra.** In Section 33-N of the principal Act in sub-section (2) in clause (e) the words “and the fees payable therefore” shall be deleted. – Vide Maharashtra Act 31 of 1989, Sec. 4.

#### SECTION 33-N-1

**Maharashtra.**– After Section 33-N principal Act, the following section shall be inserted, namely:–

*“33-N-1 Power of State Government to make rules.*– The State Government may, by notification in the Official Gazette and subject to the condition of previous publication, make rules to prescribe the fees payable for the following purpose

of this Chapter, namely:–

- a) grant or renewal of all licence for the manufacture for sale of Ayurvedic, Siddha or Unani drugs, and for sale of processed Ayurvedic, Siddha or Unani drugs.
  - b) inspection (for the purpose of grant or renewal of licences) of premises, wherein any Ayurvedic, Siddha or Unani drugs is being or is proposed to be manufactured:
  - c) test or analysis of any Ayurvedic, Siddha or Unani drug by Government Analyst; and
  - d) any other matter for which fees may be prescribed under this Chapter.”
- Vide Maharashtra Act 31 of 1989, Sec. 4.

#### 33-O. Power to amend First

**Schedule.**– The Central Government, after consultation with the Board and after giving, by notification in Official Gazette, not less than three months’ notice to its intention so to do, may, by a like notification, add to or otherwise amend the First Schedule for the purpose of this Chapter and thereupon the said Schedule shall be deemed to be amended accordingly.

## MISCELLANEOUS

## CHAPTER V

**[33p.] Power to Give Directions.**— The Central Government may give such directions to any State Government as may appear to the Central Government to be necessary for carrying into execution in the State any of the provisions of this Act or of any rule or order made thereunder.]

**34. Offences by Companies.**— (1) Where an offence under this Act has been committed by a company, every person who at the time the offence was committed, was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such

director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

*Explanation.*— For the purposes of this section –

- a) “company” means a body corporate, and includes a firm or other association of individuals; and
- b) “director” in relation to a firm means a partner in the firm.

**[34a. Offences by Government Departments.**— Where an offence under Chapter IV or Chapter IVA has been committed by any department of Government, such authority as is specified by the Central Government to be in charge of manufacture, sale or distribution of drugs or where no authority is specified, the head of the department, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this section shall render any such authority or person liable to any punishment provided in Chapter IV or Chapter IVA, as the case may be, if such authority or person proves that the offence was committed without its or his knowledge or that such authority or person exercised all due diligence to prevent the commission of such offence.]

**[34aa. Penalty for Vexatious Search Or Seizure.** – Any Inspector exercising powers under this Act or the rules made thereunder, who,–

- a) without reasonable ground of suspicion searches any place, vehicle, vessel or other conveyance; or
- b) vexatiously and unnecessarily searches any person; or
- c) vexatiously and unnecessarily seizes any drug or cosmetic, or any substance or article, or any record, register, document or other material object; or
- d) commits, as such Inspector, any other act, to the injury of any person without having reason to believe that such act is required for the execution of his duty, shall be punishable with fine which may extend to one thousand rupees.]

**35. Publication of Sentences passed under this Act.**– (1) If any person is convicted of an offence under this Act, [the Court before which the conviction takes place shall, on application made to it by the Inspector, cause] the offender's name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the Court may direct.

(2) The expenses of such publication shall be deemed to form part of the costs relating to the conviction and shall be recoverable in the same manner as those costs are recoverable.

**36. Magistrate's Power to Impose Enhanced Penalties.**– Notwithstanding anything contained in the code of Criminal Procedure, 1973 (2 of 1974)] it shall be lawful for [any

Metropolitan Magistrate or any Judicial Magistrate of the first class] to pass any sentence authorized by this Act in excess of his powers under the said Code.

**[36a. Certain Offences to be Tried Summarily.**– Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974), all offences under this Act, punishable with imprisonment for a term not exceeding three years, other than an offence under clause (b) of sub-section (1) of section 33-I, shall be tried in a summary way by a Judicial Magistrate of the first class specially empowered in this behalf by the State Government or by a Metropolitan Magistrate and the provisions of sections 262 to 265 (both inclusive) of the said Code shall, as far as may be, apply to such trial:

Provided that, in the case of any conviction in a summary trial under this section, it shall be lawful for the Magistrate to pass a sentence of imprisonment for a term not exceeding one year:

Provided further that when at the commencement of, or in the course of, a summary trial under this section it appears to the Magistrate that the nature of the case is such that a sentence of imprisonment for a term exceeding one year may have to be passed or that it is, for any other reason, undesirable to try the case summarily, the Magistrate shall, after hearing the parties, record an order to that effect and thereafter recall any witness who has been examined and proceed to hear or rehear the case in the manner provided by the said Code.]

**37. Protection of Action taken in Good Faith.**– No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good

faith done or intended to be done under this Act.]

**38. Rules to be laid before Parliament.**— Every rule made under this Act shall be laid as soon as may be after it is made before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions, [and if, before the expiry of the session immediately

following the session or the successive sessions aforesaid], both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so however that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.]

## THE FIRST SCHEDULE

### [A. AYURVEDIC AND SIDDHA SYSTEMS]

- |   |  |  |
|---|--|--|
| <b>Ayurveda</b>                             |  |  |
| 1. Arogya Kalpadruma                        | 38. Vaidya Jiwan                       | 68. Veeramamuni Nasa Kandam            |
| 2. Arka Prakasha                            | 39. Basava Rajeeyam                    | 69. Agasthiyar (600)                   |
| 3. Arya Bhishak                             | 40. Yoga Ratnakara                     | 70. Agasthiyar kanma Soothiram         |
| 4. Ashtanga Hridaya                         | 41. Yoga Tarangini                     | 71. 18 Siddhar's Chillarai Kovai       |
| 5. Ashtanga Samgraha                        | 42. Yoga Chintamani                    | 72. Yogi Vatha Kaviyam                 |
| 6. Ayurveda Kalpadruma                      | 43. Kashyapasamhita                    | 73. Therayar Tharu                     |
| 7. Ayurveda Prakasha                        | 44. Bhelasamhita                       | 74. Agasthiyar Vaidya Kaviyam (1500)   |
| 8. Ayurveda Samgraha                        | 45. Vishwanathachikitsa                | 75. Bala Vagadam                       |
| 9. Bhaishajya Ratnavali                     | 46. Vrindachikitsa                     | 76. Chimittu Rathna (Rathna) Churukkam |
| 10. Bharat Bhaishajya Ratnakara             | 47. Ayurvedachintamani                 | 77. Nagamuni (200)                     |
| 11. Bhava Prakasha                          | 48. Ayurvedachintamani                 | 78. Agasthiyar Chillarai Kovai         |
| 12. Brihat Nighantu Ratnakara               | 49. Ayurveda – ratnakar                | 79. Chikicha Rathna Deepam             |
| 13. Charaka Samhita                         | 50. Yogaratnasangraha                  | 80. Agasthiyar Nayana Vidhi            |
| 14. Chakra Datta                            | 51. Rasamrita                          | 81. Yugi Karisal (151)                 |
| 15. Gada Nigraha                            | 52. Dravyagunanighantu                 | 82. Agasthiyar Vallathi (600)          |
| 16. Kupi Pakva Rasayana                     | 53. Rasamanijari                       | 83. Therayar Thaila Varkam             |
| 17. Nighantu Ratnakara                      | 54. Bangasena                          | 84. Siddha Formulary of India          |
| 18. Rasa Chandanshu                         | 54-A. Ayurvedic Formulary of India     |  |
| 19. Rasa Raja Sundara                       | 54-B. Ayurveda Sara Sangraha           |  |
| 20. Rasaratna Samuchaya                     | 54-C. Ayurvedic Pharmacopoeia of India |  |
| 21. Rasatantra Sara Siddha Prayoga Samgraha |  |  |
| 22. Rasa Tarangini                          | <b>Siddha</b>                          |  |
| 23. Rasa Yoga Sagara                        | 55. Siddha Vaidya Thirattu             |  |
| 24. Rasa Yoga Ratnakara                     | 56. Therayar Maha Karisal              |  |
| 25. Rasa Yoga Samgraha                      | 57. Brahma Muni Karukkadai             |  |
| 26. Rasendra Sara Samgraha                  | 58. Bhogar (700)                       |  |
| 27. Rasa Pradipika                          | 59. Pulippani (500)                    |  |
| 28. Sahasrayoga                             | 60. Agasthiyar Paripuram (400)         |  |
| 29. Sarvaroga Chikitsa Ratnam               | 61. Therayar Yamagam                   |  |
| 30. Sarvayoga Chikitsa Ratnam               | 62. Agasthiyar Chenduram (300)         |  |
| 31. Sharangadhara Samhita                   | 63. Agasthiyar (1500)                  |  |
| 32. Siddha Bhaishajya Manimala              | 64. Athmarakshamrutham                 |  |
| 33. Siddha Yoga Samgraha                    | 65. Agasthiyar Pin(80)                 |  |
| 34. Sushruta Samhita                        | 66. Agasthiyar Rathna Churukkam        |  |
| 35. Vaidya Chintamani                       | 67. Therayar Karisal (300)             |  |
| 36. Vaidyaka Shabda Sindu                   |  |  |
| 37. Vaidyaka Chikitsa Sara                  |  |  |

### Unani Medicine (Part-1)

### B. - UNANI TIBB SYSTEM

1. Karabadin Qadri
2. Karabadin Kabir
3. Karabadin Azam
4. Ilaj-ul-Azam
5. Al Karabadin Jadid
6. Biaz Kabir Vol. II
7. Karabadin Jadid
8. Kitalf-ul-Taklis
9. Sanat-ul-Taklis
10. Mifta-ul-Khazain
11. Madan-ul-Aksir
12. Makhzan-ul-Murabbat
13. National Formulary of Unani Medicine
14. Unani Pharmacopoeia of India

# **DRUGS AND COSMETICS RULES, 1945**

## MANUFACTURE FOR SALE OF AYURVEDIC, (INCLUDING SIDDHA) OR UNANI DRUGS

**151. Manufacture on More Than One Set of Premises.**— If Ayurvedic (including Siddha) or Unani drugs are manufactured on more than one set of premises, a separate application shall be made and a separate licence shall be obtained in respect of each such set of premises.

**152. Licensing Authorities.**—For the purpose of this Part the State Government shall appoint such licensing authorities and for such areas as may be specified in this behalf by notification in the Official Gazette.

**153. Application for Licence to Manufacture Ayurvedic (including Siddha) or Unani Drugs.**— (1) An application for the grant or renewal of a licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be made in Form 24D to the licensing authority along with [a fee of rupees one thousand]

Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry:

Provided further that the applicant may apply for renewal after the expiry of one month but within three months of such expiry in which case [the fee payable for renewal of such licence shall be rupees one thousand and two hundred plus an additional fee of rupees six hundred]

(2) [A fee of rupees three hundred shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.]

**153A. Loan Licence.**— (1) An application for the grant or renewal of a loan licence to manufacture for sale of any Ayurvedic (including Siddha) or Unani drugs shall be made in Form 25E to the licensing authority along with [a fee of rupees six hundred]

*Explanation:*— For the purpose of this rule, a loan licence means a licence which a licensing authority may issue to an applicant who does not have his own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by a licensee in Form 25D.

Provided that in the case of renewal the applicant may apply for the renewal of the licence before its expiry or within one month of such expiry.

Provided further that the applicant may apply for renewal after the expiry of one month, but within three months of such expiry in which case [the fee payable for renewal of such licence be rupees six hundred plus an additional fee of rupees three hundred]

(2) [A fee of rupees one hundred and fifty] shall be payable for a duplicate copy of a licence issued under this rule, if the original licence is defaced, damaged or lost.]

**154. Form of Licence to Manufacture Ayurvedic (including Siddha) or Unani Drugs.**—

(1) Subject to the conditions of rule 157 being fulfilled, a licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25D. The licence shall be issued within a period of three months from the date of receipt of the application.

(2) A licence under this rule shall be granted by the licensing authority after consulting such expert in Ayurvedic (including Siddha) or Unani systems of medicine, as the case may be, which the State Government may approved in this behalf.

**[154A. Form of Loan Licence to Manufacture for Sale of Ayurvedic (including Siddha) or Unani Drugs.**—

(1) A loan licence to manufacture for sale any Ayurvedic (including Siddha) or Unani drugs shall be issued in Form 25E.

(2) A licence under this rule shall be granted by the licensing authority after consulting such expert in Ayurvedic (including Siddha) or Unani systems of medicine, as the case may be, which the State Government may approve in this behalf.

(3) The licensing authority shall, before the grant of a loan licence, satisfy himself that the manufacturing unit has adequate equipment, staff, capacity for manufacture and facilities for testing, to undertake the manufacture on behalf of the applicant for a loan licence.

**155. Certificate of Renewal.**— The certificate of renewal of a licence in Form 25D shall be issued in Form 26D.

**[155A. Certificate of Renewal of A Loan Licence.**— The certificate of

renewal of a loan licence in Form 25E shall be issued in Form 26E.]

**[155B. Certificate of Award of Good Manufacturing Practices Ayurveda, Siddha and Unani Drugs.**—

The certificate of Good Manufacturing Practices (GMP) to manufacturers of Ayurvedic (including Siddha) or Unani drugs shall be issued to licensee who comply with the requirements of Good Manufacturing Practice (GMP) of Ayurvedic Siddha or Unani drugs as laid down Schedule T.]

**156. Duration of Licence.**— An original licence in Form 25D or a renewal licence in Form 26D, unless sooner suspended or cancelled shall be [valid for a period of three years from the date of its issue]

Provided that if the application for the renewal of a licence is made before its expiry or within one month of its expiry, or if the application is made within three months of its expiry after payment of the [additional fee of rupees five hundred], the licence shall be deemed to have expired, if application for its renewal is not made within three months of its expiry.

**156A. Duration of Loan Licence.**—

An original loan licence in Form 25E or renewed loan licence in Form 26E, unless sooner suspended or cancelled shall be [valid for a period of three years from the date of its issue]:

Provided that if the application for the renewal of a licence is made in accordance with rule 153A, the loan licence shall continue to be in force until orders are passed on the application. The licence shall be deemed to have expired, if application for its renewal is not made within three months of its expiry.

**157. Conditions for the Grant or Renewal of A Licence in Form 25D.–**

Before a licence in Form 25D is granted or renewed in Form 26D, the following conditions shall be complied with by the applicant, namely:–

(1) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be carried out in such premises and under such hygienic conditions as are specified in Schedule T.

[(1A) For getting a certificate of Good Manufacturing Practices of Ayurveda-Siddha-Unani drugs, the applicant shall make an application on a plain paper, providing the information on existing infrastructure of the manufacturing unit, and the licensing authority shall after verification of the requirements as per Schedule T, issue the certificate within a period of three months in Form 26 E-I]

(2) The manufacture of Ayurvedic (including Siddha) or Unani drugs shall be conducted under the direction and supervision of competent technical staff consisting at least of one person, who is a whole-time employee and who possesses the following qualification, namely:–

- a) a degree in Ayurveda or Ayurvedic Pharmacy, Siddha or Unani system of medicine, as the case may be, conferred by a University, a State Government or Statutory Faculties, Councils and Boards of Indian Systems of Medicine recognized by the Central Government or a State Government for this purpose, or
- b) a diploma in Ayurveda, Siddha or Unani System of medicine granted by a State Government or an Institution recognized by the Central Government for this purpose, or
- c) a graduate in Pharmacy or Pharmaceutical Chemistry or Chemistry or Botany or a University

recognized by the Central Government with experience of at least two years in the manufacture of drugs pertaining to the diploma in Ayurveda, Siddha or Unani System of medicine, or

- d) a Vaid or Hakim registered in a State Register of Practitioners of indigenous system of medicines having experience of at least four years in the manufacture of Siddha or Unani drugs, or
- e) a qualification as Pharmacist in diploma in Ayurvedic (including Siddha) or Unani System of medicine, possessing experience of not less than eight years in the manufacture of Ayurvedic (including Siddha) or Unani drugs as may be recognized by the Central Government.

(3) The competent technical staff to direct and supervise the manufacture of Ayurvedic drugs shall have qualifications in Ayurveda and the competent technical staff to direct and supervise the manufacture of Siddha drugs and Unani drugs shall have qualifications in Siddha or Unani as the case may be.

**158. Conditions of Licence.–** A licence in Form 25D shall be subject to the conditions stated therein and to the following further conditions namely:–

- a) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or by any other person on his behalf, of the raw materials and finished products.
- b) The licensee shall allow an Inspector appointed under the Act to enter any premises where the manufacture of a substance in respect of which the licence is issued is carried on to inspect the premises, to take samples

of the raw materials as well as the finished products, and to inspect the records maintained under these rules.

- [c) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.]

**158A. Conditions of Loan Licence.–**

A licence in Form 25E shall be subject to the following further conditions, namely:-

- a) The licence in Form 25E shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 25D whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be, under these rules.
- b) The licensee shall comply with the provisions of the Act and of the rules and with such further requirements if any, as may be specified in any rules subsequently made under Chapter IV A of the Act, provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.
- c) The licensee shall maintain proper records of the details of manufacture and of the tests, if any, carried out by him, or by any other person on his behalf, of the raw materials and finished products.
- d) The licensee shall allow an Inspector appointed under the Act to inspect all registers and recodes maintained under these rules and shall supply to the Inspector such information

as he may require for the purpose of ascertaining whether the provisions of the Act and the rules have been observed.

- e) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.]

**159. Cancellation and Suspension of Licences.–**

(1) The licensing authority may, after giving the licensee an opportunity to show cause, within a period which shall not be less than fifteen days from the date of receipt of such notice, why such an order should not be passed, by an order in writing stating the reasons therefore, cancel a licence issued under this Part or suspend it for such period as he thinks fit, either wholly or in respect of some of the drugs to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or the rules made thereunder.

(2) A licensee whose licence has been suspended or cancelled may appeal to the State Government within a period of three months from the date of receipt of the order which shall, after considering the appeal, decide the same.

**160. Identification of Raw Materials.–**

Raw materials used in the preparation of Ayurvedic (including Siddha) or Unani drugs shall be identified and tested, wherever tests are available for their genuineness, and records of such tests as are carried out for the purpose and methods thereof shall be maintained.]



i) The premises where the tests are carried out shall be well lighted and properly ventilated except where the nature of tests of any Ayurvedic, Siddha and Unani drug warrants otherwise. Wherever necessary, the premises shall be air-conditioned so as to maintain the accuracy and functioning of laboratory instruments or to enable the performance of special tests such as sterility tests and microbiological tests.

(ii) (a) The applicant shall provide adequate space having regard to the nature and number of samples of drugs proposed to be tested:

Provided that the approving authority shall determine from time to time whether the space provided continues to be adequate. Provided further that separate section shall be provided for (i) Chemistry, (ii) Pharmacognosy, (iii) Ayurveda, Siddha and Unani, (iv) Microbiology, (v) Sample Room, (vi) Office-cum-Record Room, with proper partitions and minimum required area is 800 sq. ft.

(b) The applicant shall provide list of persons who may be employed with him as experts, such as Chemist, Botanist and expert in Ayurveda/Siddha/Unani or Pharmacist who shall possess a degree in Chemistry, Botany, Ayurved/Siddha/Unani/Bachelor in Pharmacy from a recognized University or equivalent, with experience for 2 years for carrying out tests or analysis as per the Ayurvedic, Siddha and Unani pharmacopoeias.

(c) The applicant shall provide adequate equipments essential for carrying out tests for identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs as per pharmacopoeial standards or other available standards.

List of equipment recommended is given below:

#### CHEMISTRY SECTION

1. Alcohol determination apparatus complete set.
2. Volatile oil determination apparatus.
3. Boiling point determination apparatus.
4. Melting point determination apparatus.
5. Refractometer.
6. Polarimeter.
7. Viscometer (Ostwalds, Redwood viscometer).
8. Tablet disintegration apparatus.
9. Moisture determination apparatus. (IC filtrator).
10. U.V. Spectro-Photometer.
11. Muffle furnace.
12. Electronic Balance.
13. Hot air oven (s) different range of temperature/vacuum oven.
14. Refrigerator.
15. Glass distillation apparatus/plant.
16. Water supply demineralised exchange equipment/distillation equipment.
17. Air conditioner.
18. LPG Gas Cylinder with burners.
19. Water bath (temperature controlled).
20. Heating mantle (4) or as required.
21. TLC apparatus with all accessories.
22. Sieves 10 to 120 with sieve shaker.
23. Centrifuge machine.
24. Dehumidifier (where necessary).
25. PH meter.
26. G.L.C. with F.I. detector.
27. Silica crucible.

28. Tablet friability tester.
29. Tablet dissolution tester.
30. Other related equipment, reagents, chemicals and glasswares.

#### PHARMACOGNOSY SECTION

1. Microscope binocular.
2. Dissecting Microscope.
3. Microtome.
4. Chemical balance.
5. Microslide cabinet.
6. Aluminium slide trays.
7. Hot air oven.
8. Occular Micrometer.
9. Stage Micrometer.
10. Camera Lucida Prism type and mirror type.
11. Hot plates.
12. Refrigerator.
13. LPG Cylinder with burners.
14. Other related equipments, reagents, glasswares, etc.

*Note.*— Instruments like HPLC, HPTLC, Atomic Absorption spectrophotometer could be arranged by tie up with other laboratories.

#### MICROBIOLOGY SECTION

1. Laminar air flow bench (L.A.F.).
2. B.O.D. Incubator.
3. Plain incubator.
4. Serological water bath.
5. Oven.
6. Autoclave/Sterilizer.
7. Microscope (high power).
8. Colony counter.
9. Other related equipment and reagents.

(3) The applicant shall provide and maintain suitable equipment having regard to the nature and number of samples of Ayurvedic, Siddha and Unani drugs intended to be tested which shall be adequate in the opinion of the approving authority.

(4) The testing of Ayurvedic, Siddha

and Unani drugs, as the case may be, for identity, purity, quality and strength shall be carried out under the active direction of one of the experts stated in clause (b) of sub-rule (2) who shall be the person-in-charge of testing and shall be held responsible for the reports of test issued by the applicant.

(5) The testing of Ayurvedic, Siddha and Unani drugs, as the case may be, for identity, purity, quality and strength shall be carried out by persons whose qualifications and experience of testing are adequate as stated in clause (b) of sub-rule (2).

(6) The applicant shall provide books of standard recognized under the provisions of the Act and the rules made thereunder and such books of reference as may be required in connection with the testing or analysis of the products for the testing of which approval is applied for.

(7) The applicant shall provide list of standard Ayurvedic, Siddha and Unani drugs (with Reference samples) recognized under the provisions of the Act and rules made thereunder and such reference samples kept in the laboratory may be required in connection with the testing or analysis of the products of which approval is applied for.

**160C. Duration of Approval.**— An approval granted in Form 41 or renewed in Form 42 unless sooner suspended or withdrawn, shall be valid for a period of three years from the date on which it is granted or renewed:

Provided that if an application for the renewal of an approval in Form 40 is made before its expiry or if the application is made within six months of its expiry after the payment of the additional inspection fee, the approval shall continue to be in force until orders to the contrary are passed on the

application and the approval shall be deemed to have expired if the application for renewal is not made within six months of expiry.

**160D. Conditions of Approval.**— An approval in Form 41 shall be subject to the following conditions, namely:—

- I. The Institution granted approval under this Part (hereinafter referred to as the approved laboratory) shall provide and maintain adequate staff and adequate premises and equipment as specified in rule 160 B.
- II. The approved laboratory shall provide proper facilities for storage so as to preserve the properties of the samples to be tested by it.
- III. The approved laboratory shall maintain records of tests for identity, purity, quality and strength carried out on all samples of Ayurvedic, Siddha and Unani drugs and the results thereof together with the protocols of tests showing the readings and calculation in such form as to be available for inspection and such records shall be retained in the case of substances for which date of expiry is assigned; for a period of two years from such date of expiry and in the case of other substances, for a period of three years.
- IV. The approved laboratory shall allow the Inspector appointed under this Act to enter with or without prior notice the premises where the testing is carried out and to inspect the premises and the equipment used for test and the testing procedures employed. The laboratory shall allow the Inspectors to inspect the registers and records maintained under these rules and shall supply to such Inspectors such information as they may require for

the purpose of ascertaining whether the provisions of the Act and rules made thereunder have been observed.

- V. The approved laboratory shall from time to time report to the approving authority any changes in the person-in-charge of testing of Ayurvedic, Siddha and Unani drugs or the expert staff responsible for testing, as the case may be, and any material alterations in the premises or changes in the equipment used for the purposes of testing which have been made since the date of last inspection made on behalf of the approving authority before the grant or renewal of approval.
- VI. The approved laboratory shall furnish reports of the results of tests or analysis in Form 50.
- VII. In case any sample of Ayurvedic, Siddha and Unani drug is found on test to be not of standard quality, the approved laboratory shall furnish to the approving authority and the licensing authority of the State where the manufacturer and/or sender of the Ayurvedic, Siddha and Unani drugs is located, a copy of the test report on the sample with the protocols of tests applied.
- VIII. The approved laboratory shall comply with the provisions of the Act and rules made thereunder and with such further requirements, if any as may be specified in the rules made from time to time under Chapter IVA of the Act of which the approving authority has given the approved laboratory not less than four months' notice.
- IX. The approved laboratory shall maintain an inspection book to enable the Inspector to record his impression or defects notices.

**160E. Inspection before Grant of Approval.**— Before an approval in Form 48 is granted, the approving authority shall cause the laboratory at which the testing of Ayurvedic, Siddha and Unani drugs, as the case may be, is proposed to be carried out to be inspected jointly by the Inspectors appointed or designated by the Central Government and State Government for this purpose, who shall examine the premises and the equipment intended to be used for testing of drugs and verify into the professional qualifications of the expert staff who are or may be employed by the laboratory.

**160F. Report of Inspection.**— The Inspectors appointed by the Central Government as stated in rule 160E shall forward to the approving authority a detailed report of the results of the inspection.

**160G. Procedure of Approving Authority.**— (1) If the approving authority after such further enquiry, if any, as it may consider necessary, is satisfied that the requirements of the rules made under the Act have been complied with and that the conditions of the approval and the rules made under the Act have been observed, it shall grant approval in Form 48.

(2) If the approving authority is not so satisfied, it shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which shall be satisfied before approval could be granted.

**160H. Application after Rejection.**— If within a period of six months from the rejection of an application for approval, the applicant informs the approving authority that the conditions laid down have been satisfied and

deposits inspection fee of two thousand rupees, the approving authority may, if after causing a further inspection to be made and after being satisfied that the conditions for grant of approval have been complied with, grant the approval in Form 48.

**160I. Renewal.**— On an application being made for renewal, the approving authority shall, after causing an inspection to be made and if satisfied that the conditions of the approval and the rules made under the Act have been complied with, shall issue a certificate of renewal in Form 49.

**160J. Withdrawal and Suspension of Approvals.**— (1) The approving authority may, after giving the approved laboratory an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, withdraw an approval granted under this Part or suspend it for such period as it thinks fit either wholly or in respect of testing of some of the categories of Ayurvedic, Siddha and Unani drugs to which it relates, if in his opinion the approved laboratory had failed to comply with any of the conditions of the approval or with any provision of the Act of the rules made thereunder.

(2) any approved laboratory, whose approval has been suspended or withdrawn, may, within three months of the date of the order of suspension or withdrawal, appeal to the State Government which shall dispose of the appeal in consultation with a panel of competent persons appointed by the Department of Indian Systems of Medicine and Homoeopathy, Government of India in this behalf and notified in the Official Gazette.]

## [LABELLING, PACKING AND LIMIT OF ALCOHOL IN] AYURVEDIC (INCLUDING SIDDHA) OR UNANI DRUGS

**161. [Labelling, packing and limit of alcohol.]**– (1) There shall be conspicuously displayed on the label of the container or package of an Ayurvedic (including Siddha) or Unani drug, the true list of all the ingredients used in the manufacture of the preparation together with the quantity of each of the ingredients incorporated therein and a reference to the method of preparation thereof as detailed in the standard text and adikarana, as are prescribed in the authoritative books specified in the First Schedule of the Act;

Provided that if the list of ingredients contained in the medicine is large and cannot be accommodated on the label, the same may be printed separately and enclosed with the packing and reference be made to this effect on the label.]

(2) The container of a medicine for internal use made up ready for the treatment of human ailments shall, if it is made up from a substance specified in Schedule E(1), be labelled conspicuously with the words 'Caution: to be taken under medical supervision' both English and Hindi languages.

(3) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any Ayurvedic (including Siddha) or Unani drug and

on any other covering in which the container is packed, namely:

- i) The name of the drug. For this purpose the name shall be the same as mentioned in the authoritative books included in the First Schedule of the Act.
- ii) A correct statement of the net content in terms of weight, measure of number as the case may be. The weight and volume shall be expressed in metric system.
- iii) The name and address of the manufacturer.
- iv) The number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words 'Manufacturing Licence Number' of 'Mfg Lic. No' or "M.L"
- v) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words "batch No." or "Batch" or "Lot Number" or Lot No." or "Lot" or any distinguishing prefix.
- vi) The date of manufacture. For this purpose the date of manufacture shall be the date of completion of the final products, or the date of bottling or packing for issue.

- vii) The words “Ayurvedic medicine” or Siddha medicine” or Unani medicine” as the case may be.
- viii) The words “FOR EXTERNAL USE ONLY” if the medicine is for external application.
- ix) Every drug intended for distribution to the medical profession as a free sample shall, while complying with labeling provisions under clauses (i) to (viii) further bear on the label of the container the words “Physician’s sample. Not to be sold” which shall be overprinted.
- x) (a) Preparation (Asavas) with high content of alcohol as base.

Sl. No.	Name of the drug	Maximum size of packing
i)	Kapur Asava	15 ml.
ii)	Ahiphenasava	15 ml.
iii)	Margamadasava	15 ml.

- x) (b) Preparations containing self-generated alcohol.

Sl. No.	Name of the drug	Maximum content of alcohol (Ethyl alcohol v/v)	Maximum size of packing
i)	Mritsanjivani Sura	16%	30 ml
ii)	Maha-drakshasava	16%	120 ml

(4) Nothing in these rules shall be deemed to require the labeling of any transparent cover or of any wrapper-case or other covering used solely for the purpose of packing, transport or delivery.

#### 161-A. Exemption in labelling and packing provisions for export of Ayurvedic (including Siddha) and

**Unani drugs.**– (1) Labels and packages or containers of Ayurvedic, Siddha and Unani drugs for export may be adapted to meet the specific requirements of the law of the country to which the said drug is to be exported, but the following particulars shall appear in conspicuous position on the container in which drug is packed and on every other covering in which that container is packed, namely:

- name of the Ayurvedic, Siddha and Unani drug (Single or compound formulations)
- the name, address of the manufacturer and the number of licence under which the drug has been manufactured;
- batch or lot number;
- date of manufacture, along with date for “Best for use before;”
- main ingredients, if required by the importing country;
- FOR EXPORT:

Provided that where Ayurvedic, Siddha and Unani Single or compound drug not classified under the First Schedule or Schedule E-(I), is required by the consignee to be not labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the licensing Authority mentioned in Rule 152.

(2) The provisions of Rule 161 shall not apply to a medicine made up “ready for treatment”, whether after, or without, alteration, which is supplied on the prescription of registered medical practitioner if the medicine is labelled with the following particulars namely :-

- the name and address of the suppliers;
- the words “For External Use Only”, if the medicine is for external application.

## Government Analysts and Inspectors for Ayurvedic (including Siddha) or Unani Drugs

**162. Duties of Inspectors specially authorized to inspect the Manufacture of Ayurvedic (including Siddha) or Unani Drugs.**— Subject to the instruction of the controlling authority, it shall be the duty of an Inspector authorized to inspect the manufacture of Ayurvedic (including Siddha) or Unani drugs:—

- i) to inspect not less than twice a year, all premises licensed for manufacture to Ayurvedic (including Siddha) or Unani drugs within the area allotted to him and to satisfy himself that the conditions of the license and the provisions of the Act and the rules made thereunder are being observed;
- ii) to sent forthwith to the controlling authority after each inspection a detailed report indicating whether or not the conditions of the licence and the provisions of the Act and the rules made thereunder are being observed;
- iii) to take samples of the drugs manufactured on the premises and send them for test or analysis in accordance with these rules;
- iv) to institute prosecutions in respect of violation of the Act and the rules made thereunder.

**162-A. Qualifications for State Drug Licencing Authority for Licensing of Ayurveda, Siddha and Unani Drugs:—**

- a) The Ayurvedic/Siddha/Unani

qualifications as per Schedule II of Indian Medicine Central Council Act, 1970 (84 of 1970) B.Pharma (Ayurveda) of a recognized University.

- b) At least 5 years experience in the Ayurveda/Siddha/Unani drug manufacturing or testing of Ayurvedic, Siddha and Unani drugs or enforcement of provisions of Chapter IV-A of the Drugs & Cosmetics Act, 1940 and rules made thereunder or teaching/research on clinical practice of Ayurveda/Siddha/Unani System.]

**163. Procedure for Dispatch of Sample to Government Analyst and its Receipt by the Government Analyst.**— (1) Samples for test or analysis shall be sent to the Government Analyst by registered post or by hand in a sealed package enclosed together with a memorandum in form 18-A in an outer cover addressed to the Government Analyst.

(2) The package as well as the outer cover shall be marked with distinguishing number.

(3) A copy of the memorandum and specimen impression of the seal used to seal the package shall be sent by registered post or by hand to the Government Analyst

(4) On receipt of the package from an inspector, the Government Analyst or an Officer authorised by him writing

in this behalf shall open the package and shall also record the condition of seals on package.

(5) After the test or analysis has been completed, one copy of the results of the test or analysis shall be supplied forthwith to the sender in form 13A, A copy of the result in Form 13A shall be sent simultaneously to the controlling authority and to the Drugs Controller, India.

“Pharmacopoeial Laboratory for Indian Medicines to functions as Central Drugs Laboratory for the purpose of testing or analysis of Ayurveda, Siddha and Unani drugs”.

**163A. Functions.**— The Pharmacopoeial Laboratory for Indian Medicine at Ghaziabad shall function as a Central Drugs Laboratory for the purpose of testing or analysis Ayurveda, Siddha and Unani Drugs.

Its functions shall be:—

- (1) to develop Pharmacopoeial standards and draft monographs and amendments along with standardized methods, for the Ayurveda, Siddha and Unani drugs;
- (2) to act as Central Appellate Drug Laboratory for testing of Ayurveda, Siddha and Unani drugs,
- (3) to analyse or test such samples of Ayurvedic, Siddha and Unani drugs, as may be sent to it under sub-section (2) of section 11, or under sub-section (4) of section 25, of the Act,
- (4) to maintain reference museum and herbarium for the drugs used in Ayurveda, Siddha and Unani (ASU) system.
- (5) to run a training centre for quality control methods in the Ayurveda, Siddha or Unani systems of medicines;
- (6) to carry out such other duties as

may be entrusted to it by the Government of India.

**163-B.** The functions of the Central Drug Laboratory in respect of Ayurvedic, Siddha and Unani drugs shall be carried out at the Pharmacopoeial Laboratory for Ayurvedic, Siddha and Unani medicine, Ghaziabad, (Uttar Pradesh) and the functions of the Director in respect of the said drugs shall be exercised by the Director of the said laboratory.

**163-C. Dispatch of Samples for Test or Analysis.**— (1) Samples for testing or analysis of Ayurveda, Siddha and Unani drugs under Sub-section (2) of Section 11 be sent by registered post in a sealed packet, enclosed with a memorandum in Form 1A specified in Schedule A, in an outer cover addressed to the Director, Pharmacopoeial Laboratory for Indian Medicine.

(2) The packet as well as the outer cover, shall be marked with a distinguishing number.

(3) A copy of the memorandum in Form 1A and a specimen impression of the seal used to seal the packet shall be sent separately by registered post to the Director, Pharmacopoeial Laboratory for Indian Medicine.

**163-D. Recording of Condition of Seals.**— On receipt of the packet, it shall be opened by an officer authorized in writing on that behalf by the Director, Pharmacopoeial laboratory for Indian Medicine, who shall record the condition of the seal on the packet.

**163-E. Report of result of test or analysis.**— After test or analysis, the result of the test or analysis, together with full protocols of the test applied, shall be supplied forthwith to the sender

in Form 2A of as specified in the said schedule.

**163-F. Fees.**– The fees for test and analysis shall be as specified in Schedule B-1.

**163-G. Signature on Certificates.**– Certificates issued under these rules by the Pharmacopoeial Laboratory for Indian Medicine, shall be signed by the Director or by an officer authorized by the Central Government to sign such certificates.”

**164. Method of Test or Analysis to be Employed in Relation to Ayurvedic (including Siddha) or Unani Drugs.**– The method of test or analysis to be employed in relation to an Ayurvedic (including Siddha) or Unani drugs shall be such as may be specified in the Ayurvedic (including Siddha) or Unani Pharmacopoeia, or if no such pharmacopoeia are available or if no tests are specified in such pharmacopoeias such tests as the Government Analyst may employ, such tests being scientifically established to determine whether the drug contains the ingredients as stated on the label.

**165. Qualifications of Government Analyst.**– A person who is appointed a Government Analyst under Section 33 – F of the Act shall be a person possessing the qualifications prescribed in Rule 44 or a degree in Ayurveda, Siddha or Unani system, as the case may be conferred by a University a State Government or Statutory Faculties, Councils and Boards of Indian Systems of Medicine recognized by the Central or State Government, as the case may be, for this purpose and has had not less than three years post graduate experience in the analysis of drugs in a

laboratory under the control of (i) a Government Analyst appointed under the Act, or (ii) a Chemical Examiner to Government or (iii) the head of an institution specially approved for the purpose by the appointing authority.

**Rule 44. Qualifications of Government Analyst.**– A person appointed as a Government Analyst under the Act shall be a person who:–

- a) is a graduate in Medicine or Science or Pharmacy or Pharmaceutical Chemistry of a [University established in India by the law or has an equivalent qualification recognized and notified by the Central Government for such purpose] and has had not less than five years’ training on testing of drugs in a laboratory under the control of (i) a Government Analyst appointed under the Act, or (ii) the head of an Institution or testing laboratory approved for the purpose by the appointing authority [or has completed two years training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory], or
- b) possesses a post-graduate degree in Medicine or Science or Pharmacy of Pharmaceutical Chemistry of a [University established in India by the law or has an equivalent qualification recognized and notified by the Central Government for such purpose] or possesses the Associate ship Diploma of the Institution of Chemists (India) obtained by passing the said examination with ‘Analysis of Drugs and Pharmaceuticals’ as one of the subjects and has had after obtaining the said post-graduate degree or diploma not less than three Years’ experience in the testing of drugs

in a laboratory under the control of (i) a Government Analyst appointed under the Act, or (ii) the head or an Institution of testing laboratory approved for the purpose by the appointing authority [or has completed two years' training on testing of drugs, including items stated in Schedule C, in Central Drugs Laboratory]:

Provided that –

- i) the purpose of examination of items in Schedule C,–
  - (ia) the persons appointed under clause (a) or (b) and having degree in Medicine, Physiology, Pharmacology, Microbiology, Pharmacy should have experience or training in testing of said items in an institution or laboratory approved by the appointing authority for a period of not less than six months;
  - (ib) the person appointed under clause (a) or (b) but not having degree in the above subject should have experience or training in testing of the said Schedule C drugs for a period of not less than three years in an institution or laboratory approved by the appointing authority or have completed two years training on testing of drugs including item stated in Schedule C in Central Drugs Laboratory;]
- (ii) for a period of four years from the date on which Chapter IV of the Act takes effect in the States, persons, whose training and experience are regarded by the appointing authority as affording, subject to such further training, if any, as may be considered necessary, a reasonable guarantee of adequate knowledge and competence may be appointed as Government Analysts. The persons so appointed may, if

the appointing authority so desires, continue in service after the expiry of the said period of four years;

- (iii) no person who is engaged directly or indirectly in any trade or business connected with the manufacture of drugs shall be appointed as a Government Analyst for any area:

Provided further that for the purpose of examination of Antisera, Toxoid and Vaccines and Diagnostic Antigens for Veterinary use, the person appointed shall be a person who is a graduate in Veterinary Science, or general science, or medicine or pharmacy and has had not less than five years' experience in the standardization of biological products or a person holding a post-graduate degree in Veterinary Science, or General Science, or medicine or Pharmacy or Pharmaceutical Chemistry with an experience of not less than three years in the standardization of biological products:

Provided also that persons, already appointed as Government Analysts may continue to remain in service, if the appointing authority so desires, notwithstanding the fact that they do not fulfill the qualifications as laid down in clause (a) clause (b) or the preceding proviso.

#### **166. Duties of Government Analyst.–**

- (1) The Government Analyst shall analyse or test or cause to be analysed or tested such sample of Ayurvedic (including Siddha) or Unani drugs as may be sent to him by Inspectors or any other persons or authority authorized by the Central Government or a State Government under the provisions of Chapter IV-A of the Act and shall furnish reports of the results or test or analysis in accordance with these

rules.

(2) A Government Analyst appointed under Section 33 F shall from time to time forward to the Government reports giving the results of analytical work and research with a view to their publication at the discretion of the Government.

**167. Qualification of Inspector.**— A person who is appointed an Inspector under Section 33-G shall be a person who –

- a) has the qualifications laid down under Rule 49 and shall have undergone practical training in the manufacture of Ayurvedic (including Siddha) or Unani drug, as the case may be; or
- b) has degree in Ayurvedic or Siddha or Unani system or a degree in Ayurveda Pharmacy, as the case may be, conferred by a University or a State Government or a Statutory Faculty, Council or Board of Indian Systems of Medicine recognized by the Central Government or the State Government for this purpose; or
- c) has a diploma in Ayurveda, Siddha or Unani System, as the case may be, granted by a State Government or an Institution recognized by the Central Government or a State Government for this purpose).

**{49. Qualifications of Inspectors.**—

A person who is appointed an Inspector under the Act shall be a person who has a degree in Pharmacy or Pharmaceutical Sciences or Medicine with specialization in Clinical Pharmacology or Microbiology from a University established in India by law:

Provided that only those Inspectors—

- i) who have not less than 18 months' experience in the manufacture of at least one of the substances specified in Schedule C, or
- ii) who have not less than 18 months' experience in testing of at least one of the substances in Schedule C in a laboratory approved for this purpose by the licensing authority, or
- iii) who have gained experience of not less than three years in the inspection of firm manufacturing any of the substances specified in Schedule C during the tenure of their services as Drugs Inspectors; shall be authorized to inspect the manufacture of the substances mentioned in Schedule C:}

[Provided further that the requirement as to the academic qualification shall not apply to persons appointed as Inspectors on or before the 18<sup>th</sup> day of October, 1993.}]

## Standards of Ayurvedic, Siddha and Unani Drugs

**168.** Standards to be complied with in manufacture for sale or for distribution of Ayurvedic, Siddha and Unani Drugs.-

Sl.No.	Class of Drugs	Standards to be complied with
1.	[***] drugs included in Ayurvedic Pharmacopoeia	The standards for identity, Purity and strength as given in the editions of Ayurvedic Pharmacopoeia of India for the time being in force.
2.	Asavas and Aristas	The upper limit of alcohol as self generated alcohol should not exceed 12% v/v excepting those that are otherwise notified by the Central Government from time to time.

**169. Permitted Excipients.**— Permitted Excipients, *i.e.* additives, preservatives, antioxidants, colouring agents, flavoring agents, alternate sweeteners specified in column 2) of the Table below are permitted in Ayurveda or Siddha or Unani drugs as per reference standard or grade under the prevention of Food Adulteration Act (PFA), Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), United States, National Formulary (USNF) and others as mentioned in column (3) of the Table, namely:

Sl.No.	Permitted Excipients	Reference Standard/Grade
<b>A.</b>	<b>Additives:</b>	
1.	Activated Charcoal	IP
2.	Agar	PFA
3.	Alginic Acid & its salts	PFA
4.	Arachis Oil	PFA
5.	Beeswax	IP
6.	Bentonite	IP
7.	Calcium Carbonate	PFA
8.	Calcium Phosphate Dibasic	IP
9.	Calcium Phosphate Tribasic	IP
10.	Carbomer	IP
11.	Carmellose Sodium	IP
12.	Carnauba Wax	IP
13.	Cellulose & its derivatives	IP
14.	Cetocetyl alcohol	IP
15.	Citric acid & its salts	PFA
16.	Colloidal Silicon Dioxide	IP

Sl.No.	Permitted Excipients	Reference Standard/Grade
17.	Dextrin & its derivatives	PFA/IP
18.	Dextrose	PFA
19.	Emulsifying Anionic Wax	IP
20.	Gelatin	IP
21.	Glucose	PFA
22.	Glycerin	IP
23.	Guar Gum	PFA
24.	Gum Acacia	PFA
25.	Hard Paraffin	IP
26.	Hydrogenated Vegetable Oil	PFA
27.	Icing Sugar	PFA
28.	Invert Sugar Syrup	BP
29.	Isopropyl myristate	IP
30.	Isopropyl palmitate	BP
31.	Kokam Butter	PFA
32.	Lactose	IP
33.	Lecithin/Soya Lecithin	USNF
34.	Light magnesium Carbonate	IP
35.	Light Mineral Oil	IP
36.	Liquid Glucose	PFA
37.	Liquid Paraffin	IP
38.	Magnesium aluminium silicate	BP
39.	Magnesium Carbonate	IP
40.	Magnesium Oxide	IP
41.	Malic Acid	PFA
42.	Malt Extract	IP
43.	Maltodextrin	USNF
44.	Mannitol	IP
45.	Methacrylic acid ethylacrylate	USNF
46.	Microcrystalline Wax	IP
47.	Pectic Enzyme	In house specification
48.	Pectic Enzyme	PFA
49.	Poloxamer	USNF
50.	Polyethylene Glycol	IP
51.	Polymethacrylate	IP
52.	Polysorbates	IP
53.	Polyvinyl acetate phthalate	IP
54.	Polyvinyl alcohol	IP
55.	Polyvinyl pyrrolidone	IP
56.	Potassium Bicarbonate	IP
57.	Povidone & its derivatives	IP
58.	Propylene Glycol	IP
59.	Shellac	IP
60.	Skimmed Milk Powder	PFA
61.	Sodium Bicarbonate	IP
62.	Sodium Chloride	PFA
63.	Sodium Edeate	PFA
64.	Sodium Hydroxide	IP
65.	Sodium Lauryl Sulphate	IP
66.	Sodium Silicate	IP

Sl.No.	Permitted Excipients	Reference Standard/Grade
67.	Sodium Starch Glycollate	IP
68.	Sodium Stearyl Fumarate	IP
69.	Soft Paraffin	IP
70.	Sorbitan Esters	IP
71.	Sorbitol	IP
72.	Starch & its derivatives	IP
73.	Stearic Acid & its salts	IP
74.	Sucrose	IP
75.	Talc	IP
76.	Tartaric Acid & its salt	PFA
77.	Titanium Dioxide	IP
78.	Wax microfine	IP
79.	Wax non-ionic emulsifying IP	
80.	White petroleum jelly	IP
81.	Xanthan Gum	USNF
82.	Xylitol	USNF
83.	Yeast	PFA
84.	Yellow petroleum jelly	IP
85.	Yellow petroleum wax	IP
86.	Zinc oxide	IP
<b>B.</b>	<b>Preservatives:</b>	
1.	Acetic acid	PFA
2.	Benzalkonium chloride	IP
3.	Benzethonium chloride	IP
4.	Benzoic acid & its salts	PFA
5.	Bronopol	BP
6.	Butyl paraben	BP
7.	Cetrimide	IP
8.	Ethyl paraben	BP
9.	Imid urea	In house specification
10.	Methyl Paraben & its salts	PFA
11.	Phenyl mercuric nitrate	IP
12.	Propionic acid & its salts	PFA
13.	Propyl parabe & its salts	PFA
14.	Sorbic acid & its salts	PFA
<b>C.</b>	<b>Antioxidants:</b>	
1.	Ascorbic acid & its salts & esters	PFA
2.	Butylated hydroxyl anisole	PFA
3.	Butylated hydroxyl toluene	PFA
4.	Gallic acid esters	PFA
5.	Potassium metabisulphite	PFA
6.	Sodium metabisulphite	PFA
<b>D.</b>	<b>Colouring agents:</b>	
	As permitted under rule 127 of Drugs and Cosmetics Rules 1945	
<b>E.</b>	<b>Flavouring agents</b>	
	As permitted under Fruit Product Order and PFA Act, Rule 163.	
<b>F.</b>	<b>Alternate Sweeteners:</b>	
	As permitted under Fruits Product Order.	

FORM-1A

SCHEDULE-A

# Memorandum to the Pharmacopoeial Laboratory for Indian Medicine (PLIM)

.....

From.....  
(Full name, Designation & Postal address of the sender)

Serial No.....

To the Director, Pharmacopoeial Laboratory for Indian Medicine,

I send herewith under the provisions of section 11(2)/section 33-H of the Drugs and Cosmetics Act, 1940, sample(s) of a drug purporting to be ..... for test or analysis and request that a report of the result of the test or analysis may be supplied to this Court.

2. The Distinguishing number on the packet is .....
3. Particulars of offence alleged .....
4. Matter on which opinion is required .....
5. A fee of Rs. .... has been deposited in Court.

Date.....

.....  
Magistrate/Authorized Signatory

## FORM-2A

## Certificate of Test or Analysis from the Pharmacopoeial Laboratory for Indian Medicine or Government Analyst

.....

Certified that the samples, bearing number ..... purporting to be a sample of ..... received on ..... with memorandum No. .... dated ..... from ..... has been tested/analyzed and that the result of such test/analysis is as stated below.

2. The condition of the seals on the packet on receipt was as follows:-

\*3. In the opinion of the undersigned the sample is of standard quality as defined in the Drugs and Cosmetics Act, 1940, or rules thereunder for the reasons given below.

Or

In the opinion of the undersigned the sample is not of standard quality as defined in the Drugs and Cosmetics Act, 1940, or rules thereunder for the reasons given below.

Note: \*delete whichever is not applicable”

(Signature of the Analyst Person-in-Charge of testing)

Date

Place

Name & Designation & Seal.....

Name & Address of the Laboratory.....

## FORM-8

## Application for Licence to Import Drugs (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules, 1945

---

I/we ..... (full address with telephone number, fax number and e-mail address) hereby apply for a licence to import drugs specified below manufactured by M/s. .... (full address, with telephone number, fax, and e-mail no.)

2. Names of the drugs to be imported:

i)

ii)

iii)

3. I/we ....., enclose herewith an undertaking in Form 9 dated ..... signed by the manufacturer as required by rule 24 of the Drugs and Cosmetics Rule 1945.

4. I/we ....., enclose herewith a copy of Registration Certificate concerning the drug to be imported in India, issued under Form 41 of the rules, *vide* Registration Certificate No..... Dated ..... Issued ..... through M/s ..... (name and full address) ..... valid upto .....

5. I/we, ....., hold a valid wholesale licence for sale or distribution of drugs or valid licence to manufacture drugs, under the provisions of the Act and rules made thereunder. A copy of the said licence is enclosed.

6. A fee of ..... has been credited to Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs

## FORM-9

## Form of Undertaking to Accompany an Application for an Import Licence

.....

Whereas ..... of ..... intends to apply for a licence under the Drugs manufactured by us, we ..... of ..... hereby give this undertaking that for the duration of the said licence:-

- 1) the said application shall be our agent for the import into India;
- 2) we shall comply with the conditions imposed on a licence by [Rule 74 and 78] of the Drugs and Cosmetics Rules, 1945;
- 3) we declare that we are carrying on the manufacture of the drugs mentioned in this undertaking at the premises specified below, and we shall from time to time report any change of premises on which manufacture will be carried on and in cases where manufacture is carried on in more than one factory any change in the distribution of functions between the factories;
- 4) we shall comply with the provisions of Part IX of the Drug and Cosmetics Rules, 1945;
- 5) every drug manufactured by us for import under licence into India shall as regards strength, quality and purity conform with the provisions of Chapter III of the Drugs and Cosmetics Rules, 1945;
- 6) we shall comply with such further requirement, if any, as may be specified by Rules, by the Central Government under the Act and of which the licensing authority has given to the licensee not less than four months notice.

Particulars of premises where manufacture is carried on.

Date .....

Signature .....

Name .....

Designation .....

Seal/Stamp of manufacturer or on behalf of the manufacturer

## FORM-10

# Licence to Import Drugs (excluding those specified in Schedule X) to the Drugs and Cosmetics Rules, 1945

.....

Licence Number .....

Date.....

1. .... (Name and full address of the importer) .....  
..... is hereby licensed to import into India during the period for which this licence is in force, the drugs specified to import into India during the period for which this licence is in force, the drugs specified below, manufactured by M/s. .... (name and full address) and any other drugs manufactured by the said manufacturer as may from time to time be endorsed on this licence.

2. This licence shall be in force from ..... to ..... unless it is sooner suspended or cancelled under the said rules.

3. Names of drugs to be imported:

Place .....

Date .....

Licensing Authority  
Seal/Stamp

## FORM-11

## Licence to Import Drugs for the Purpose of Examination, Test or Analysis

.....

I, ....., of ..... is hereby licensed to import from ..... the drugs specified below for the purposes of examination, test or analysis at ..... Or in such other places as the licensing authority may from time to time authorize.

2. This license is subject to the conditions prescribed in the Rules under the Drugs and Cosmetics Act, 1940.

3. This licence shall, unless previously suspended or revoked, be in force for a periods of one year from the date specified below:-

Names of drugs

Quantities which may be imported

Date .....

Licensing Authority

## FORM-11A

## Licence to Import Drugs by a Government Hospital or Autonomous Medical Institution for the Treatment of Patients

.....

Licence No. .... Date .....

Dr. .... Designation .....

(Name of College/Hospital/Autonomous Institution) .....  
is hereby licensed to import from M/s. .... (name and full  
address) the drugs specified below for the purpose of treatment of patients for the  
disease (name of the disease) ..... at ..... or in such other  
places as the licensing authority may from time to time authorize.

2. This licence shall, unless previously suspended or revoked, be in force for a  
period of one year from the date of issue specified above.

3. Names of drugs to be imported:

Names of drugs	Quantity which may be imported

Place.....

LICENSING AUTHORITY

Date .....

Seal/Stamp

1. The licence shall be displayed in the office of the Medical Superintendent of Government Hospital/Head of Institution of Autonomous Medical Institution.
2. The licensee shall store the drugs imported under this licence under proper storage conditions.
3. The drugs under this licence shall be exclusively used for the treatment of patients, and a record shall be maintained in this regard, by a registered pharmacist giving the full name(s) and address (es) of the patients, diagnosis, dosage schedule, total quantity of drugs imported and issued, and shall be countersigned by the Medical Superintendent of the Government Hospital of Head of the Autonomous Medical Institution which shall be produced, on demand by an Inspector appointed under the Act.



## FORM-13A

## Certificate of Tests or Analysis by Government Analyst under Section 33-H of the Drugs and Cosmetics Act, 1940

.....

1. Name of Inspector from whom received .....
2. Serial No. and date of Inspector's memorandum .....
3. Number of sample .....
4. Date of receipt .....
5. Name of ingredients purporting to have been used in the preparation of the sample .....
6. Condition of seal on the package .....
7. Results of test or analysis .....

Date .....

Government Analyst .....

## FORM-18A

## Memorandum to Government Analyst

.....

Serial No.....

From

To

The Government Analyst

The portion of sample/container described below is sent herewith for test of analysis under the provisions of Section 33-H of the Drugs and Cosmetic Act, 1940. The portion of sample/container has been marked by me with the following mark.

Details of portion of sample or container with name of ingredients from which it is claimed to be made.

Date .....

Inspector.....]

## FORM-24D

## Application for the Grant/Renewal of Licence to Manufacture for Sale of Ayurvedic/Siddha or Unani Drugs

.....

1. I/We ..... of ..... hereby apply for the grant renewal of a licence to manufacture Ayurvedic (including Siddha) or Unani drugs on the premises situated at .....
2. Names of drugs to be manufactured (with details).
3. Names qualifications and experience of technical staff employed for manufacture and testing of Ayurvedic (including Siddha) or Unani drugs .....
4. A fee of rupees ..... has been credited to the Government under the head of account ..... and the relevant Treasury Challan in enclosed herewith.

Date .....

Signature .....  
(applicant)

Note: The application should be accompanied by a plan of the premises.

## FORM-24E

**Application for Grant or  
Renewal of a Loan Licence to  
Manufacture for Sale Ayurvedic  
(including Siddha) or Unani Drugs**

.....

1. I/We ..... of ..... hereby apply for the grant renewal of a loan licence to manufacture Ayurvedic (including Siddha) or Unani Drugs on the premises situated at ..... C/o .....
2. Names of drugs to be manufactured (with details).
3. The Names, qualifications and experience of technical staff actually connected with the manufacture and testing of Ayurvedic (including Siddha) or Unani drugs in the manufacturing premises.
4. I/We enclose.
  - (a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.
  - (b) A true copy of a letter from the manufacturing concern that they agree to lend the service of their competent technical staff, equipment and premises for the manufacture of each item required by me/us and that they shall maintain the registers of raw materials and finished products separately in this behalf.
  - (c) Specimen of labels cartons of the drugs proposed to be manufactured.
5. A fee of Rs..... has been credited to Government under the head of account ..... and the relevant Treasury Challan is enclosed herewith.

Date .....

Signature .....  
(applicant)

## FORM-25D

## Licence to Manufacture for the Sale of Ayurvedic (including Siddha) or Unani Drugs

.....

No. of licence.....

1. .... is/are hereby licensed to manufacture the following Ayurvedic (including Siddha) or Unani drugs on the premises situated at ..... under the direction and supervision of the following technical staff:-

a) Technical staff (names).

b) Names of drugs (each item to be separately specified).

2. The licence shall be in force from ..... to .....

3. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act 1940.

Date of Issue .....

Signature.....

Designation .....

## FORM-25E

## Loan Licence to Manufacture for Sale Ayurvedic (including Siddha) or Unani Drugs

.....

1. Number of licence .....
2. .... of ..... is hereby granted a loan licence to manufacture for sale Ayurvedic (including Siddha) and Unani drugs, on the premises situated at ..... C/o ..... under the direction and supervision of the following expert, technical staff:
  - a) Technical Staff (Names) .....
  - b) Name of drugs (each item to be separately specified)
3. The licence shall be in force from ..... to .....
4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date of Issue .....

Signature .....

Designation .....

## FORM-26D

## Certificate of Renewal of Licence to Manufacture for Sale Ayurvedic (including Siddha) or Unani Drugs

.....

1. Certified that licence No..... granted on the ..... to Shri/Messrs ..... for the manufacture of Ayurvedic/Siddha or Unani drugs at the premises situated at ..... has been renewed from ..... to .....
2. Names of technical staff .....
3. Names of drugs (each item to be separately specified).

Date .....

Signature .....

Designation .....

## FORM-26E

## Certificate of Renewal of Loan Licence to Manufacture for Sale Ayurvedic (including Siddha) or Unani Drugs

.....

1. Certified that loan licence No..... granted on the .....  
to ..... for the manufacture of Ayurvedic/Siddha/Unani drugs at  
the premises situated at ..... C/o ..... has been  
renewed from ..... to .....

2. Names of technical staff ..... Date .....

Date .....

Signature .....

Designation .....

## FORM-26E-1

## Certificate, of Good Manufacturing Practices (GMP) to Manufacturer of Ayurvedic (including Siddha) or Unani Drugs

.....

1. Certified that manufacturing unit licensee, namely ..... situated  
at ..... State ..... Licence No.....  
comply with the requirements of Good Manufacturing Practices of Ayurvedic-  
Siddha -Unani drugs as laid down in Schedule T of the Drugs and Cosmetic Rules,  
1945.

This certificate is valid for a period of three years.

Date .....

Signature .....

Place .....

Designation .....



- |   |                          |
|---|--------------------------|
| 17. Sattva-Sattu  | 17. Marham, Qairooti     |
| 18. Kupipakva Rasayana-Kuppi Centuram   | 18. Humool, Furzaja      |
| 19. Parpati   | 19. Bakhoor              |
| 20. Pishti  | 20. Nabati Advia         |
| 21. Bhasma-Parpam   | 21. Maadni Advia         |
| 22. Mandura-Atai Kutinir  | 22. Ajsad Advia          |
| 23. Rasayoga-Centuram   | 23. Haiwani Advia        |
| 24. Lauha   | 24. Jauhar               |
| 25. Ghana Sattva  | 25. Natool               |
| 26. Kvath Pravahi-Kutinir   | 26. Nashooq, Naswar      |
| 27. Panak (Syrup)-Manappaku   | 27. Shamoom              |
| 28. Tablet-Mattirai   | 28. Saoot (Nasal drops)  |
| 29. Capsule   | 29. Mazoogh              |
| 30. Ointment-Kalimapu   | 30. Tila                 |
| 31. Phalavrti   | 31. Lashooq              |
| 32. Dhoomravarti/Doopan   | 32. Gulqand              |
| 33. Kshar Suta/Kshar Varti  | 33. Fateela              |
| 34. Single drugs:   | 34. Ghaza, Ubtan, Sabagh |
| a) Plant based  |                          |
| b) Mineral based  |                          |
| c) Metal based  |                          |
| d) Animal based   |                          |
| e) Synthetic  |                          |
| f) Any other Ayurvedic,<br>Siddha, Unani formulation  |                          |
| 35. Pushp (Phool)   | 35 Capsule               |
| 36. Nasya   | 36. Haqna                |
| 37. Swarasa (Fresh juice)   | 37. Naurah               |
| 38. Karna Bindu (Ear drops)   | 38. Latookh              |
| 39. Any other dosage form of<br>patent and Proprietary and<br>Ayurvedic, Siddha, Unani Drug | 39. Vajoor (Throat pain) |
| 40. Mazmazah (Mouth washer)   |                          |

1. Names, qualifications and experience of experts employed for testing and the person-in-charge of testing.
2. List of testing equipment provided.
3. I/We enclose a plan of the testing premises showing the location and area of the different sections thereof
4. An inspection fee of rupees ..... has been credited to Government under the head of account .....

Date .....

Signature .....

## FORM-48

**Approval for carrying out tests  
or analysis on Ayurvedic, Siddha and  
Unani drugs or raw Materials used in  
the manufacture thereof on behalf of  
licensees for manufacture for sale of  
Ayurvedic, Siddha and Unani drugs**

.....

Number of approval and date of issue :

1. Approval is hereby granted to ..... for carrying out tests for identity, purity, quality and strength on the following categories of Ayurvedic, Siddha or Unani drugs and the raw materials used in the manufacture thereof on the premises situated at .....

Categories of Ayurvedic, Siddha and Unani drugs:

.....  
.....  
.....

2. Names of experts employed for testing and the person-in-charge of testing ..... (experts) and ..... (person-in-charge).

3. The approval shall be in force from ..... to .....

4. The approval is subject to the conditions stated below and such other conditions as may be specified in the rules for the time being in force under the Act.

Date .....

Signature .....

Place .....

Designation .....

Seal of state Licensing Authority

**Condition of Approval**

1. This approval and any certificate of renewal in Form 42 shall be displayed in the approval premises and shall be produced at the request of the Inspectors appointed under the Act.
2. If the applicant wishes to undertake during the currency of the approval the testing of any other category of Ayurvedic, Siddha or Unani drugs it should apply to the approving authority for necessary endorsement as provided in rule 160A. This approval will be deemed to the item so endorsed..
3. Any change in the experts or in the person-in-charge of the testing shall be forthwith reported to the approving authority.
4. The applicant shall inform the approving authority in writing in the event of any change of the constitution of the laboratory operating under this Form. Where any change in the constitution of the laboratory takes place, the current approval shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh approval has been taken from the approving authority in the name of the laboratory with the changed constitution.

Full address of the Applicant





## Fees for the Test or Analysis by the Pharmaopoeial Laboratory for Indian Medicine (PLIM) or the Government Analyst

.....

Type of testing/analysis	Cost of testing or analysis in Rupees
1. Test for Sterility	250.00
2. Abnormal toxicity of undue toxicity of safety test	750.00
3. Determination of lethal doses LD 50 to 10 on Mice	2500.00
4. Chemical test for each ingredient	500.00
5. Disinfectants	1000.00
6. Any other test requiring animal experimentation	500.00
7. Microbiological assay	750.00
8. Microscopic examination of single drugs	250.00
9. Microscopic examination of raw material of compounds	500.00
10. Chemical identifications as per Pharmacopoeia	250.00
11. Disintegration of tablets and capsules	
(a) Ordinary	100.00
(b) Sugar coated	200.00
(c) Enteric coated	400.00
12. Physiochemical Assays	300.00
13. Tests other than assay (limit tests for impurities, ash content, total solids, acid value, iodine value, saponification value, loss on drying etc.) for each test	100.00
14. Optical rotation	250.00
15. Refractive Index	250.00
16. Arsenic testing	250.00
17. Paper chromatography	250.00
18. Thin layer chromatography	300.00
19. Column chromatography	2500.00
20. Gas liquid chromatography	1000.00
21. H.P.T.L.C. restricted to single drugs qualitative	1000.00
22. Atomic absorption Spectrophotometry for Hg,Pb, As, Cd.	500.00
23. Cosmetics/tailas/creams	500.00
24. Identification test for raw material of plant origin (other than assay of constituents)	125.00
25. Identification test for raw material of chemical origin (other than assay)	100.00
26. Limit test for drugs of chemical origin	150.00
27. Other miscellaneous tests	1000.00

Note: Sample testing charges will be determined/revised by the Director or Government Analyst of the Pharmacopoeial Laboratory for Indian Medicine, as the case may be in consultation with Department of Ayurveda, Yoga, Unani, Siddha and Homoeopathy, Ministry of Health and Family Welfare.”

# List of Poisonous Substances under the Ayurvedic (including Siddha) and Unani Systems of Medicine

## A. AYRVEDIC SYSTEM

### I. Drugs of vegetable origin

Ahipena	<i>Papaver somniferum</i> Linn.
Arka	<i>Colotropis gigantean</i> (Linn.) R. Br. Ex. Ait.
Bhallataka	<i>Semecarpus anacardium</i> Linn. f.
Bhanga	<i>Cannabis sativa</i> Linn.
Danti	<i>Baliospermum montanum</i> Mall. Arg.
Dhattura	<i>Datura metel</i> Linn.
Gunj	Abrus
Jaipala (Jayapala)	<i>Croton tiglium</i> Linn.
Karaveera	<i>Nerium indicum</i> Mill.
Langali	<i>Gloriosa superba</i> Linn.
Parasilka Yavani	<i>Hyocyamus inibar</i> Linn.
Snuhi	<i>Euphorbia nerifolia</i> Linn.
Vatsanabha	<i>Acontium dasmanthum</i> Stapfex Holm.
Vishmushti	<i>Strychnos nuxvomica</i> Linn.
Shringivisha	<i>Acontium dasmanthum</i> Stapfex Holm.

### II. Drugs of Animal Origin

Sarpa Visha	Snake poison.
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### III. Drugs of Mineral Origin

Gauripashna	Arsenic
Hartala	Arseno sulphide
Manahashila	Arseno sulphide
Parada	Mercury
Rasa Karpura	Hydragyri subchloridum
Tuttha	Copper sulphate
Hingula	Cinnabar
Sindura	Red oxide of lead
Girisindura	Red oxide of mercury.

## B. SIDDHA SYSTEM

Abini	<i>Papaver somniferum</i> Linn.
Alari	<i>Nerium indicum</i> Mill.
Azhavanam	<i>Lawsonia inermis</i> Linn.
Attru Thumatti	<i>Citrullus colocynthis</i> Scharad.
Anai Kunri	<i>Adenanthera pavonina</i> Linn.
Rattha Polam	<i>Aloe barbadensis</i> Mill.

Ilaikalli	<i>Euphorbia neriifolia</i> Linn.
Eezhaththalari	<i>Plumeria acuminata</i> Ait.
Gomatthai	<i>Datura stramonium</i> Linn.
Etti	<i>Strychnos nuxvomica</i> Linn.
Ganja	<i>Cannabis sativa</i> Linn.
Kalappaik Kizhangu	<i>Gloriosa superba</i> Linn.
Kodikkalli	<i>Euphorbia tituqalli</i> Linn.
Chadurakkalli	<i>Euphorbia antiquorum</i> Linn.
Keria polarn	Atloe sp.
Kattamanakku	<i>Jatropha glandulifera</i> Roxb.
Kattu thumatti	<i>Cucumis trigonus</i> Roxb.
Kunri	<i>Arbus precatorusi</i> Linn.
Cheran Kottai	<i>Semicarpis anacardium</i> Linn.
Thillai	<i>Enoecaria agallocha</i> Linn.
Nabi	<i>Aconitum feron</i> Wall.
Nervalam	<i>Croton tiglium</i> Linn.
Pugai Elai	<i>Nicotiana tobacum</i> Linn.
Marukkarai	<i>Randia dumertorum</i> Linn.
Mansevikkalli	<i>Euphorbia</i> sp.

### C. UNANI SYSTEM

#### I. Drugs of Vegetable Origin

Afiyun	<i>Papaver somniferum</i> Linn.
Bazrul-banj	<i>Hyoscyamus niger</i> Linn.
Bish	<i>Aconitum chasmanthum</i> Stapfex Holmes.
Bhang	<i>Cannabis sativa</i> Linn.
Charas	<i>Cannabis sativa</i> Linn.
Dhatura seeds	<i>Datura metal</i> Linn.
Kuchla	<i>Strychnos nuxvomica</i> Linn.
Shokran	<i>Conium maculatum</i> Linn.

#### II. Drugs of Animal Origin

Sanp (head)	Snake (head)
Telni makkhi	<i>Mylabaris cichorii</i> Linn.
	<i>Mylabaris Pustulata</i> Thumb
	<i>Mylabaris rnicilenta</i>

#### III. Drugs of Mineral Origin

Darachikna	Hydrargyri perchloridum
Hira	Diamond
Ras Kapoor	Hydrargyri perchloridum
Shingruf	Hydrargyri bisulphuratum
Zangar	Cupri subaccetas
Sammul-Far (Abyaz, Asfar, Aswad) and Ahmar)	Arsenic (white, yellow, black and red)
Tootiya	Copper Sulphate
Para	Hydrargyrum
Hartal	Arsenic trisulphide (yellow).]

**SCHEDULE FF**  
(See Rule 126-A)  
**Standards for Ophthalmic Preparations**

**PART-A**  
**Ophthalmic Solutions & Suspension**

*Ophthalmic Solutions and Suspensions shall –*

(a) be sterile when dispensed or sold in the unopened container of the manufacture, except in case of those ophthalmic solutions and suspensions which are not specifically required to comply with the test for 'Sterility' in the Pharmacopoeia;

(b) Contain one or more of the following suitable substances to prevent the growth of microorganisms.

(i) Benzalkonium Chloride, 0.01 per cent (This should not be used in solutions of nitrates or salicylates).

(ii) Phenyl mercuric nitrate: 0.001 per cent.

(iii) Chlorbutanol: 0.5 per cent.

(iv) Phenyl ethyl alcohol: 0.5 per cent.

Provided that solutions used in surgery shall not have any preservatives and be packed in single dose container.

Provided further that the licensing authority may in his discretion authorize the use of any preservatives or vary the concentration prescribed on being satisfied that its use affords equal guarantee for preventing the growth of microorganisms.

(c) be free from foreign matter;

(d) be contained in bottles made of either neutral glass or soda glass specially treated to reduce the

amount of alkali released when in contact of aqueous, or in suitable plastic containers which would not in any way be incompatible with the solutions;

The droppers to be supplied with the containers of ophthalmic solutions and suspension shall be made of neutral glass or of suitable plastic material and when supplied separately shall be packed in sterile cellophane, or other suitable packings.

(e) In addition to complying with the provisions of the labeling laid down in the rules the following particulars shall also be shown on the label of container:

(i) The statement 'Use the solution within one month after opening the container'.

(ii) Name and concentration of the preservatives, if used.

(iii) The words 'NOT FOR INJECTION'.

*Of containers or Carton or Package leaf-let:*

(i) Special instructions regarding storage, wherever applicable.

(ii) A cautionary legend reading as.

**WARNING**

(i) If irritation persists or increases, discontinue the use and consult physician.

(ii) Do not touch the dropper tip or other dispensing tip to any surface since this may contaminate solutions.

## PART-B

# Ophthalmic Ointments

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*Ophthalmic ointment shall –*

- (a) be sterile when dispensed or when sold in the unopened container of the manufacture;
- (b) be free from foreign matter;
- (c) in addition to complying with the provisions for labeling laid down in the rules the following particulars shall be shown on the container or

carton or package leaflet –

- (i) Special instructions regarding storage wherever applicable.
- (ii) A cautionary legend reading.

### **WARNING**

If irritation persists or increases discontinue the use and consult physician.

## Ophthalmic Preparations in Ayurveda, Siddha and Unani Medicines

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All Eye Ointment and other ophthalmic preparation should confirm to the

Schedule FF of Drugs and Cosmetics Rule.



between different drugs or components thereof and avoid the risk of omission of any manufacturing or control step.

- iii) Designed, constructed and maintained to prevent entry of insects and rodents. Interior surface (walls, floors and ceilings) shall be smooth and free from cracks and permit easy cleaning and disinfection. The walls of the room in which the manufacturing operations are carried out shall be impervious to and be capable of being kept clean. The flooring shall be smooth and even and shall be such as not to permit retention or accumulation of dust or waste products.
- iv) Provide with proper drainage system in the processing area. The sanitary fitting and electrical fixtures in the manufacturing area shall be proper and safe.
- v) Furnace Bhatti section could be covered with tin roof and proper ventilation, but sufficient care should be taken to prevent flies and dust.
- vi) There should be fire safety measures and proper exits should be there.

**1.1(C) Water Supply.**— The water used in manufacture shall be pure and of potable quality. Adequate provision of water for washing the premises shall be made.

**1.1(D) Disposal of Waste.**— From the manufacturing sections and laboratories the waste water and the residues which might be prejudicial to the workers or public health shall be disposed off after suitable treatment as per guidelines of pollution control authorities to render them harmless.

**1.1(E) Container's Cleaning.**— In factories where operations involving the use of containers such as bottles, vials and jars are conducted, there shall be adequate arrangements separated from the manufacturing operations for washing, cleaning and drying of such containers.

**1.1(F) Stores.**— Storage should have proper ventilation and shall be free from dampness. It should provide independent adequate space for storage of different types of material, such as raw material, packaging material and finished products.

**1.1(F)(A) Raw Materials.**— All raw materials procured for manufacturing will be stored in the raw materials store. The manufacture based on the experience and the characteristics of the particular raw material used in Ayurveda, Siddha and Unani system shall decide the use of appropriate containers which would protect the quality of the raw material as well as prevent it from damage due to dampness, microbiological contamination or rodent and insect infestation, etc. If certain raw materials require such controlled environmental conditions, the raw materials stores may be sub-divide with proper enclosures to provide such conditions by suitable cabinization. While designing such containers, cabins or areas in the raw materials store, care may be taken to handle the following different categories of raw materials:—

- 1) Raw material of metallic origin.
- 2) Raw material of mineral origin.
- 3) Raw material of animal source.
- 4) Fresh Herbs.
- 5) Dry Herbs or plant parts.
- 6) Excipients etc.

- 7) Volatile oils/perfumes & flavors.
- 8) Plant extracts and exudates/resins.

Each container used for raw material storage shall be properly identified with the label which indicates name of the raw material, source of supply and will also clearly state the status of raw material such as 'UNDER TEST' or 'APPROVED' or 'REJECTED' The labels shall further indicate the identity of the particular supply in the form of Batch No. or Lot. No. and the date of receipt of the consignment.

All the raw materials shall be sampled and got tested either by the in-house Ayurvedic, Siddha and Unani experts (Quality control technical person) or by the laboratories approved by the Government and shall be used only on approval after verifying. The rejected raw material should be removed from other raw material store and should be kept in a separate room. Procedure of 'First in first out' should be adopted for raw materials wherever necessary. Records of the receipt, testing and approval or rejection and use of raw material shall be maintained.

**1.1(F)(B) Packaging Materials.**— All packaging materials such as bottles, jars, capsules etc. shall be stored properly. All containers and closure shall be adequately cleaned and dried before packing the products.

**1.1(F)(C) Finished Goods Stores.**— The finished goods transferred from the production area after proper packaging shall be stored in the finished goods stores within an area marked "Quarantine" After the quality control laboratory and the experts have checked the correctness of finished goods with reference to its packing/labeling as well as the finished product quality as

prescribed, then it will be moved to "Approved Finished Goods Stock" area. Only approved finished goods shall be dispatched as per marketing requirements. Distribution records shall be maintained as required.

If any Ayurvedic, Siddha and Unani drug needs special storage conditions. finished goods store shall provide necessary environments requirements.

**1.1(G) Working space.**— The manufacturing area shall provide adequate space (manufacture and quality control) for orderly placement of equipment and material used in any of the operations for which these are employed so as to facilitate easy and safe working and to minimize or to eliminate any risk of mix-up between different drugs, raw materials and to prevent the possibility of cross contamination of one drug by another drug that is manufactured, stored or handled in the same premises.

**1.1(H) Health Clothing, Sanitation and Hygiene of Workers.**— All works employed in the Factory shall be free from contagious diseases. The clothing of the workers shall consist of proper uniform suitable to the nature of work and the climate and shall be clean. The uniform shall also include cloth or synthetic covering for hands, feet and head wherever required. Adequate facilities for personal cleanliness such as clean towels, soap and scrubbing brushes shall be provided. Separate provision shall be made for lavatories to be used by men and women, and such lavatories shall be located at places separated from the processing rooms. Workers will also be provided facilities for changing their clothes and to keep their personal belongings.

**1.1(I) Medical Services.**– The manufacturer shall also provide:–

- c) adequate facilities for first aid;
- d) medical examination of workers at the time of employment and periodical check up thereafter by a physician once a year, with particular attention being devoted to freedom from infections. Records thereof shall be maintained.

**1.1(J) Equipments.**– For carrying out manufacturing depending on the size of operation and the nature of product manufactured, suitable equipment either manually operated or operated semi-automatically (Electrical or steam based) or fully automatic machinery shall be made available. These may include machines for use in the process of manufacture such as crushing, grinding, powdering, boiling, mashing, burning, roasting, filtering, drying, filling, labeling and packing etc. To ensure ease in movement of workers and orderliness in operations a suitably adequate space will be ensured between two machines or rows of machines. These equipments have to be properly installed and maintained with proper cleaning.

Proper standard operational procedures (SOPs) for cleaning, maintaining and performance of every machine should be laid down.

**1.1(K) Batch Manufacturing Records.**– The licensee shall maintain batch manufacturing record of each batch of Ayurvedic, Siddha and Unani drugs manufactured irrespective of the type of product manufactured (classical preparation or patent and proprietary medicines.) Manufacturing records are required to provide an account of the list of raw material and their quantities obtained from the store, tests conducted during the various stages of manufacture

like taste, colour, physical characteristics and chemical tests as may be necessary or indicated in the approved books of Ayurveda, Siddha and Unani mentioned in the First Schedule of the Drugs and Cosmetics Act, 1940 (23 of 1940). These tests may include any in-house or pharmacopoeial test adopted by the manufacturer in the raw material or in the process material and in the finished product. These records shall be duly signed by Production and Quality Control Personnel respectively. Details or transfer of manufactured drug to the finished products store including dates and quantity of drugs transferred along with record of testing of the finished product, if any, and packaging, records shall be maintained. Only after the manufactured drugs have been verified and accepted quality shall be allowed to be cleared for sale.

It should be essential to maintain the record of date, manpower, machine and equipments used and to keep in process record of various shodhana, Bhavana, burning in fire and specific grindings in terms of internal use.

**1.1(L) Distribution Records.**– Records of sale and distribution of each batch of Ayurvedic, Siddha and Unani Drugs shall be maintained in order to facilitate prompt and complete recall of the batch, if necessary.

**1.1(M) Record of Market Complaints.**– Manufactures shall maintain a register to record all reports of market complaints received regarding the products sold in the market. The manufacturer shall enter all data received on such market complaints investigations carried out by the manufacturers regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints

shall also submit the record of such complaints to the licensing authority. The Register shall also be available for inspection during any inspection of the premises.

Reports of any adverse reaction resulting from the use of Ayurvedic, Siddha and Unani drugs shall also be maintained in a separate register by each manufacturer. The manufacturer shall investigate any of the adverse reaction to find if the same is due to any defect in the product, and whether such reactions are already reported in the literature or it is a new observation.

**1.1(N) Quality Control.**— Every licensee is required to provide facility for quality control section in his own premises or through Government approved testing laboratory. The test shall be as per the Ayurvedic, Siddha and Unani pharmacopoeial standard. Where the tests are not available, the test should be performed according to the manufacturers specification or other information available. The quality control section shall verify all the raw materials monitor in process, quality checks and control the quality of finished product being released to finished goods store/warehouse. Preferably for such quality control there will be a separate expert. The quality control section shall have the following facilities:

1. There should be 150 sq feet area for quality control section.
2. For identification of raw drugs, reference books and reference samples should be maintained.
3. Manufacturing records should be maintained for the various process.
4. To verify the finished products controlled samples of finished products of each batch will be kept for 3 years.
5. To supervise and monitor adequacy

of conditions under which raw material, semi-finished products and finished products are stored.

6. Keep record in establishing shelf life and storage requirements for the drugs.
7. Manufactures who are manufacturing patent proprietary Ayurveda, Siddha and Unani medicines shall provide their own specification and control references in respect of such formulated drugs.
8. The record of specific method and procedure of preparation, that is “Bhavana”, “Mardana” and “Putā” and the record of every process carried out by the manufacturer shall be maintained.
9. The standards for identity, purity and strength as given in respective pharmacopoeias of Ayurvedic, Siddha and Unani systems of medicines published by Government of India shall be complied with.
10. All raw materials will be monitored for fungal, bacterial contamination with a view to minimize such contamination.
11. Quality control section will have a minimum of
  - a) one person with Degree qualification in Ayurveda/ Siddha/Unani (A.S.U) as per Schedule II of Indian Medicine Central Council Act, 1970 (84 of 1970) of a recognized university of Board.
  - b) Provided that Bachelor of Pharmacy, Pharmacognosy and Chemistry may be associated with the quality control section.

### **3.0 Requirement for Sterile Product:**

**A) Manufacturing Areas.**— For the manufacture of sterile Ayurvedic, Unani and Siddha drugs, separate enclosed

areas specifically designed for the purpose shall be provided. These areas shall be provided with air locks for entry and shall be essentially dust free and ventilated with an air supply. For all areas where aseptic manufacture has to be carried out, air supply shall be filtered through bacteria retaining filters (HEPA Filters) and shall be at a pressure higher than in the adjacent areas. The filters shall be checked for performance on installation and periodically thereafter the record of checks shall be maintained. All the surfaces in sterile manufacturing areas shall be designed to facilitate cleaning and disinfection. For sterile manufacturing routine microbial counts of all Ayurvedic, Siddha and Unani drug manufacturing areas shall be carried out during operations. Result of such count shall be checked against established in-house standards and record maintained.

Access to manufacturing areas shall be restricted to minimum number of authorized personnel. Special procedure to be followed for entering and leaving the manufacturing areas shall be written down and displayed.

For the manufacture of Ayurvedic, Siddha and Unani drug that can be sterilized in their final containers, the design of the areas shall preclude the possibility of the products intended for sterilization being mixed with or taken to be products already sterilized. In case of terminally sterilized products, the

design of the areas shall preclude the possibility of mix up between non-sterile and sterile products.

#### **B) Precautions against contamination and mix:-**

- a) Carrying out manufacturing operations in a separate block of adequately isolated building or operating in an isolated enclosure within the building.
- b) Using appropriate pressure differential in the process area.
- c) Providing a suitable exhaust system.
- d) Designing laminar flow sterile air systems for sterile products.
- e) The germicidal efficiency of UV lamps shall be checked and recorded indicating the burning hours or checked using intensity.
- f) Individual containers of liquids and ophthalmic solutions shall be examined against black-white background fitted with diffused light after filling to ensure freedom from contamination with foreign suspended matter.
- g) Expert technical staff approved by the Licensing Authority shall check and compare actual yield against theoretical yield before final distribution of the batch.

All process controls as required under master formula including room temperature, relative humidity, volume filled, leakage and clarity shall be checked and recorded.

## PART-II

## A. List of Machinery, Equipment and Minimum Manufacturing Premises required for the Manufacture of Various Categories of Ayurvedic, Siddha System of Medicines

Sl. No.	Category of Medicine	Minimum manufacturing Space required	Machinery/equipment recommended
		1200 square feet covered area with separate cabins, Partitions for each activity. If Unani medicines are manufactured in same premises and additional area of 400 sq. feet will be required.	
1.	Anjana/Pisti	100 sq. feet	Karel/mechanized/motorized, kharel. End runner/Ball – Mill Sieves/Shifter
2.	Churan/Nasya/Manjan Lepa/Kwath Churn	200 sq. feet	Grinder/Disintegrator/Pulverizer/Powder Mixer/sieves/shifter
3.	Pills/Vatti/Gutika	100 sq. feet	Ball Mill, Mass Mixer Powder mixer Granulator drier. Tablet compressing machine pill/vati cutting machine, stainless steel trays/containers for storage and sugar coating, polishing pan in case of sugar coated tablets, mechanised chattoo (for mixing of guggul) where required.

Sl. No.	Category of Medicine	Minimum manufacturing Space required	Machinery/equipment recommended
4.	Kupi pakva/Ksara/ Parpati/Lavana Bhasma Satva/Sindura Kapur/ Uppu Param	150 sq. feet	Bhatti, Karahi/Stainless steel Vessels/Patila Flask, Multani/Matti/Plaster of Paris, Copper Rod, Earthen container, Gaj Put Bhatti, Muffle furnace (Electrically operated) End/Edge Runner, Exhaust Fan, Wooden/S.S. Spatula.
5.	Kajal	100 sq. feet	Earthen lamps for collection of Kajal, Tipple Roller Mill, End Runner, Sieves, S.S Patila, Filling/packing and manufacturing room should be provided with exhaust fan and ultra violet lamps.
6.	Capsules	100 sq. feet	Air Conditioner de-humidifier, hygrometer, Thermometer, Capsule filling machine and chemical balance.
7.	Ointment/Marham Passi	100 sq. feet	Tube filling machine Crimping Medicine/Ointment Mixer, End Runner/Mill (Where required) S.S Storage Container S.S Patila.
8.	Pak/Avaleh/Khand/ Modak/Lakayam	100 sq. feet	Bhatti section fitted with Exhaust Fan and should be fly proof. Iron Kadahi/S.S Patila and S.S Storage Container.
9.	Panak Syrup/Pravahi Kwath Manapaku	150 sq. feet	Tinctum press, exhaust fan fitted and fly proof Bhatti section. Bottle washing machine, filter press Gravity filter Liquid filling machine, P.P. Capping Machine,
10.	Asava/Aristha	200 sq. feet	Same as mentioned above. Fermentation tanks containers and Distillation plant where necessary, Filter Press.

Sl. No.	Category of Medicine	Minimum manufacturing Space required	Machinery/equipment recommended
12.	Sura	100 sq. feet	Same as mentioned above plus Distillation plant and Transfer pump.
13.	Ark Tinir	100 sq. feet	Maceration tank, Distillation plant, Liquid filling tank with tap/Gravity filter/Filter press, Visual inspection box.
14.	Tail Ghrit Nev	100 sq. feet	Bhatti, Kadahi/S.S. Patila S.S. Storage Containers, Filtration Equipment filling tank with tap/Liquid filling machine.
15.	Aschyotan/Netra Malham Panir Karn bindu, Nasa bindu	100 sq. feet	Hot air oven electrically heated with thermo-static control, cattle gas or electrically heated with suitable mixing arrangement collation mill or ointment mill, tube filling equipment, mixing and storage tanks or stainless steel or of other suitable material sintered glass funnel, seitz filter or filter candle, liquid filling equipment, autoclave.
16.	Each manufacturing unit will have a separate area for Bhatti, furnaces, boilers, puta, etc. This will have proper ventilation, removal of smoke, prevention of flies, insects, dust etc. The furnace section could have tin roof.	200 sq. feet	

## B. List of Machinery, Equipment and Minimum Manufacturing Premises Required for the Manufacture of Various Categories of Unani System of Medicines

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One medicine indicated for one category of medicine could be used for the manufacturing of other category of medicine also. Similarly some of the manufacturing area like powdering, furnace, packing of liquids could also be shared for these items.

Sl. No.	Category of Medicine	Minimum manufacturing Space required	Machinery/equipment recommended
1.	Itrifal Tiryao majoon/Laooq/Jawarish Khamiras	1200 square feet covered area with separate cabins, partitions for each activity. If Ayurveda/Siddha, Medicines are also Manufactured in same premises an additional area of 400 square feet will be required. 100 sq. feet	Grinder/Pulveriser, Sieves, powder mixer (if required), S.S Patilas, Bhatti and other accessories. Planter mixer for Khamiras.
2.	Arq.	100 sq. feet	Distillation Plant (garembic) S.S Storage Tank, Boiling Vessel, Gravity filter, Bottle Filling machine. Bottle washing machine. Bottle drier.
3.	Habb (Pills) and Tablets	200 sq. feet	Ball Mill, Mass Mixer Powder mixer Granulator drier. Tablet compressing machine pill/vati cutting

Sl. No.	Category of Medicine	Minimum manufacturing Space required	Machinery/equipment recommended
			machine, stainless steel trays/containers for storage and sugar coating, polishing pan in case of sugar coated tablets, mechanised chattoo (for mixing of guggul) where required.
4.	Sufoof (Powder)	100 sq. feet	Grinder/Pulveriser, Sieves, Trays, Scoops, Powder mixer (Where required).
5.	Raughan (oils) (Crushing & boiling)	100 sq. feet	Oil Expeller, S.S. Patilas oil Filter bottle, Filling machine, Bottle drier, Bhatti.
6.	Shiyaf, Surma, Kajal	100 sq. feet	End runner, mixing S.S. Vessel
7.	Marham, Zimad (Ointment)	100 sq. feet	Kharal, Bhatti, End runner, Grinder, Pulveriser, Tripple Roller Mill (if needed)
8.	Qurs (Tab)	100 sq. feet	Grinder/Pulveriser, Sieves, Powder mixer (where needed), Granulator, Drier Tablet Compressing Machine, Die punches Trays, O.T. Apparatus, Balance with weights. Scoops, Sugar Coating Pan, polishing pan Heater.
9.	Kushta	100 sq. feet	Bhatti, Kharal, Sil Batta, Earthen pots
10.	Murabba	100 sq. feet	Aluminium Vessels 50-100 kgs. Capacity, Gendna, Bhatti

Sl. No.	Category of Medicine	Minimum manufacturing Space required	Machinery/equipment recommended
11.	Capsule	100 sq. feet	Pulveriser, Powder mixer (where needed), capsule filling machine. Air Conditioner, De humidifier Balance with weights, storage containers, glass.
12.	Sharbat & Jushanda	100 sq. feet	Tinctum Press, exhaust fan fitted, Bhatti section, Bottle washing machine, Filter Press, Gravity filter, Liquid filling tank with tap/liquid filling machine, Hot air oven electrically heated with thermostatic control, Kettle.  Hot air oven eclectically heated with thermostatic control, cettle.
13.	Qutoor Chasm and Marham (Eye drops, eye ointment)	100 sq. feet	
14.	Each manufacturing unit will have a separate area for Bhatti, furnaces, boilers, putta, etc. This will have proper ventilation, removal or smoke, prevention of files, insects, dust etc.	200 sq. feet	

## C. List of Equipment Recommended for In-House Quality Control Section

(Alternatively unit can get the testing done from the government approved laboratory)

(A) Chemistry section	(B) Pharmacognosy section
1. Alcohol Determination Apparatus (complete set)	1. Microscope Binocular
2. Volatile Oil Determination Apparatus	2. Dissecting Microscope
3. Boiling Point Determination Apparatus	3. Microtome
4. Melting Point Determination Apparatus	4. Physical balance
5. Refractometer	5. Aluminium Slide trays
6. Polarimeter	6. Stage Micrometer
7. Viscometer	7. Camera Lucida (Prism and Mirror Type)
8. Tablet Disintegration Apparatus	8. Chemicals, Glass-ware etc.
9. Moisture Meter	
10. Muffle Furnace	
11. Electronic Balance	
12. Magnetic Stirrer	
13. Hot Air Oven	
14. Refrigerator	
15. Glass/Steel Distillation Apparatus	
16. LPG Gas Cylinders with Burners	
17. Water Bath (Temperature Controlled)	
18. Heating Mantles/Hot Plates	
19. TLC apparatus with all Accessories (Manual)	
20. Paper Chromatography apparatus with accessories	
21. Sieve Size 10 to 120 with Sieve shaker	
22. Centrifuge machine	
23. De-humidifier	
24. pH Meter	
25. Limit Test Apparatus	

*Note:* The above requirement of machinery, equipments, space, qualifications are made subject to the modification at the discretion of the Licensing Authority; if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter then in the circumstances in a particular case.

# Order issued by Govt. of India, Deptt. of Ayush

F.No. K-11020/5/97-DCC (AYUSH)

Government of India

Ministry of Health & Family Welfare

(Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy)  
(AYUSH)

Red Cross Building, 1, Red Cross Road,  
New Delhi-110001

Dated: October 10, 2005

## ORDER

In exercise of the powers conferred under Section 33P of the Drugs & Cosmetics Act, 1940 Government of India in the Ministry of Health & Family Welfare, Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) directs the state Licensing Authorities of Ayurveda, Unani and Siddha (ASU) drugs to ensure full compliance by all ASU drug manufacturers of the provisions of Rule 161 (1) and (2) relating to displaying on the label of the container or package of an Ayurveda, Siddha, and Unani drug, the true list of all the ingredients (official and botanical names) used in the manufacture of the preparation together with the quantity of each of the

ingredients incorporated therein. In case all the ingredients can not be mentioned on the label because of their large number the same shall be indicated in the leaflet to be inserted in the package. Further that the container of a medicine shall conspicuously display the words 'Caution to be taken under medical supervision' if the list of ingredients contains a substance specified in Schedule E (1) of the Drugs & Cosmetics Rules 1945. The State ASU Drug Licensing Authorities shall forthwith cancel or suspend the licenses of the defaulting ASU Drug Manufactures under Rule 159 of the Drugs & Cosmetics Rules, 1945.

Sd/-

Shiv Basant

Joint Secretary to Govt. of India

F.No. K-11020/5/97-DCC (AYUSH)  
Government of India  
Ministry of Health & Family Welfare  
(Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy)  
(AYUSH)  
Red Cross Building, 1, Red Cross Road,  
New Delhi-110001

Dated: October 13, 2005

### ORDER

Whereas it has come to the notice of the Government of India in the Ministry of Health & Family Welfare, Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) that the Good Manufacturing Practices (GMP) as prescribed for the preparation of Ayurveda, Unani and Siddha (ASU) drugs under Rule 157 of the Drugs & Cosmetics Rules 1945 and Schedule T thereto are not being followed by a very large number of Ayurveda, Siddha and Unani Drug Manufacturers in spite of sufficient time being allowed and financial assistance being provided to the ASU drug manufactures to become GMP compliant.

Now, therefore, in pursuance of Section 33P of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Government of India in the Ministry of Health and Family Welfare, Department of AYUSH, hereby directs that all the State ASU Drug Licensing Authorities take action against the defaulting ASU drug manufactures for revocation of their licenses under Rules 157, 158 and 159 of the Drugs & Cosmetics Rules, 1945 for failure to comply with the Good Manufacturing Practices notified under Schedule 'T' of the Drugs and Cosmetics Rules, 1945.

Sd/-  
Shiv Basant  
Joint Secretary to Govt. of India

F.No. K-11020/5/97-DCC (AYUSH)  
 Government of India  
 Ministry of Health & Family Welfare  
 (Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy)  
 (AYUSH)  
 Red Cross Building, 1, Red Cross Road,  
 New Delhi-110001

Dated: October 14, 2005

### ORDER

Whereas it has come to the notice of the Government of India in the Ministry of Health & Family Welfare, Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) that due to unsatisfactory Agricultural and cultivation practices relating to the medicinal plants used in preparation of Ayurveda, Siddha & Unani (ASU) and general environmental pollution, the presence of heavy metals above the permissible limit therein cannot be ruled out. Therefore, it has become expedient in the interest of public health to introduce mandatory testing for heavy metals for every batch of Ayurveda, Unani and Siddha drug manufactured by all licensees.

Now, therefore, in pursuance of the powers conferred under Section 33 EEB of the Drugs and Cosmetics Act, 1940, (23 of 1940), Government of India in the Ministry of Health & Family Welfare, Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and

Homoeopathy (AYUSH) hereby makes testing for heavy metals namely, Arsenic, Lead, Mercury and Cadmium will be as recommended by WHO publication "Quality Control Methods For Medicinal Plants Materials" In case of Mercury, the permissible limit will be one ppm.

Conspicuous display on the container of purely herbal Ayurveda, Siddha and Unani drugs to be exported the words HEAVY METALS WITHIN PERMISSIBLE LIMITS" will be mandatory with effect from 1<sup>st</sup> January, 2006.

ASU Drug manufactures who do not have in-house laboratory facility shall get their drugs tested by any approved drug testing laboratory.

This is a process of self-certification for export purposes and the ASU drug manufacturer will be held responsible if proper batch-wise testing is not done before self-certification. This process of self-certification would be extended for sale within the country in due course.

Sd/-  
 Shiv Basant  
 Joint Secretary to Govt. of India

F.No. K-11020/5/97-DCC (AYUSH)  
 Government of India  
 Ministry of Health & Family Welfare  
 (Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy)  
 (AYUSH)  
 Red Cross Building, 1, Red Cross Road,  
 New Delhi-110001

Dated: October 14, 2005

### ORDER

Central Government vide its Order of even number dated 14.10.2005 has made testing for heavy metals, namely, Arsenic, Lead, Mercury and Cadmium mandatory for export purposes in respect of every batch of purely herbal Ayurveda, Siddha and Unani medicines by every licensee. Representations have been received from Ayurveda Drugs Manufacturers Association (ADMA) that the exporters may find it difficult to print the certificate "Heavy metals within permissible limit" on the container of the medicines as container and label are to be approved by the regulatory authorities of the importing countries and it may not be possible to get revised containers and labels approved by the regulatory authorities of the importing countries by 1<sup>st</sup> January, 2006.

In view of the above difficulties brought to the notice of the Central Government, the above mentioned order of even number dated 14.10.2005 is hereby partially modified as follows:

In case any manufacturer of purely herbal Ayurveda, Siddha and Unani medicines finds it difficult to display on container of purely herbal Ayurveda, Siddha and Unani medicines to be exported the words "Heavy metals within regulatory requirements of the importing country, the manufacturer shall submit batch wise testing reports in respect of every purely herbal Ayurveda, Siddha and Unani medicine to be exported from approved laboratories certifying that the medicine contains heavy metals within permissible limits as laid down by the Central Government vide the order of even number dated 14.10.2005. The test report of an approved laboratory will

be an essential part of the consignment papers to be submitted by any exported from 1<sup>st</sup> January, 2006 which will be examined by the representative of the DCG (I) at the Airport/port of shipment. The manufacturers/exporters of purely herbal Ayurveda, Siddha and Unani medicines shall be responsible for the genuineness of the test report of the approved laboratory submitted along with other consignment papers at the Airport/Port of Shipment. All GLP/NABL accredited laboratories are approved by the Central Government for the above mandatory testing. The list of approved laboratories and the permissible limits of heavy metals have been posted on the website of the Department of AYUSH, Ministry of Health and Family Welfare, Government of India [www.indianmedicine.nic.in](http://www.indianmedicine.nic.in).

The order issued by the Central Government under Section 33 EEB of the Drugs and Cosmetics Act, 1940 dated 14.10.2005 as modified hereby shall come into force from 1<sup>st</sup> January, 2006. All exporters of purely herbal Ayurveda, Siddha and Unani medicines are hereby directed to either conspicuously display on the container of purely herbal Ayurveda, Siddha and Unani medicines to be exported the words "Heavy metals within permissible limit" or furnish the above mentioned certificate from an approved laboratory along with other consignment papers. It will be the responsibility of the representative of DCG (I) deployed at the Airport/port of shipment to examine and ensure that all exporters of purely herbal Ayurveda, Siddha and Unani medicines comply with this Order w.e.f 1<sup>st</sup> January 2006.

Sd/-

Shiv Basant

Joint Secretary to Govt. of India

# The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

(21 OF 1954)

[30<sup>th</sup> April, 1954]

An Act to control the advertisement of drugs in certain cases, to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith.

**1. Short Title, Extent And Commencement.**— (1) This Act may be called the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.

(2) It extends to the whole of India except the State of Jammu and Kashmir, and applies also to persons domiciled in the territories to which this Act extends who are outside the said territories.

(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

**2. Definitions.**— In this Act, unless the context otherwise requires,—

- a) 'advertisement' includes any notice, circular, label, wrapper, or other document, and any announcement made orally or by any means of producing or transmitting light, sound or smoke;
- b) 'drug' includes—
- (i) a medicine for the internal or external use of human beings or animals;

(ii) any substance intended to be used for or in the diagnosis, cure, mitigation, treatment or prevention of disease in human beings or animals;

(iii) any article, other than food, intended to affect or influence in any way the structure or any organic function of the body of human beings or animals;

(iv) any article intended for use as a component of any medicine, substance or article, referred to in sub-clauses (i), (ii) and (iii);

c) 'magic remedy' includes a talisman, mantra, kavacha, and any other charm of any kind which is alleged to possess miraculous powers for or in the diagnosis, cure, mitigation, treatment or prevention of any disease in human beings or animals or for affecting or influencing in any way the structure or any organic function of the body of human beings or animals;

[(cc) 'registered medical practitioner' means any person,—

(i) who holds a qualification granted by an authority specified in, or notified under, section 3 of the Indian Medical Degrees Act, 1916 (7 of 1916) or specified in the Schedules to the Indian Medical Council Act, 1956 (102 of 1956); or

- (ii) who is entitled to be registered as a medical practitioner under any law for the time being in force in any State to which this Act extends relating to the registration of medical practitioners;]
- d) 'taking any part in the publication of any advertisement' includes-
  - (i) the printing of the advertisement;
  - (ii) the publication of any advertisement outside the territories to which this Act extends by or at the instance of a person residing within the said territories.

### **3. Prohibition of Advertisement of Certain Drugs for Treatment of Certain Diseases and Disorders.–**

Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for –

- a) the procurement of miscarriage in women or prevention of conception in women; or
- b) the maintenance or improvement of the capacity of human beings for sexual pleasure; or
- c) the correction of menstrual disorder in women; or
- d) the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule, or any other disease, disorder or condition (by whatsoever name called) which may be specified in the rules made under this Act:

Provided that no such rule shall be made except,–

- (i) in respect of any disease, disorder or condition which requires timely

treatment in consultation with a registered medical practitioner or for which there are normally no accepted remedies, and

- (ii) after consultation with the Drugs Technical Advisory Board constituted under the Drugs and Cosmetics Act, 1940 (23 of 1940) and, if the Central Government considers necessary, with such other persons having special knowledge or practical experience in respect of Ayurvedic or Unani systems of medicines as that Government deems fit.]

### **4. Prohibition of Misleading Advertisements Relating to Drugs.–**

Subject to the provisions of this Act, no person shall take any part in the publication of any advertisement relating to a drug if the advertisement contains any matter which-

- a) directly or indirectly gives a false impression regarding the true character of the drug; or
- b) makes a false claim for the drug; or
- c) is otherwise false or misleading in any material particular.

### **5. Prohibition of Advertisement of Magic Remedies for Treatment of Certain Diseases and Disorders.–**

No person carrying on or purporting to carry on the profession of administering magic remedies shall take any part in the publication of any advertisement referring to any magic remedy which directly or indirectly claims to be efficacious for any of the purposes specified in section 3.

### **6. Prohibition of Import into, and Export from, India of Certain Advertisements.–**

No person shall import into, or export from, the territories to which this Act extends any document containing an advertisement

of the nature referred to in section 3, or section 4, or section 5, and any documents containing any such advertisement shall be deemed to be goods of which the import or export has been prohibited under section 19 of the Sea Customs Act, 1878 (8 of 1878) and all the provisions of that Act shall have effect accordingly, except that section 183 thereof shall have effect as if for the word 'shall' therein the word 'may' were substituted.

**7. Penalty.**— Whoever contravenes any of the provisions of this Act [or the rules made there under] shall, on conviction, be punishable –

- a) in the case of a first conviction, with imprisonment which may extend to six months, or with fine, or with both;
- b) in the case of a subsequent conviction, with imprisonment which may extend to one year, or with fine, or with both.

**8. Powers of Entry, Search, etc.**— (1) Subject to the provisions of any rules made in this behalf, any Gazetted Officer authorised by the State Government may, within the local limits of the area for which he is so authorized,—

- a) enter and search at all reasonable times, with such assistants, if any, as he considers necessary, any place in which he has reason to believe that an offence under this Act has been or is being committed;
- b) seize any advertisement which he has reason to believe contravenes any of the provisions of this Act:

Provided that the power of seizure under this clause may be exercised in respect of any document, article or thing which contains any such advertisement, including the contents, if any, of such

document, article or thing, if the advertisement cannot be separated by reason of its being embossed or otherwise, from such document, article or thing without affecting the integrity, utility or saleable value thereof;

- c) examine any record, register, document or any other material object found in any place mentioned in clause (a) and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

(2) The provisions of the Code of Criminal Procedure, 1898 (5 of 1898) shall, so far as may be, apply to any search or seizure under this Act as they apply to any search or seizure made under the authority of a warrant issued under section 98 of the said Code.

(3) Where any person seizes anything under clause (b) or clause (c) of sub-section (1), he shall, as soon as may be, inform a Magistrate and take his orders as to the custody thereof.]

**9. Offences By Companies.**— (1) If the person contravening any of the provisions of this Act is a company, every person who, at the time the offence was committed, was in charge of, and was responsible to, the company for the conduct of the business of the company as well as the company shall be deemed to be guilty of the contravention and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1) where an offence under this Act has been committed by a company and it is proved that the offence was committed with the consent or connivance of, or is attributable to any neglect on the part of, any director or manager, secretary or the officer of the company, such director, manager, secretary or other officer of the company shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation.— For the purposes of this section,—

- a) 'company' means any body corporate and includes a firm or other association of individuals, and
- b) 'director' in relation to a firm means a partner in the firm.

**[9a. Offences to be Cognizable.—** Notwithstanding anything contained in the Code of Criminal Procedure, 1898 (5 of 1898), an offence punishable under this Act shall be cognizable.]

**10. Jurisdiction To Try Offences.—** No court inferior to that of a Presidency Magistrate or a Magistrate of the first class shall try any offence punishable under this Act.

**[10A. Forfeiture.—** Where a person has been convicted by any court for contravening any provision of this Act or any rule made thereunder, the court may direct that any document (including all copies thereof), article or thing, in respect of which the contravention is made, including the contents thereof where such contents are seized under clause (b) of sub-section (1) of section 8, shall be forfeited to the Government.]

**11. Officers to be Deemed to be Public Servants.—** Every person authorized under section 8 shall be

deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860).

**12. Indemnity.—** No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act.

**13. Other Laws Not Affected.—** The provisions of this Act are in addition to, and not in derogation of the provisions of any other law for the time being in force.

**14. Saving.—** Nothing in this Act shall apply to —

- a) any signboard or notice displayed by a registered medical practitioner on his premises indicating that treatment for any disease, disorder or condition specified in section 3, the Schedule or the rules made under this Act is undertaken in those premises; or
- b) any treatise or book dealing with any of the matters specified in section 3 from a bona fide scientific or social standpoint; or
- c) any advertisement relating to any drug sent confidentially in the manner prescribed under section 16 only to a registered medical practitioner; or
- d) any advertisement relating to a drug printed or published by the Government; or
- e) any advertisement relating to a drug printed or published by any person with the previous sanction of the Government granted prior to the commencement of the Drugs and Magic Remedies (Objectionable Advertisements) Amendment Act, 1963 (42 of 1963):

Provided that the Government may, for reasons to be recorded in

writing, withdraw the sanction after giving the person an opportunity of showing cause against such withdrawal.]

**15. Power to Exempt from Application of Act.**— If in the opinion of the Central Government public interest requires that the advertisement of any specified drug or class of drugs [or any specified class of advertisements relating to drugs] should be permitted, it may, by notification in the Official Gazette, direct that the provisions of sections 3, 4, 5 and 6 or any one of such provisions shall not apply or shall apply subject to such conditions as may be specified in the notification to or in relation to the advertisement of any such drug or class of drugs [or any such class of advertisements relating to drugs].

**16. Power to Make Rules.**— (1) The Central Government may, by notification in the Official Gazette, make rules for carrying out the purposes of this Act.

(2) In particular and without prejudice to the generality of the

foregoing power, such rules may-

- a) specify any [disease, disorder or condition] to which the provisions of section 3 shall apply;
- b) prescribe the manner in which advertisements of articles or things referred to in clause (c) of section 14 may be sent confidentially.

[(3) Every rule made under this Act shall be laid, as soon as may be after it is made, before each of House of Parliament while it is in session for a total period of thirty days which be comprised in one session or in two or more successive sessions and if before the expiry of the session in which it is so laid or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.]

## SCHEDULE

# Diseases and Ailments (by whatever Name described) which a Drug may not Purport to Prevent or Cure or Make Claims to Prevent or Cure

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1. Appendicitis
2. Arteriosclerosis
3. Blindness
4. Blood poisoning
5. Bright's disease
6. Cancer
7. Cataract
8. Deafness
9. Diabetes
10. Diseases and Disorders of brain
11. Diseases and Disorders of the optical system
12. Diseases and Disorders of the uterus
13. Disorders of menstrual flow
14. Disorders of the nervous system
15. Disorders of the prostatic gland
16. Dropsy
17. Epilepsy
18. Female diseases (in general)
19. Fevers (in general)
20. Fits
21. Form and structure of the female bust
22. Gall stones, kidney stones and bladder stones
23. Gangrene
24. Glaucoma
25. Goitre
26. Heart diseases
27. High/Low Blood Pressure
28. Hydrocele
29. Hysteria
30. Infantile paralysis
31. Insanity
32. Leprosy
33. Leucoderma
34. Lockjaw
35. Locomotor ataxia
36. Lupus
37. Nervous debility
38. Obesity
39. Paralysis
40. Plague
41. Pleurisy
42. Pneumonia
43. Rheumatism
44. Ruptures
45. Sexual impotence
46. Smallpox
47. Stature of persons
48. Sterility in women
49. Trachoma
50. Tuberculosis
51. Tumours
52. Typhoid fever
53. Ulcers of the gastro-intestinal tract
54. Venereal diseases, including syphilis, gonorrhoea, soft chancre, venereal granuloma and lympho granuloma.]

# The Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955

In exercise of the powers conferred by section 16 of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (21 of 1954), the Central Government hereby makes the following rules, namely:-

**1. Short Title and Commencement.**— (1) These rules may be called the Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955.

(2) They shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

**2. Definitions.**— In these rules, unless the context otherwise requires,—

(1) the “Act” means the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (21 of 1954); and

(2) “section” means a section of the Act.

**[3] Scrutiny of Misleading Advertisements Relating to Drugs.**— [Any person authorized by the State Government in this behalf may, if satisfied, that an advertisement relating to a drug contravenes the provisions of section 4], by order, require the manufacturer, packer, distributor or seller of the drug to furnish, within such time as may be specified in the order or such further time as may be allowed in this behalf by the person so authorized

information regarding the composition of the drug or the ingredients thereof or any other information in regard to that drug as he deems necessary for holding the scrutiny of the advertisement and where any such order is made, it shall be the duty of the manufacturer, packer, distributor or seller of the drug to which the advertisement relates to comply with the order. Any failure to comply with such order shall, for the purposes of section 7, be deemed to be a contravention of the provisions of section 4:

Provided that no publisher or advertising agency of any medium for the dissemination of any advertisement relating to a drug shall be deemed to have made any contravention merely by reason of the dissemination by him or if any such advertisement, unless such publisher or advertising agency has failed to comply with any discretion made by the authorized person in this behalf calling upon him or it to furnish the name and address of the manufacturer, packer, distributor, seller or advertising agency, as the case may be, who or which caused such advertisement to be disseminated.

**[4] Procedure to be followed in prohibiting Import into, and Export from India of Certain Advertisements.**— (1) If the Customs Collector has reasons to believe that any consignment contains documents of the

nature referred to in section 6, he may and if requested by an officer appointed for the purpose by the Central Government, shall detain the consignment and dispose it of in accordance with the provisions of the Sea Customs Act, 1878 (VIII of 1878), and the rules made thereunder, and shall also inform the importer or exporter of the order so passed:

Provided that if the importer or exporter feels aggrieved by an order passed by the Customs Collector under this sub-rule and makes a representation to him within one week of the date of the order and has given an undertaking in writing not to dispose of the consignment without the consent of the Customs Collector and to return the consignment when so required to do by the Customs Collector, the Customs Collector shall pass an order making over the consignment to the importer or exporter, as the case may be:

Provided further that before passing any order under this sub-rule or under the first proviso thereto, the Customs Collector shall consult the officer appointed for the purpose by Central Government.

(2) If the importer or exporter who has given an undertaking under the first proviso to sub-rule (1) is required by

the Customs Collector to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of the receipt of the notice.

**[5] [Manner in which Advertisements may be sent Confidentially.]**— All documents containing advertisements relating to drugs referred to in clause (c) of sub-section (1) of section 14, shall be sent by post to a registered medical practitioner by name or to a wholesale or retail chemist, the address of such registered medical practitioner or wholesale or retail chemist being given. Such document shall bear at the top, printed in indelible ink in a conspicuous manner, the words. “For the use only of registered medical practitioners or a hospital or a laboratory”].

**[6] Prohibition of Advertisement of Drugs for Treatment of Disease, etc.]**— No person shall also take part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder, or condition specified in the Schedule annexed to these rules.

#### SCHEDULE (See Rule 6)

1. Asthma
2. AIDS

# Monographs Published in Ayurvedic Pharmacopoeia of India

MONOGRAPHS

## PART-I, VOL. I

1. Ajagandha (Sd.) *Cleome gynandra* Linn.
2. Ajamoda (Fr.) *Apium leptophyllum* (Pers.) F.V.M. ex Benth.
3. Amalaki (Fr. Frt. Pulp) *Embllica officinalis* Gaertn.
4. Amalaki (Drd. Frt.) *Embllica officinalis* Gaertn.
5. Aragvadha (Fr. Pulp.) *Cassia fistula* Linn.
6. Arka (Rt.) *Calotropis procera* (Ait.) R. Br.
7. Arka (Lf.) *Calotropis procera* (Ait.) R. Br.
8. Asana (Ht.Wd.) *Pterocarpus marsupium* Roxb.
9. Ashoka (St. Bk.) *Saraca asoca* (Rosc.) DC. Willd.
10. Asvagandha (Rt.) *Withania somnifera* Dunal.
11. Asvattha (Bk.) *Ficus religiosa* Linn.
12. Atasi (Sd.) *Linum usitatissimum* Linn.
13. Atibala (Rt.) *Abutilon indicum* (Linn.) Sw.
14. Ativisa (Rt.) *Aconitum heterophyllum* Wall. ex Royle
15. Babbula (St.Bk.) *Acacia nilotica* (Linn.) Willd. ex Del. sp. *indica* (Benth.) Brenan
16. Bakuci (Fr.) *Psoralea corylifolia* Linn.
17. Bibhitaka (Fr.) *Terminalia belerica* Roxb.
18. Bilva (Fr. Pulp) *Aegle marmelos* Corr.
19. Candrasura (Sd.) *Lepidium sativum* Linn.
20. Citraka (Rt.) *Plumbago zeylanica* Linn.
21. Dhanyaka (Fr.) *Coriandrum sativum* Linn.
22. Dhataki (Fl.) *Woodfordia fruticosa* (Linn.) Kurz.
23. Eranda (Rt.) *Ricinus communis* Linn.
24. Gambhari (Rt. Bk.) *Gmelina arborea* Roxb
25. Goksura (Rt.) *Tribulus terrestris* Linn.
26. Goksura (Fr.) *Tribulus terrestris* Linn.
27. Guduci (St.) *Tinospora cordifolia* (Willd.) Miers.
28. Guggulu (Exudate) *Commiphora wightii* (Arn.) Bhand.
29. Gunja (Sd.) *Abrus precatorius* Linn.
30. Haridra (Rz.) *Curcuma longa* Linn.
31. Haritaki (Fr.) *Terminalia chebula* Retz.
32. Hingu (Oleo-Gum-Resin) *Ferula foetida* Regel.
33. Jatamansi (Rz.) *Nardostachys jatamansi* DC.
34. Jatiphala (Sd.) *Myristica fragrans* Houtt.
35. Kampilla (Fr.) *Mallotus philippinensis* Muell.-Arg.
36. Kancanara (St. Bk.) *Bauhinia variegata* Blume

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|-------------------------------|---|
| 37. Kankola (Fr.)             | <i>Piper cubeba</i> Linn. f.                        |
| 38. Kantakari (W.P.)          | <i>Solanum surattense</i> Burm. f.                  |
| 39. Kanyasara (Lf.)           | <i>Aloe barbadensis</i> Mill.                       |
| 40. Karanja (Sd.)             | <i>Pongamia pinnata</i> (Linn.) Merr.               |
| 41. Karavira (Lf.)            | <i>Nerium indicum</i> Mill.                         |
| 42. Karkatasrangi (Gall)      | <i>Pistacia chinensis</i> Burgo                     |
| 43. Karpasa (Sd.)             | <i>Gossypium herbaceum</i> Linn.                    |
| 44. Kaseru (Rz.)              | <i>Scirpus kysoor</i> Roxb.                         |
| 45. Ketaki (Rt.)              | <i>Pandanus tectorius</i> Soland. ex Parkinson      |
| 46. Khadira (Ht.Wd.)          | <i>Acacia catechu</i> (Linn. f.) Willd.             |
| 47. Kiratatikta (W.P.)        | <i>Swertia chinata</i> Buch.-Ham.                   |
| 48. Krsnajiraka (Fr.)         | <i>Carum carvi</i> Linn.                            |
| 49. Kulattha (Sd.)            | <i>Vigna unguiculata</i> (Linn.) Walp.              |
| 50. Kustha (Rt.)              | <i>Saussurea lappa</i> C.B. Clarke                  |
| 51. Kutaja (St. Bk.)          | <i>Holarrhena antidysenterica</i> (Roth) A. DC.     |
| 52. Lavanga (Fl. Bud)         | <i>Syzygium aromaticum</i> (Linn.) Merr. & M.Perry  |
| 53. Lodhra (St. Bk.)          | <i>Symplocos racemosa</i> Roxb.                     |
| 54. Madana (Fr.)              | <i>Xeromphis spinosa</i> (Thunb.) Keay              |
| 55. Misreya (Fr.)             | <i>Foeniculum vulgare</i> Mill.                     |
| 56. Nyagrodha (St. Bk.)       | <i>Ficus bengalensis</i> Linn.                      |
| 57. Pasanabheda (Rz.)         | <i>Bergenia ciliata</i> (Haw.) Sternb.              |
| 58. Patha (Rt.)               | <i>Cissampelos pareira</i> Linn.                    |
| 59. Puga (Sd.)                | <i>Areca catechu</i> Linn.                          |
| 60. Punarnava (Rakta) (W.P.)  | <i>Boerhaavia diffusa</i> Linn.                     |
| 61. Saptaparna (St. Bk.)      | <i>Alstonia scholaris</i> (Linn.) R. Br.            |
| 62. Sati (Rz.)                | <i>Hedychium spicatum</i> Ham. ex Smith             |
| 63. Snuhi (St.)               | <i>Euphorbia nerifolia</i> Linn.                    |
| 64. Suksmaila (Fr.)           | <i>Elettaria cardamomum</i> (Linn.) Maton           |
| 65. Sunthi (Rz.)              | <i>Zingiber officinale</i> Roxb.                    |
| 66. Svarnapatri (Lf.)         | <i>Cassia angustifolia</i> Vahl.                    |
| 67. Svetajiraka (Fr.)         | <i>Cuminum cyminum</i> Linn.                        |
| 68. Sveta Sariva (Rt.)        | <i>Hemidesmus indicus</i> (Linn.) R. Br.            |
| 69. Tagara (Rz.)              | <i>Valeriana wallichii</i> DC.                      |
| 70. Tamalaki (Rt., St. & Lf.) | <i>Phyllanthus fraternus</i> Webst.                 |
| 71. Tvak (Bk.)                | <i>Cinnamomum zeylanicum</i> Blume                  |
| 72. Tvakapatra (Lf.)          | <i>Cinnamomum tamala</i> (Buch.-Ham.) Nees & Eberm. |
| 73. Udumbara (Bk.)            | <i>Ficus racemosa</i> Linn.                         |
| 74. Upakuncika (Sd.)          | <i>Nigella sativa</i> Linn.                         |
| 75. Varuna (St. Bk.)          | <i>Crataeva nurvala</i> Buch.-Ham.                  |
| 76. Vasa (Lf.)                | <i>Azadirachta indica</i> (Linn.) Nees              |
| 77. Vidanga (Fr.)             | <i>Embelia ribes</i> Burm.f.                        |
| 78. Vijaya (Lf.)              | <i>Cannabis sativa</i> Linn.                        |
| 79. Yasti (St. & Rt.)         | <i>Glycyrrhiza glabra</i> Linn.                     |
| 80. Yavani (Fr.)              | <i>Trachyspermum ammi</i> (Linn.) Sprague ex Turrit |

## PART-I, VOL. II

1. Akarakarabha (Rt.)	<i>Anacyclus pyrethrum</i> DC.
2. Aksoda (Cotldn.)	<i>Juglans regia</i> Linn.
3. Amrata (St. Bk.)	<i>Spondias pinnata</i> (Linn. f.) Kurz.
4. Apamarga (W.P.)	<i>Achyranthes aspera</i> Linn.
5. Aparajita (Rt.)	<i>Clitoria ternatea</i> Linn.
6. Ardraka (Rz.)	<i>Zingiber officinale</i> Rosc.
7. Arimeda (St.Bk.)	<i>Acacia leucophloea</i> Willd.
8. Arjuna (St.Bk.)	<i>Terminalia arjuna</i> W.& A.
9. Bhallataka (Frt.)	<i>Semecarpus anacardium</i> Linn.
10. Bhrngaraja (W.P.)	<i>Eclipta alba</i> Hassk.
11. Brahmi (W.P.)	<i>Bacopa monnieri</i> (Linn.) Wettst.
12. Brhati (Rt.)	<i>Solanum indicum</i> Linn.
13. Cavya (St.)	<i>Piper retrofractum</i> Vahl.
14. Dadima (Sd.)	<i>Punica granatum</i> Linn.
15. Daruharidra (St.)	<i>Berberis aristata</i> DC.
16. Dronapuspi (W.P.)	<i>Leucas cephalotes</i> Spreng.
17. Ervaru (Sd.)	<i>Cucumis melo</i> var. <i>utilissimus</i> Duthie & Fuller
18. Gajapippali (Frt.)	<i>Scindapsus officinalis</i> Schoott.
19. Gambhari (Frt.)	<i>Gmelina arborea</i> Roxb.
20. Gangeru (St.Bk.)	<i>Grewia tenax</i> (Forsk.) Aschers & Schwf.
21. Gunja (Rt.)	<i>Abrus precatorius</i> Linn.
22. Iksu (St.)	<i>Saccharum officinarum</i> Linn.
23. Indravaruni (Rt.)	<i>Citrullus colocynthis</i> Schrad.
24. Indravaruni (Lf.)	<i>Citrullus colocynthis</i> Schrad.
25. Jambu (Sd.)	<i>Syzygium cuminii</i> (Linn.) Skeels
26. Jambu (St.Bk.)	<i>Syzygium cuminii</i> (Linn.) Skeels
27. Jayapala (Sd.)	<i>Croton tiglium</i> Linn.
28. Jayanti (Lf.)	<i>Sesbania sesban</i> (Linn.) Merr.
29. Jyotismati (Sd.)	<i>Celastrus paniculatus</i> Willd.
30. Kadamba (St.Bk.)	<i>Anthocephalus cadamba</i> Miq.
31. Kakamaci (W.P.)	<i>Solanum nigrum</i> Linn.
32. Kamala (Fl.)	<i>Nelumbo nucifera</i> Gaertn.
33. Kapittha (Frt.Pulp)	<i>Feronia limonia</i> (Linn.) Swingle
34. Karamarda (St.Bk.)	<i>Carissa carandas</i> Linn.
35. Karanja (Rt.Bk.)	<i>Pongamia pinnata</i> (Linn.) Merr.
36. Karanja (Rt.)	<i>Pongamia pinnata</i> (Linn.) Merr.
37. Karanja (St.Bk.)	<i>Pongamia pinnata</i> (Linn.) Merr.
38. Karanja (Lf.)	<i>Pongamia pinnata</i> (Linn.) Merr.
39. Karavallaka (Fr. Frt.)	<i>Momordica charantia</i> Linn.
40. Katuka (Rz.)	<i>Picrorhiza kurroa</i> Royle ex Benth.
41. Kokilaksa (W.P.)	<i>Asteracantha longifolia</i> Nees
42. Kokilaksa (Rt.)	<i>Asteracantha longifolia</i> Nees
43. Kokilaksa (Sd.)	<i>Asteracantha longifolia</i> Nees
44. Kozuppa (W.P.)	<i>Portulaca oleracea</i> Linn.

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| 45. Lajjalu (W.P.)      | <i>Mimosa pudica</i> Linn.                   |
| 46. Madhuka (Fl.)       | <i>Madhuca indica</i> J.F. Gmel.             |
| 47. Matsyaksi (W.P.)    | <i>Alternanthera sessilis</i> (Linn.) R. Br. |
| 48. Methi (Sd.)         | <i>Trigonella foenum-graecum</i> Linn.       |
| 49. Mulaka (W.P.)       | <i>Rapbanus sativus</i> Linn.                |
| 50. Mulaka (Rt.)        | <i>Rapbanus sativus</i> Linn.                |
| 51. Mura (Rt.)          | <i>Selinium candollei</i> DC.                |
| 52. Murva (Rt.)         | <i>Marsdenia tenacissima</i> Wight. & Arn.   |
| 53. Nagakesar (Stmn.)   | <i>Mesua ferrea</i> Linn.                    |
| 54. Nili (Lf.)          | <i>Indigofera tinctoria</i> Linn.            |
| 55. Nili (Rt.)          | <i>Indigofera tinctoria</i> Linn.            |
| 56. Nimba (Lf.)         | <i>Azadirachta indica</i> A. Juss.           |
| 57. Nimba (St.Bk.)      | <i>Azadirachta indica</i> A. Juss.           |
| 58. Palasa (St.Bk.)     | <i>Butea monosperma</i> (Lam.) Kuntze        |
| 59. Paribhadra (St.Bk.) | <i>Erythrina indica</i> Lam.                 |
| 60. Pippalimula (St.)   | <i>Piper longum</i> Linn.                    |
| 61. Plaksa (St.Bk.)     | <i>Ficus lacor</i> Buch.-Ham.                |
| 62. Prasarini (W.P.)    | <i>Paederia foetida</i> Linn.                |
| 63. Priyala (Sd.)       | <i>Buchanania lanzan</i> Spreng.             |
| 64. Priyangu (Infl.)    | <i>Callicarpa macrophylla</i> Vahl.          |
| 65. Sali (Rt.)          | <i>Oryza sativa</i> Linn.                    |
| 66. Sankhapuspi (W.P.)  | <i>Convolvulus pluricaulis</i> Choisy        |
| 67. Saptala (W.P.)      | <i>Euphorbia dracunculoides</i> Lam.         |
| 68. Satahva (Frt.)      | <i>Anethum sowa</i> Roxb. ex Flem.           |
| 69. Sigru (Lf.)         | <i>Moringa oleifera</i> Lam.                 |
| 70. Sthulaela (Sd.)     | <i>Amomum subulatum</i> Roxb.                |
| 71. Tejovati (St.Bk.)   | <i>Zanthoxylum armatum</i> DC.               |
| 72. Tulasi (W.P.)       | <i>Ocimum sanctum</i> Linn.                  |
| 73. Tulasi (Lf.)        | <i>Ocimum sanctum</i> Linn.                  |
| 74. Vaca (Rz.)          | <i>Acorus calamus</i> Linn.                  |
| 75. Vatsanabha (Rt.)    | <i>Aconitum chasmanthum</i> Stapf ex Holmes  |
| 76. Vidari (Tub.Rt.)    | <i>Pueraria tuberosa</i> DC.                 |
| 77. Yava (Frt.)         | <i>Hordeum vulgare</i> Linn.                 |
| 78. Yavasaka (W.P.)     | <i>Albati pseudalbagi</i> (Bieb.) Desv.      |

### PART-I, VOL. III

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| 1. Adhaki (Rt.)      | <i>Cajanus cajan</i> (Linn.) Millsp.    |
| 2. Agnimantha (Rt.)  | <i>Clerodendrum plomidis</i> Linn. f.   |
| 3. Ambasthaki (Rt.)  | <i>Hibiscus sabdariffa</i> Linn.        |
| 4. Amra (Sd.)        | <i>Mangifera indica</i> Linn.           |
| 5. Amra (St. Bk.)    | <i>Mangifera indica</i> Linn.           |
| 6. Amrata (St.)      | <i>Spondias pinnata</i> (Linn.f.) Kurz. |
| 7. Apamarga (Rt.)    | <i>Achyranthes aspera</i> Linn.         |
| 8. Araluka (St. Bk.) | <i>Ailanthus excelsa</i> Roxb.          |
| 9. Arka (St. Bk.)    | <i>Calotropis procera</i> (Ait.) R. Br. |

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| 10. Asana (St. Bk.)     | <i>Pterocarpus marsupium</i> Roxb.           |
| 11. Asthisamhrta (St.)  | <i>Cissus quadrangularis</i> Linn.           |
| 12. Atmagupta (Sd.)     | <i>Mucuna prurita</i> Hook.                  |
| 13. Bharangi (Rt.)      | <i>Clerodendrum serratum</i> Linn.           |
| 14. Bijapura (Frnt.)    | <i>Citrus medica</i> Linn.                   |
| 15. Bilva (Rt.)         | <i>Aegle marmelos</i> Corr.                  |
| 16. Bimbi (W.P.)        | <i>Coccinia indica</i> W. & A.               |
| 17. Cangeri (W.P.)      | <i>Oxalis corniculata</i> Linn.              |
| 18. Cirabilva (Frnt.)   | <i>Holoptelea integrifolia</i> Planch        |
| 19. Danti (Rt.)         | <i>Baliospermum montanum</i> Muell-Arg.      |
| 20. Dhattura (Sd.)      | <i>Datura metel</i> Linn.                    |
| 21. Draksa (Frnt.)      | <i>Vitis vinifera</i> Linn.                  |
| 22. Durva (Rt.)         | <i>Cynodon dactylon</i> (Linn.) Pers.        |
| 23. Eranda (Lf.)        | <i>Ricinus communis</i> Linn.                |
| 24. Eranda (Sd.)        | <i>Ricinus communis</i> Linn.                |
| 25. Gambhari (St.)      | <i>Gmelina arborea</i> Roxb.                 |
| 26. Gojihva (Aer. Pt.)  | <i>Onosma bracteatum</i> Wall.               |
| 27. Granthiparni (Rt.)  | <i>Leonotis nepetaefolia</i> R. Br.          |
| 28. Hamsapadi (W.P.)    | <i>Adiantum lunulatum</i> Burm               |
| 29. Hapusa (Frnt.)      | <i>Juniperus communis</i> Linn.              |
| 30. Indravaruni (Frnt.) | <i>Citrullus colocynthis</i> Schrad.         |
| 31. Indrayava (Sd.)     | <i>Holarbena antidysenterica</i> Wall.       |
| 32. Isvari (Rt.)        | <i>Aristolochia indica</i> Linn.             |
| 33. Jati (Lf.)          | <i>Jasminum officinale</i> Linn.             |
| 34. Kadali (Rz.)        | <i>Musa paradisiaca</i> Linn.                |
| 35. Kakajangha (Rt.)    | <i>Peristrophe bicalyculata</i> Linn.        |
| 36. Kakanasika (Sd.)    | <i>Martynia annua</i> Linn.                  |
| 37. Kakoli (Tub. Rt.)   | <i>Lilium polyphyllum</i> D. Don             |
| 38. Kamala (Rz.)        | <i>Nelumbo nucifera</i> Gaertn.              |
| 39. Karavira (Rt.)      | <i>Nerium indicum</i> Mill.                  |
| 40. Karinkara (Rt.)     | <i>Carissa carandas</i> Linn.                |
| 41. Kasa (Rt. Stock)    | <i>Saccharum spontaneum</i> Linn.            |
| 42. Katphala (Frnt.)    | <i>Myrica esculenta</i> Buch.-Ham. ex D. Don |
| 43. Katphala (St. Bk.)  | <i>Myrica esculenta</i> Buch.-Ham. ex D. Don |
| 44. Kola (Frnt. Pulp)   | <i>Zizyphus jujuba</i> Lam.                  |
| 45. Kola (St. Bk.)      | <i>Zizyphus jujuba</i> Lam.                  |
| 46. Kosataki (W.P.)     | <i>Luffa acutangula</i> (Linn.) Roxb.        |
| 47. Kumuda (Fl.)        | <i>Nymphaea alba</i> Linn.                   |
| 48. Kusa (Rt. St.)      | <i>Desmostachya bipinnata</i> Stapf.         |
| 49. Langali (Rz.)       | <i>Gloriosa superba</i> Linn.                |
| 50. Lasuna (Bulb)       | <i>Allium sativum</i> Linn.                  |
| 51. Mahabala (Rt.)      | <i>Sida rhombifolia</i> Linn.                |
| 52. Manjistha (St.)     | <i>Rubia cordifolia</i> Linn.                |
| 53. Marica (Frnt.)      | <i>Piper nigrum</i> Linn.                    |
| 54. Masaparni (W.P.)    | <i>Teramnus labialis</i> Spreng.             |
| 55. Masura (Sd.)        | <i>Lens culinaris</i> Medic.                 |

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| 56. Mudga (Sd.)                | <i>Pbseolus radiatus</i> Linn.                  |
| 57. Mulaka (Sd.)               | <i>Rapbanus sativus</i> Linn.                   |
| 58. Munditika (Lf.)            | <i>Sphaeranthus indicus</i> Linn.               |
| 59. Musta (Rz.)                | <i>Cyperus rotundus</i> Linn.                   |
| 60. Nagavalli (Lf.)            | <i>Piper betle</i> Linn.                        |
| 61. Narikela (Endo.)           | <i>Cocos nucifera</i> Linn.                     |
| 62. Nicula (Fr.)               | <i>Barringtonia acutangula</i> (Linn.) Gaertn.  |
| 63. Nili (W.P.)                | <i>Indigofera tinctoria</i> Linn.               |
| 64. Nirgundi (Lf.)             | <i>Vitex negundo</i> Linn.                      |
| 65. Padmaka (Ht. Wd.)          | <i>Prunus cerasoides</i> D. Don                 |
| 66. Patalai (Rt.)              | <i>Stereospermum suaveolens</i> DC.             |
| 67. Phalgu (Fr.)               | <i>Ficus bispida</i> Linn.                      |
| 68. Phalgu (Rt.)               | <i>Ficus bispida</i> Linn.                      |
| 69. Prapunnada (Sd.)           | <i>Cassia tora</i> Linn.                        |
| 70. Raktacandana (Ht.Wd.)      | <i>Pterocarpus santalinus</i> Linn.             |
| 71. Raktapunarnava (Rt.)       | <i>Boerhaavia diffusa</i> Linn.                 |
| 72. Ramasitalika (W. P.)       | <i>Amaranthus tricolor</i> Linn.                |
| 73. Rasna (Lf.)                | <i>Pluchea lanceolata</i> Oliver & Hiem.        |
| 74. Sahacara (W.P.)            | <i>Barleria prionitis</i> Linn.                 |
| 75. Sahadevi (W.P.)            | <i>Vernonia cinerea</i> Lees.                   |
| 76. Saileya (Lichen-'Thallus') | <i>Parmelia perlata</i> (Huds.) Ach.            |
| 77. Saka (Ht. Wd.)             | <i>Tectona grandis</i> Linn.                    |
| 78. Sakhotaka (St. Bk.)        | <i>Streblus asper</i> Lour.                     |
| 79. Salaparni (Rt.)            | <i>Desmodium gangeticum</i> DC.                 |
| 80. Sali (Fr.)                 | <i>Oryza sativa</i> Linn.                       |
| 81. Salmali (St.Bk.)           | <i>Bombax ceiba</i> Linn.                       |
| 82. Sana (Sd.)                 | <i>Crotolaria juncea</i> Linn.                  |
| 83. Sara (Rt.)                 | <i>Saccharum bengalense</i> Retz.               |
| 84. Sarala (Ht. Wd.)           | <i>Pinus roxburghii</i> Sargent                 |
| 85. Sarala (Rt.)               | <i>Pinus roxburghii</i> Sargent                 |
| 86. Sarsapa (Sd.)              | <i>Brassica campestris</i> Linn.                |
| 87. Satapatrika (Fl.)          | <i>Rosa centifolia</i> Linn.                    |
| 88. Simsapa (Ht. Wd.)          | <i>Dalbergia sissoo</i> Roxb.                   |
| 89. Simsapa (St. Bk.)          | <i>Dalbergia sissoo</i> Roxb.                   |
| 90. Sirisa (St. Bk.)           | <i>Albizzia lebbeck</i> Benth.                  |
| 91. Sthauneya (Lf.)            | <i>Taxus baccata</i> Linn.                      |
| 92. Surana (Corm.)             | <i>Amorphoballus campanulatus</i> (Roxb.) Bl.   |
| 93. Svetacandana (Ht.Wd.)      | <i>Santalum album</i> Linn.                     |
| 94. Syonaka (Rt.)              | <i>Oroxylum indicum</i> Vent.                   |
| 95. Tala (Infl.)               | <i>Borassus flabellifer</i> Linn.               |
| 96. Trivrtta (Rt.)             | <i>Operculina turpethum</i> (Linn.) Silva Manso |
| 97. Tumbini (Fr.)              | <i>Lagenaria siceraria</i> (Mol.) Standl.       |
| 98. Udambara (Fr.)             | <i>Ficus glomerata</i> Roxb.                    |
| 99. Usira (Rt.)                | <i>Vetiveria zizanioides</i> (Linn.) Nash       |
| 100. Utpala (Fl.)              | <i>Nymphaea stellata</i> Willd                  |

## PART-I, VOL. IV

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| 1. Adhaki (Sd.)               | <i>Cajanus cajan</i> Linn.                   |
| 2. Agarū (Ht. Wd.)            | <i>Aquilaria agallocha</i> Roxb.             |
| 3. Aklari (Endm.)             | <i>Lodoicea maldivica</i> Pers.              |
| 4. Aparajita (Lf.)            | <i>Clitoria ternatea</i> Linn.               |
| 5. Atmagupta (Rt.)            | <i>Mucuna prurita</i> Hook.                  |
| 6. Bilva (St. Bk.)            | <i>Aegle marmelos</i> Corr.                  |
| 7. Champaka (Fl.)             | <i>Michelia champaca</i> Linn.               |
| 8. Cinca (Ft. Pl.)            | <i>Tamarindus indica</i> Linn.               |
| 9. Dadima (Fr. Fruit)         | <i>Punica granatum</i> Linn.                 |
| 10. Dadima (Ft. Rind)         | <i>Punica granatum</i> Linn.                 |
| 11. Dadima (Lf.)              | <i>Punica granatum</i> Linn.                 |
| 12. Devadaru (Ht. Wd.)        | <i>Cedrus deodara</i> (Roxb.) Loud.          |
| 13. Dhattura (W.P.)           | <i>Datura metel</i> Linn.                    |
| 14. Durva (W.P.)              | <i>Cynodon dactylon</i> (Linn.)              |
| 15. Gambhari (St. Bk.)        | <i>Gmelina arborea</i> Linn.                 |
| 16. Iksu (Rt. Stock)          | <i>Saccharum officinarum</i> Linn.           |
| 17. Kadali (Fl.)              | <i>Musa paradisiaca</i> Linn.                |
| 18. Karcura (Rz.)             | <i>Curcuma zedoaria</i> Rosc.                |
| 19. Kasturilatika (Sd.)       | <i>Hibiscus abelmoschus</i> Linn.            |
| 20. Kataka (Sd.)              | <i>Strychnos potatorum</i> Linn. f.          |
| 21. Kharjura (Drd. Ft.)       | <i>Phoenix dactylifera</i> Linn.             |
| 22. Kharjura (Fr. Ft.)        | <i>Phoenix dactylifera</i> Linn.             |
| 23. Krsnasariva (Rt.)         | <i>Cryptolepis buchanani</i> Roem. & Schult. |
| 24. Kunduru (Exud.)           | <i>Boswellia serrata</i> Roxb.               |
| 25. Kunkuma (Sty. & Stg.)     | <i>Crocus sativus</i> Linn.                  |
| 26. Kusmanda (Ft.)            | <i>Benincasa hispida</i> (Thunb.) Cogn.      |
| 27. Madayanti (Lf.)           | <i>Lawsonia inermis</i> Linn.                |
| 28. Mahanimba (St. Bk.)       | <i>Melia azedarach</i> Linn.                 |
| 29. Mandukaparni (W.P.)       | <i>Centella asiatica</i> (Linn.) Urban       |
| 30. Mayakku (Gall)            | <i>Quercus infectoria</i> Oliv.              |
| 31. Mudgaparni (W.P.)         | <i>Vigna trilobata</i> (Linn.) Verdc.        |
| 32. Munditika (W.P.)          | <i>Sphaeranthus indicus</i> Linn.            |
| 33. Nayagrodha Jata (Ar. Rt.) | <i>Ficus bengalensis</i> Linn.               |
| 34. Nimbu (Fr. Ft.)           | <i>Citrus limon</i> (Linn.) Burm. f.         |
| 35. Nirgundi (Rt.)            | <i>Vitex negundo</i> Linn.                   |
| 36. Palasa (Fl.)              | <i>Butea monosperma</i> (Lam.) Kuntze.       |
| 37. Palasa (Gum)              | <i>Butea monosperma</i> (Lam.) Kuntze.       |
| 38. Palasa (Sd.)              | <i>Butea monosperma</i> (Lam.) Kuntze.       |
| 39. Parpata (W.P.)            | <i>Fumaria parviflora</i> Lam.               |
| 40. Patalai (St. Bk.)         | <i>Stereospermum belonoides</i> (L.F.)DC.    |
| 41. Pattanga (Ht. Wd.)        | <i>Caesaplina sappan</i> Linn.               |
| 42. Pippali (Ft.)             | <i>Piper longum</i> Linn.                    |
| 43. Plaksa (Ft.)              | <i>Ficus lacor</i> Buch. – Ham.              |
| 44. Priyala (St. Bk.)         | <i>Buchanania lanzan</i> Spreng.             |

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| 45. Priyangu (Fruit)    | <i>Callicarpa macrophylla</i> Vahl.            |
| 46. Prsniparni (W.P.)   | <i>Unaria picta</i> Desv.                      |
| 47. Puskara (Rt.)       | <i>Inula racemosa</i> Hook. f.                 |
| 48. Rudraksa (Sd.)      | <i>Elaeocarpus sphaericus</i> Gaertn. K. Schum |
| 49. Saraja (Exud.)      | <i>Vateria indica</i> Linn.                    |
| 50. Satavari (Rt.)      | <i>Asparagus recemosus</i> Willd.              |
| 51. Sigru (Rt. Bk.)     | <i>Moringa oleifera</i> Lam.                   |
| 52. Sigru (Sd.)         | <i>Moringa oleifera</i> Lam.                   |
| 53. Sigru (St. Bk)      | <i>Moringa oleifera</i> Lam.                   |
| 54. Srngataka (Drd.Sd)  | <i>Trapa natans</i> Linn.                      |
| 55. Sruvavrksa (Lf.)    | <i>Flacourtia indica</i> Merr.                 |
| 56. Sruvavrksa (St. Bk) | <i>Flacourtia indica</i> Merr.                 |
| 57. Talamuli (Rz.)      | <i>Curculigo orchioides</i> Gaertn.            |
| 58. Talisa (Drd. Lf.)   | <i>Abies webbiana</i> Lindl.                   |
| 59. Tila (Sd.)          | <i>Sesamum indicum</i> Linn.                   |
| 60. Tulasi (Sd.)        | <i>Ocimum sanctum</i> Linn.                    |
| 61. Tumburu (Ft.)       | <i>Zanthoxylum armatum</i> DC.                 |
| 62. Utingana (Sd.)      | <i>Blepharis persica</i> (Burm.f.) O. Kuntze.  |
| 63. Varahi (Rz.)        | <i>Dioscorea bulbifera</i> Linn.               |
| 64. Varsabhu (Rt.)      | <i>Trianthema portulacastrum</i> Linn.         |
| 65. Vasa (Rt.)          | <i>Adbatoda zeylanica</i> Medic.               |
| 66. Visamusti (Sd.)     | <i>Strychnos nux-vomica</i> Linn.              |
| 67. Vrscikalli (W.P.)   | <i>Tragia involucrata</i> Linn.                |
| 68. Yava (W.P.)         | <i>Hordeum vulgare</i> Linn.                   |

## PART-I, VOL. V

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| 1. Amra Haridra (Rz.)       | <i>Curcuma amada</i> Roxb.                   |
| 2. Anisoon (Fr.)            | <i>Pimpinella anisum</i> Linn.               |
| 3. Ankola (Lf.)             | <i>Alangium salviifolium</i> (Linn.f.) Wang. |
| 4. Aragvadhya (St.Bk.)      | <i>Cassia fistula</i> Linn.                  |
| 5. Asphota (Rt.)            | <i>Vallisneria spiralis</i> Linn.            |
| 6. Bastantri (Rt.)          | <i>Argyria nervosa</i> (Burm.f.) Boj.        |
| 7. Bhurja (St.Bk.)          | <i>Betula utilis</i> D.Don                   |
| 8. Canda (Rt.)              | <i>Angelica archangelica</i> Linn.           |
| 9. Coraka (Rt. & Rt. Stock) | <i>Angelica glauca</i> Edgw.                 |
| 10. Darbha (Rt.)            | <i>Imperata cylindrica</i> (Linn.) Beauv.    |
| 11. Dhanvayasa (Wh.Pl.)     | <i>Fagonia cretica</i> Linn.                 |
| 12. Dravanti (Sd.)          | <i>Jatropha glandulifera</i> Roxb.           |
| 13. Dugdhika (Wh.Pl.)       | <i>Euphorbia prostrata</i> W. Ait.           |
| 14. Elavaluka (Sd.)         | <i>Prunus avium</i> Linn.f.                  |
| 15. Gandira (Rt.)           | <i>Coleus forskoblii</i> Briq.               |
| 16. Gavedhuka (Rt.)         | <i>Coix lacryma-jobi</i> Linn.               |
| 17. Ghonta (Fr.)            | <i>Ziziphus xylopyrus</i> Willd.             |
| 18. Gundrah (Rz. & Rt.)     | <i>Typha australis</i> Schum. and Thonn.     |
| 19. Himsra (Rt.)            | <i>Capparis spinosa</i> Linn.                |

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| 20. Hingupatri (Lf.)       | <i>Ferula jaeschkeana</i> Vatke                    |
| 21. Itkata (Rt.)           | <i>Sesbania bispinosa</i> W.F.Wight                |
| 22. Itkata (St.)           | <i>Sesbania bispinosa</i> W.F.Wight                |
| 23. Jalpippalika (Wh.Pl.)  | <i>Phyla nodiflora</i> Greene                      |
| 24. Jivak (Pseudo-bulb)    | <i>Malaxis acuminata</i> D.Don                     |
| 25. Kadara (Ht. Wd.)       | <i>Acacia suma</i> Buch.-Ham.                      |
| 26. Kakajangha (Sd.)       | <i>Peristrophe bicalyculata</i> (Retz.) Nees       |
| 27. Kakanaja (Fr.)         | <i>Physalis alkekengi</i> Linn.                    |
| 28. Kapitan (St.Bk.)       | <i>Thespesia populnea</i> (L.) Soland. ex Correa   |
| 29. Karkash (Rt.)          | <i>Momordica dioica</i> Roxb. ex Willd.            |
| 30. Karnasphota (Sd.)      | <i>Cardiospermum halicacabum</i> Linn.             |
| 31. Karnasphota (Rt.)      | <i>Cardiospermum halicacabum</i> Linn.             |
| 32. Kattrna (Wh.Pl.)       | <i>Cymbopogon citratus</i> (DC.) Stapf             |
| 33. Kebuka (Rz.)           | <i>Costus speciosus</i> (Koerning ex Retz.) Smith. |
| 34. Khaskhas (Sd.)         | <i>Papaver somniferum</i> Linn.                    |
| 35. Khatmi (Rt.)           | <i>Althaea officinalis</i> Linn.                   |
| 36. Khatmi (Sd.)           | <i>Althaea officinalis</i> Linn.                   |
| 37. Khubkalan (Sd.)        | <i>Sisymbrium irio</i> Linn.                       |
| 38. Kodrava (Grain)        | <i>Paspalum scrobiculatum</i> Linn.                |
| 39. Ksirakakoli (Bulb)     | <i>Fritillaria roylei</i> Hook.                    |
| 40. Kshiravidari (Rt.)     | <i>Ipomoea digitata</i> Linn.                      |
| 41. Kulanjan (Rz.)         | <i>Alpinia galanga</i> Willd.                      |
| 42. Kumbhikah (Sd.)        | <i>Careya arborea</i> Roxb.                        |
| 43. Latakaranja (Sd.)      | <i>Caesalpinia bonduc</i> (Linn.) Roxb.            |
| 44. Lavaliphala (Fr.)      | <i>Phyllanthus acidus</i> (Linn.) Skeels           |
| 45. Madhulika (Rt.)        | <i>Eleusine corocana</i> (L.) Gaertn.              |
| 46. Mahameda (Rz.&Rt.)     | <i>Polygonatum cirrbifolium</i> Royle              |
| 47. Mahdusnuhi (Tub.Rt.)   | <i>Smilax china</i> Linn.                          |
| 48. Maramanjil (Rt. & St.) | <i>Coscinium fenestratum</i> (Gaertn.) Colebr.     |
| 49. Medasakah (St.Bk.)     | <i>Litsea chinensis</i> Lam.                       |
| 50. Medasakah (Wd.)        | <i>Litsea chinensis</i> Lam.                       |
| 51. Mesasrangi (Lf.)       | <i>Gymnema sylvestre</i> R.Br.                     |
| 52. Mesasrangi (Rt.)       | <i>Gymnema sylvestre</i> R.Br.                     |
| 53. Nandi (Rt.)            | <i>Ficus arnottiana</i> Miq.                       |
| 54. Nilajhintika (Rt.)     | <i>Barleria strigosa</i> Willd.                    |
| 55. Nimba (Rt.Bk.)         | <i>Azadirachta indica</i> A.Juss.                  |
| 56. Nimba (Fl.)            | <i>Azadirachta indica</i> A.Juss.                  |
| 57. Nimba (Fr.)            | <i>Azadirachta indica</i> A.Juss.                  |
| 58. Palas (Sd.)            | <i>Butea monosperma</i> (Lam.) Kuntze              |
| 59. Palas (Fl.)            | <i>Butea monosperma</i> (Lam.) Kuntze              |
| 60. Parasikayavani (Sd.)   | <i>Hyoscyamus niger</i> Linn.                      |
| 61. Pattura (Wh.Pl.)       | <i>Aerva lanata</i> (Linn.) Juss.                  |
| 62. Pilu (Fr.)             | <i>Salvadora persica</i> Linn.                     |
| 63. Pilu (Lf.)             | <i>Salvadora persica</i> Linn.                     |
| 64. Pilu (Rt.Bk.)          | <i>Salvadora persica</i> Linn.                     |
| 65. Potagala (Rt.)         | <i>Typha elephantina</i> Roxb.                     |

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| 66. Pudina (Aerial Part)    | <i>Mentha viridis</i> Linn.                        |
| 67. Pullani (Lf.)           | <i>Calycopterus floribunda</i> Lam.                |
| 68. Pullani (Rt.)           | <i>Calycopterus floribunda</i> Lam.                |
| 69. Pullani (St.)           | <i>Calycopterus floribunda</i> Lam.                |
| 70. Putikaranjah (St.Bk.)   | <i>Caesalpinia crista</i> Linn.                    |
| 71. Renuka (Fr.)            | <i>Vitex negundo</i> Linn.                         |
| 72. Riddhi (Tuber)          | <i>Habenaria intermedia</i> D.Don                  |
| 73. Rohisa (Wh.Pl.)         | <i>Cymbopogon martinii</i> (Roxb.) Wats            |
| 74. Rumimustagi (Resin)     | <i>Pistacia lentiscus</i> Linn.                    |
| 75. Sarala (Exudate)        | <i>Pinus roxburghii</i> Sargent                    |
| 76. Sarpagandha (Rt.)       | <i>Rauwolfia serpentina</i> (Linn.) Benth. ex Kurz |
| 77. Svetapunarnava (Rt.)    | <i>Boerbaavia verticillata</i> Poir.               |
| 78. Tailaparna (Lf.)        | <i>Eucalyptus globulus</i> Labill.                 |
| 79. Tinisha (Wd.)           | <i>Ougeinia oojeinensis</i> (Roxb.) Hochr.         |
| 80. Tintidika (Aerial Part) | <i>Rhus parviflora</i> Roxb.                       |
| 81. Trapusa (Sd.)           | <i>Cucumis sativus</i> Linn.                       |
| 82. Tuni (St.Bk.)           | <i>Cedrela toona</i> Roxb.                         |
| 83. Vanda (Lf.)             | <i>Dendrophthoe falcata</i> (Linn.f.) Ettingsh.    |
| 84. Vanda (St.)             | <i>Dendrophthoe falcata</i> (Linn.f.) Ettingsh.    |
| 85. Vanda (Aerial Rt.)      | <i>Dendrophthoe falcata</i> (Linn.f.) Ettingsh.    |
| 86. Vanda (Fl.)             | <i>Dendrophthoe falcata</i> (Linn.f.) Ettingsh.    |
| 87. Vanda (Fr.)             | <i>Dendrophthoe falcata</i> (Linn.f.) Ettingsh.    |
| 88. Vanyajiraka (Fr.)       | <i>Centratberum antbelmanticum</i> (L.) Kuntze     |
| 89. Vidarikand (Tuber)      | <i>Pueraria tuberosa</i> DC.                       |
| 90. Virala (St.Bk.)         | <i>Diospyros exsculpta</i> Buch.-Ham.              |
| 91. Visala (Rt.)            | <i>Trichosanthes bracteata</i> (Lam.) Voigt        |
| 92. Vyaghranakhi (Fr.)      | <i>Capparis horrida</i> Linn.                      |

## Monographs Published in Unani Pharmacopoeia of India

### PART-I, VOL. I

1. Aak *Calotropis Procera* (Ait). R.Br.
2. Aamla *Emblica officianalis* Gaertn. Syn. *Phyllanthus emblica* Linn.
3. Asgand *Withania somnifera* Dunal.
4. Asl-us-Soos *Glycyrrhiza glabra* Linn.
5. Atees Shireen *Aconitum heterophyllum* Wall ex. Royle
6. Babchi *Psoralea corylifolia* Linn.
7. Badiyan *Foeniculum vulgare* Mill
8. Balela *Terminalia belerica* Roxb
9. Baobarang *Embelia ribes* Burm.f.
10. Belgiri *Aegle marmelos* Corr.
11. Chiraita *Swertia chirata* Buch. Ham.
12. Darchini *Cinnamomum zeylanicum* Blume
13. Fufal *Areca catechu* Linn.
14. Gilo *Tinospora cordifolia* (Wild) Miers.
15. Halela Zard *Terminalia chebula* Retz
16. Heel Khurd *Elettaria cardamomum* (Linn.) Maton
17. Hilteet *Ferula foetida* Regel, *Ferula narthex* Boiss
18. Jauzbuwa *Myristica fragrans* Houtt
19. Kababchini *Piper cubeba* Linn
20. Kalonji *Nigella sativa* Linn.
21. Kamila *Mallotus philippinensis* Muell. Arg.
22. Kaner *Nerium indicum* Mill.
23. Karanj *Pongamia pinnata* (Linn) Merr.
24. Katan *Linum usitatissimum* Linn.
25. Khar-e-Khasak Khurd *Tribulus terrestris* Linn

26. Khiyar Shambar	<i>Cassia fistula</i> Linn.
27. Kishneez	<i>Coriandrum sativum</i> Linn
28. Kulthi	<i>Vigna unguiculata</i> (Linn.) walp syn. <i>Dolichos biflorus</i> Linn.
29. Lodh Pathani	<i>Symplocos racemosa</i> Roxb.
30. Mainphal	<i>Xeromphis spinosa</i> (Thunb) Keay. Syn. <i>Randia dumetorum</i> Lam.
31. Muqil	<i>Commiphora wightii</i> (Arn.) Bhand. Syn. <i>Balsamodendron mukul</i> Hook ex stocks
32. Pambadana	<i>Gossypium herbaceum</i> Linn.
33. Post-e-Gular	<i>Ficus racemosa</i> Linn.
34. Qaranful	<i>Syzygium aromaticum</i> (Linn.) Merr. & L.M. Perry
35. Qinnab	<i>Cannabis sativa</i> Linn.
36. Qust	<i>Saussurea lappa</i> C.B. Clarke
37. Sana	<i>Cassia angustifolia</i> Vahl
38. Sazaj Hindi	<i>Cinnamomum tamala</i> (Buch. Ham.) Nees & Eberm
39. Sheetraj (Hindi)	<i>Plumbago zeylanica</i> Linn.
40. Sibr	<i>Aloe barbadensis</i> Mill. Syn. <i>Aloe vera</i> Tourn. ex Linn.
41. Sumbul-ut-Teeb	<i>Nardostachys jatamansi</i> DC
42. Tagar	<i>Valeriana wallichii</i> DC
43. Zanjabeel	<i>Zingiber officinale</i> Roxb
44. Zard Chob	<i>Curcuma longa</i> Linn.
45. Zeera Siyah	<i>Carum carvi</i> Linn.

# Addresses of State Drugs Controllers/Licensing Authorities under ISM&H

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1. The Commissioner (ISM&H) & Licensing Authority,  
Government of Andhra Pradesh,  
Clock Tower, Secunderabad-500003 (Andhra Pradesh).
2. The Drug Controller,  
Directorate of Health Services,  
Government of Arunachal Pradesh,  
Naharlagun-791110 (Arunachal Pradesh).
3. The Drug Controller,  
Directorate of Health Services,  
Government of Assam,  
Dispur, Hengrabari, Guwahati-6 (Assam).
4. The Drug Controller,  
Directorate of Health Services,  
Government of Bihar,  
4<sup>th</sup> Floor, Vikas Bhawan, New Secretariat, Patna-800015.
5. The Drug Controller,  
Food & Drugs Administration,  
Chhatisgarh, Raipur.
6. The Director (ISM&H),  
Government of NCT Delhi,  
Tibbia College, Karol Bagh, New Delhi-110005.
7. The Director,  
Food & Drugs Administration,  
Government of Goa,  
Old G.M.C. Building, Panji-403001.
8. The Commissioner,  
Food & Drugs Control Administration,  
Government of Gujarat,  
1<sup>st</sup> Floor, Block-8, Dr. Jivraj Mehta Bhawan, Gandhinagar-382010. Gujarat.
9. The Licensing Authority-cum-Director (Ayurveda),  
Government of Haryana,  
SCO No. 2-A, Sector 7-C, Madhya Marg, Chandigarh-160007 (Haryana).

10. Director (Ayurveda) & Licensing Authority,  
Government of Himachal Pradesh,  
Kasumpti, Block No. 26, Himachal Pradesh-171009.
11. The Controller,  
Drugs & Food Control Organization,  
Patoli Mangotrian, P.O. Janipur, Jammu Tavi-180001.
12. Assistant Director (Ayurveda),  
Government of Jharkhand,  
Nepal House, Doranda, Ranchi (Jharkhand).
13. The Licensing Authority,  
Directorate of ISM&H,  
Government of Karnataka,  
Dhanvantari Road, Bangalore-560009 (Karnataka).
14. Drug Controller & Licensing Authority,  
Government of Kerala,  
Public Health Laboratory Campus, Red Cross Road,  
Thiruvananthapuram-695037.
15. The Controller,  
Food & Drugs Administration,  
Idgah Hills, Bhopal (Madhya Pradesh).
16. The Commissioner,  
Food & Drugs Administration,  
Government of Maharashtra,  
Survey No. 341, Bandra Kurla Complex,  
Bandra (East), Mumbai-400051.
17. Drug Controller & Director,  
Medical and Health Services,  
Government of Manipur,  
Imphal-795004 (Manipur).
18. Director of Health Services,  
Government of Meghalaya,  
Department of Health & Family Welfare,  
Shillong-793001 (Meghalaya).
19. Director of Health Services,  
Government of Mizoram,  
Department of Health & Family Welfare,  
Chaltlang, Aizawl-796012 (Mizoram).
20. Deputy Drug Controller,  
Directorate of Health Services,  
Government of Nagaland, Kohima-795001 (Nagaland).

21. Director & Licensing Authority,  
Directorate of Indian Medicine & Homoeopathy,  
Government of Orissa,  
3<sup>rd</sup> Floor, Head of Department (Annexe Building),  
Bhubaneswar-751001 (Orissa).
22. State Drug Controlling Authority,  
Government of Punjab,  
Department of Health & Family Welfare,  
Sector-34-A, Chandigarh-160015 (Punjab).
23. Director of Ayurveda & Licensing Authority,  
Government of Rajasthan,  
Directorate of Ayurveda,  
Lehgal Road, Ajmer-305001 (Rajasthan).
24. The Licensing Authority,  
Drugs and Cosmetics Cell,  
Department of Health & Family Welfare,  
Gangtok-737101 (Sikkim).
25. Controlling Authority & Deputy Drugs Controller,  
Government of Tripura,  
Assam Rifles Office Complex, Kunjaban, Agartala-799006 (Tripura).
26. Drug Controller,  
Government of Tamilnadu,  
258-261, Anna Salai, Tenampet, Chennai-600006.
27. Director (Ayurveda),  
Government of Uttaranchal,  
Sachivalaya, Dehradun (Uttaranchal).
28. Director, Ayurveda & Unani Services,  
Government of Uttar Pradesh,  
9<sup>th</sup> Floor, Indira Bhawan, Ashok Marg, Lucknow.
29. Director, Drugs Control,  
Government of West Bengal,  
Directorate of Health Services,  
141, A.J.C. Bose Road, Calcutta-700014 (West Bengal).

## List of Government Drug Testing Laboratories (Ayush)

1. **Chief Supdt. Drug Testing Laboratory,**  
Govt. Indian Medicine Pharmacy (Ayu.),  
Kattedan, Hyderabad-500077 (AP).
2. **Dy. Director, Govt. Drug Testing Laboratory,**  
Government Central Pharmacy,  
Jayanagar, I-Block Near Ashoka Pillar, Bangalore, Karnataka.
3. **Dean, Drug Testing Laboratory,**  
Government Ayurvedic & Unani Pharmacy,  
Vazirabad, Nanded, Maharashtra-431602.
4. **S.S.O. & Government Analyst,**  
Pharmacognosy Division, Food & Drug Laboratory,  
Near Polytechnic, Vadodara, Gujarat.
5. **Manager, Ayurveda Drug Testing Laboratory,**  
Government Ayurvedic Pharmacy,  
Pushkar Road, Ajmer, Rajasthan.
6. **Government Analyst Drug Testing Laboratory,**  
Ayurvedic & Unani Medicine,  
32, Sarojini Naidu Marg, Lucknow (UP).
7. **Incharge Drug Testing Laboratory,**  
Research Institute in ISM,  
Joginder Nagar, Distt. Mandi-176120 (HP).  
Phone: 01904-22048.
8. **Principal/Supdt.,**  
Government Drug Testing Laboratory,  
Rishikul State Ayurvedic College,  
Haridwar, Uttaranchal.  
Phone: 0133-427003.
9. **S.R.O. (Chemistry), Drug Testing Laboratory,**  
Ayurvedic Research Institute,  
Drug Standardization Unit,  
Poojappura, Thiruvananthpuram, Kerala.
10. **Dy. Supdt., State Drug Testing Laboratory,**  
Government Ayurvedic Hospital,  
Nagarwartangi, P.O. BJB Nagar, Bhubaneshwar, Orissa-751014,  
Phone: 0674-432347.
11. **Supdt., Government Drug Testing Laboratory for ISM,**  
Arignar Anna Government Hospital of Indian Medicine Complex,  
Arumbakkam, Chennai, Tamilnadu-106.  
Phone: 6216244, 6214844.

12. **Director,**  
State Pharmacopoeial Laboratory & Pharmacy for Indian Medicine,  
Kalyani, Nadia West Bengal.  
Phone: 50626281.
13. **Government Analyst, Food & Drug Testing Laboratory,**  
A-20, Lawrence Road Industrial Area, Delhi.
14. **Incharge, Drug Testing Laboratory,**  
Government Ayurvedic Pharmacy Compound,  
Amkho Lashkar, Gwalior-474009. (M.P.)
15. **Supdt., Drug Testing Laboratory of AYUSH,**  
Government Ayurvedic Pharmacy,  
GE Road, Raipur, Chhatisgarh.
16. **Controller, Combined Food & Drug Laboratory,**  
Patoli, Mangotrian, Jammu-180007 (J&K).
17. **Incharge, State Drug Testing Laboratory for ISM Drugs,**  
Government Ayurvedic College,  
Guwahati,  
Phone: 0361-2570455.
18. **Dy. Drug Controller, State Drug Testing Laboratory (ISM),**  
Aushadh Niyantran Bhawan,  
Pt. Nehru Office Complex, Agartala, Tripura-799006.
19. **Nodal Officer (ISM&H),**  
Central Medical Store,  
Zamabawak, Aizawl, Mizoram.
20. **Director, Health Services,**  
Government DTL (ISM),  
Food & Drug Laboratory, Pesteur Institute,  
Shillong, Meghalaya-793001.
21. **Director, Health Services,**  
Government DTL (ISM),  
Neheralagrum, Itanagar, Arunachal Pradesh.
22. **Assistant Director (ISM & H), Directorate of Health Services,**  
Government of Nagaland,  
Government Drug Testing Laboratory for AYUSH, Kohima, Nagaland.
23. **Superintendent, Drug Testing Laboratory of ASU Drugs,**  
Central Pharmacy and Stores,  
Old Press Road, Patiala, Panjab-147001.
24. **Principal and Incharge, Drug Testing Laboratory (ISM),**  
Shri Krishna Government Ayurveda College & Hospital,  
Kurukshetra, Haryana.
25. **Dy. Director (AYUSH), Government Drug Testing Laboratory,**  
Government of Jharkhand, Ranchi.
26. **Head, Department of Natural Product,**  
NIPER, Incharge, Drug Testing Laboratory (AYUSH),  
Mohali, Punjab.

## List of Approved Ayurveda, Siddha & Unani Private Drug Testing Laboratories under Rule 160 A to J of the Drugs and Cosmetics Rules 1945

Sl.No.	Name of the Laboratory	Telephone & Fax
1.	M/s. Varun Herbals Pvt. Ltd., 5-8-293/A, Mahesh Nagar, Chirag Ali Lane, Hyderabad.	040-23202731 Fax: 040-23202731
2.	M/s. Sipra Labs Pvt. Ltd., 407, Nilgiri, Adiya Enclave, Ameetpet, Hyderabad-500038.	040-23734720/ 040-23746873 Fax: 040-23746871
3.	Captain Srinivasa Murti Drug Research Institute for Ayurveda (CCRAS), Arumbakkam, Chennai-600106.	040-26214823 Fax: 26214809
4.	M/s. Sowparnika Herbal Extracts & Pharmaceuticals Pvt. Ltd., No. 31-A/2A, North Phase, SIDCO Industrial Estate, Chennai-600098.	26252590 Fax: 26521607 0191-2544382,
5.	Regional Research Laboratory (CSIR), Canal Road, Jammu Tavi, Jammu-180001.	0191-2547493 Fax: 0191-2543829, 0191-2547850
6.	ARBRO Pharmaceuticals Ltd., 4/9, Kirti Nagar Industrial Area, New Delhi-110015.	011-255457188, 011-25457923 Fax: 91-11-25463784
7.	Shriram Institute for Industrial Research, 14 & 15 Sathyamangala Industrial Area, Whitefield Road, Bangalore-560048.	080-28410165 080-28410172 Fax: 080-28410189
8.	Bangalore Test House, 65/20 <sup>th</sup> Main Morenhalli, Vijayanagar, Bangalore.	
9.	FRLHT, 74/2 Jarakabande Kaval, Post Attur Via Yelahanka, Bangalore-560064.	080-3336909, 080-3434465 Fax: 080-3334167
10.	M.S. Ramaiah Drugs and Allied Products Testing Laboratories, M.S. Ramaiah Nagar, M.S.R.I.T. (POST), Bangalore-560054.	

11. Ozone Pharmaceuticals Ltd.,  
(Analytical Lab.) MIE, Bahadurgarh,  
Dist. Jajjhar, Haryana-124507. 01276-267792,  
01276-227137  
01276-268037
12. M/s. Standard Analytical & Research Laboratories,  
358/4, Laxmibai Nagar, Industrial Estate,  
Kilamaidan, Indore, M.P.-452004. 0731-2412818  
Fax: 0731-2410204
13. M/s. Anusandhan Analytical & Biochemical  
Research Laboratory Pvt. Ltd.,  
Indore, 435, M.G. Road, Shiv Vilas Place,  
Rajwada, Indore, M.P.-452004. 0731-2534167,  
5054924
14. M/s. Choksi Laboratories Ltd.,  
6/3, Manoramganj, Indore, M.P.-452001. +91 731 2490592,  
2493592/93,  
5070019  
Fax:+91 731 2490593
15. M/s. Quality Control Laboratory,  
Plot No. 17, Malviya Nagar, Bhopal,  
M.P.-462003. 0755-2573935,  
5222448
16. J.R.D. Tata Foundation for Research in  
Ayurveda and Yoga Sciences,  
Arogyadham (Deendayal Research Institute)  
Chitrakoot, Satna, M.P.-485331. 07670-265632,  
265609, 265353  
Fax: 07670-265477,  
265623, 265510
17. Shriram Institute for Industrial Research,  
University Road, Delhi. 9511-27667267,  
27667860  
Fax: 9511-27667676
18. Vaidya Rathnam, Aushadhshala, Ollur, Thrissur. 0487-2352338,  
0487-2352398
19. Arya Vaidyashala Kotakkal, Malapuram. 0483-2742216, 19
20. M/s. Natural Remedies Pvt. Ltd., Bangalore. 080-4020 9999,  
4020 9703  
Fax: 080-4020 9817
21. Drug Testing Laboratory, NIPER,  
Mohali, Chanidgarh. 0172-2214695  
0172-2214683  
Fax: 0172-2214695
22. M/s. Standard Analytical Laboratory Pvt. Ltd.,  
69, Functional Industrial Estate, Patparganj,  
Delhi-92.
23. International Testing Centre  
86, Industrial Area, Phase-I,  
Panchkula 0172-2561543,  
0172-256825  
Fax: 0172-2561543
24. Laboratories Service Division,  
Sargam Metals Pvt. Ltd., Chennai.
25. M/s. Amol Pharmaceutical Pvt. Ltd.,  
Sanganer Jaipur, Rajasthan. 0141-2771132,  
0141-2771150  
Fax: 0141-2770744

# NABL Accredited Laboratories

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## **Delhi Test House, New Delhi**

**Address:**

A62/3, G.T. Karnal Road Industrial Area  
Opp. Hans Cinema, Azadpur,  
New Delhi-110033, India.

Nature of Lab: Open to others

Operations at: permanent facility

**Contact Details:**

Tel No. 011-27437327, 27435509

Fax No. 011-27435509, 27456917

E-mail: deltest@bol.net.in

## **Central Quality Assurance Laboratory, Nestle India Limited, Moga**

**Address:**

Post Box No. 11, Firozpur-Ludhiana Road,  
Moga-142001, Punjab, India.

Nature of Lab: In-house

Operations at: permanent facility

**Contact Details:**

Tel No. 01636-236280, 290

Fax No. 01636-236279

E-mail: vijendra\_prakash.gupta@in.nc

## **Central Laboratory, Bureau of Indian Standards, Sahibabad**

**Address:**

Plot No. 20/9 Site-IV,  
Sahibabad Industrial Area,  
Sahibabad-201010, Uttar Pradesh, India.

Nature of Lab: Open to others

Operations at: permanent facility

**Contact Details:**

Tel No. 0120-2770032, 2770821

Fax No. 0120-2770219

E-mail: biscl@nda.vsnl.net.in

## **Spectro Analytical Labs (P) Ltd., New Delhi**

**Address:**

C-55, Okhla Industrial Area Phase-I  
New Delhi-110020, India.

Nature of Lab: Open to others

Operations at: permanent facility

**Contact Details:**

Tel No. 011-26817949/50/51

Fax No. 011-26817954

E-mail: umesh@spectrolabindia.com

## **Shriram Institute for Industrial Research, Delhi**

**Address:**

19, University Road,  
Delhi-110007, India.

Nature of Lab: Open to others

Operations at: permanent facility

**Contact Details:**

Tel No. 011-27667267/27667860

Fax No. 011-27667676/27666013

E-mail: sridlhi@vsnl.com

## **SGS India (P) Ltd, General Laboratory, Gurgaon**

**Address:**

250, Udyog Vihar, Phase-IV,  
Gurgaon, Haryana, India

Nature of Lab: Open to others

Operations at: permanent facility

**Contact Details:**

Tel No. 0124-2399990-98

Fax No. 0124-2399765

E-mail: kurian\_plus@sgs.com

**Quality Control Laboratory for Processed Foods, Ludhiana**

Address: Punjab Horticultural Post Harvest  
Technology Centre, PAU Campus,  
Ludhiana-141004, Punjab, India.  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 0161-2405257  
Fax No. 0161-2405257  
E-mail: ptc@satyam.net.in

**Food Research and Analysis Centre, New Delhi**

Address: Plot 2A, Sector 8, Dwaraka,  
New Delhi-110045, India.  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 011-25360791-4  
Fax No. 011-25360802  
E-mail: frac@del3.vsnl.net.in

**International Testing Centre, Panchkula**

Address: 86, Industrial Area, Phase-I  
Panchkula-134109, Haryana, India.  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel. No. 0172-2561543/2565825  
Fax No. 0172-2561543  
E-mail: kesho@mantraonline.com

**National Agriculture and Food Analysis and Research Institute, Pune**

Address: 3<sup>rd</sup> Floor, MCCIA Building, Tilak Road,  
Pune-411002, Maharashtra, India.  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 020-24440079  
Fax No. 020-24441776  
E-mail: nafari@vsnl.net

**Reliable Analytical Laboratories**

Address: A-I, 5 Acres, Kothari Compounds,  
Near Tikuji-ni-wadi, Manpada,  
Thane (W)-400605, Maharashtra, India.  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 022-25899490/25899491  
Fax No. 022-25899492  
E-mail: reliablelabs@vsnl.net

**Bureau of Indian Standards (WROL), Mumbai**

Address: Manakalaya, E-9, MIDC,  
Behind Marol Telephone Exchange,  
Andheri (E), Mumbai-400093, Maharashtra  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 022-28327856/7891  
Fax No. 022-28262057  
E-mail: wrol@bis.org.in

**Ashco Analytical Services, Mumbai**

Address: Lab House Plot No. F-13, Opp Seepz,  
MIDC, Andheri (E), Mumbai-400093  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 022-28361002/28376701  
Fax No. 022-28350286  
E-mail: mohite@ashcoindustries.com

**SGS India Limited**

## Address:

Behaia Industrial Complex, Phase-II,  
1st Floor, 620, Diamond Harbour Road,  
Kolkata-700001, West Bengal, India.

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details

Tel No. 033-24463275

Fax No. 033-24470267

E-mail: [nemai\\_ghosh@sgs.com](mailto:nemai_ghosh@sgs.com)

**Choksi Laboratories Limited, Indore**

## Address:

6/3, Manoramaganj, Indore-452001, M.P

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details

Tel No. 0731-2490592, 2493592-93

Fax No. 0731-2490593

E-mail: [choksi@vsn.comcll@touchtell](mailto:choksi@vsn.comcll@touchtell)

**Tea Research Institute (Upasi Tea Research Foundation)**

## Address:

Plot No-2, S.P. Biotech Park,  
Genome Valley, Hyderabad-500078, A.P.

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details

Tel No. 04253-255301/235303

Fax No. 04253-235302

E-mail: [upasi@vsnl.com](mailto:upasi@vsnl.com)

**Trace Analysis Lab of Vimta Specialities (P) Ltd., Hyderabad.**

## Address:

Plot No. 2, S.P. Biotech Park,  
Genome Valley, Hyderabad-500078, A.P.

Nature of Lab: Open to others

## Contact Details:

Tel No. 040-27264400,093978786

Fax No. 040-27263657

E-mail: [vimtahq@vimta.com](mailto:vimtahq@vimta.com)

**Sipra Labs Private Ltd., Hyderabad**

## Address:

4<sup>th</sup> Floor, Nilgiri, Adity Enclave, Amerpet,  
Hyderabad-500038, A.P., India.

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details

Tel No. 040-23776879/23734720

Fax No. 040- 23746871

E-mail: [director@sipralabs.com](mailto:director@sipralabs.com)

**Shiva Analytical (I) Ltd., Hoskote**

## Address:

Plot No. 24D (P) & 34 D,  
KIADB Industrial Area,  
Bangalore Rural North, Hoskote-562114  
Karnataka, India.

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details:

Tel No. 08079-71713/71322

Fax No. 08079-71321

E-mail: [gupta@shivatcindia.com](mailto:gupta@shivatcindia.com)

**SGS India (P) Ltd, Cochin**

## Address:

Aspinwall compound, Subramanian Rd.  
Cochin-682003, Kerala, India.

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details

Tel No. 0484-2668913-14

Fax No. 0484-2668912

E-mail: [sunnykuttu\\_abraham@sgs.com](mailto:sunnykuttu_abraham@sgs.com)

**SGS India (P) Ltd, Chennai**

Address:

21, New Street, Kottur, Chennai-600085  
Tamil Nadu, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 044-24473929

Fax No. 044-24470317

E-mail: mariappan\_meena@sgs.com

**Laboratory Services Division, Sargam Metals (P) Ltd, Chennai**

Address:

2, Ramavaram Road, Manapakkam,  
Chennai-600089, Tamil Nadu, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel. No. 044-25541442

Fax No. 044-22541087

E-mail: sro@bis.org.in

**Bangalore Test House, Bangalore**

Address:

65, 20<sup>th</sup> Main, Marenahalli, Vijaynagar,  
Bangalore-560046, , Karnataka, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 080-23356415, 2338988895

Fax No. 080-23385979

E-mail: testhouse@satyam.net.in

**Chemieco Labs of Envirosigns & Equipments, Kochi**

Address:

44/150, SRM Road Ernakulum,  
Kochi-628018, Kerala, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 0484-2403154

E-mail: endesign@sancharnet.in

**C.E.P.C. Laboratory & Technical Division, Kollam**

Address:

V-Floor, Ponnamma Chambers, Hospital Rd  
Kollam-691001, Kerala, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 0474-2472704, 2761003

Fax No. 0474-274704

E-mail: cepclab@cashewindia.org

**Vimta Labs Ltd, Hyderabad**

Address:

142, IDA Phase- II, Cherlapally,  
Hyderabad-500051,  
Andhra Pradesh, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 040-27264141

Fax No. 040- 27263657

E-mail: vimtalab@hd1vsnl.net.ingrove

**Regional Testing Centre (N.R), Okhla, New Delhi**

Address:

Sahid Capt. Gaur Marg,  
Opposite Modi Flour Mills,  
Okhla, New Delhi-110020, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 011- 26847973/26312671

Fax No. 011-26847973

E-mail: rtcnr@nde.vsnl.net.in

**Anulab Industrial Testing & Analytical Laboratories, Agra**

Address:	Contact Details
33, Gandhi Nagar, Agra-282003, U.P., India.	Tel No. 0562-382093,355664 Fax No. 0562-358826 E-mail: anulab@agraonline.com
Nature of Lab: Open to others	
Operations at: permanent facility	

**Bureau of Indian Standards (NRL), Mohali**

Address:	Contact Details:
B-69, Phase VII, Industrial Focal Point S.A.S. Nagar-160051, Distt. Ropar (Punjab)	Tel No. 0172-2236218/722 Fax No. 0172-2236218 E-mail: nrol@bis.org.in
Nature of Lab: Open to others	
Operations at: permanent facility	

**Star Wire (I) Ltd, (Diagnostic Centre), Ballabgarh**

Address:	Contact Details
21, Mathura Rd, Ballabgarh-121004, Haryana, India.	Tel. No. 0129-2241263/64 Fax No. 0129-2241265 E-mail: starwire@giasdl01.vsnl.net.in
Nature of Lab: Open to others	
Operations at: permanent facility	

**Sunbeam Auto Ltd. (Testing R&D Centre)**

Address:	Contact Details
38/6, K.M. Stone, Delhi-Jaipur Highway, Narsingpur, Gurgaon-122001 Haryana, India.	Tel No. 0124-26372580/26372980 Fax No. 0124-26371010 E-mail: lab@sunbeamauto.com
Nature of Lab: Open to others	
Operations at: permanent facility	

**VXL Technologies Ltd. (Metallurgical lab)**

Address:	Contact Details
20/3, Mathura Rd. Faridabad-121006, Haryana, India.	Tel No. 0129-2305600/1/2 Fax No. 0129-2305608 E-mail: vtl@vxltechno.com
Nature of Lab: Open to others	
Operations at: permanent facility	

**Geological & Metallurgical Labs**

Address:	Contact Details
105x, 3 <sup>rd</sup> Main, 3 <sup>rd</sup> Cross, II Stage, Yeswasnthpur Ind. Sub. Goranguntepalya, India. Pin 560022	Tel No. 088-23472020/2347065 Fax No. 088-23471011 E-mail: gml980@vsnl.net
Nature of Lab: Open to others	
Operations at: permanent facility	

**National Test House**

Address:	Contact Details
Taramani, Chennai-600058, Tamil Nadu, India.	Tel No. 044-2432374/2431157 Fax No. 044-2433158 E-mail: nthsr@tn.nic.in
Nature of Lab: Open to others	
Operations at: permanent facility	

**Microlab, Chennai**

## Address:

170/2, Vanagaram Rd, Athipet,  
Chennai-600058, Tamil Nadu, India.

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details

Tel No. 044-26531514, 26530205

Fax No. 044-26530589

E-mail: balajialloys@yahoo.co.inmicro

**Laboratory Services Division, Sargam Metals (P) Ltd., Chennai**

## Address:

2, Ramavaram Rd, Manapakkam,  
Chennai-600089,

Tamil Nadu, India.

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details

Tel No. 044-22491117/6736

Fax. No. 044-22491651

E-mail: lab@sargammetals.com

**Regional Testing Centre (E.R), Kolkata**

## Address:

111 & 112, B.T. Road, Kolkata-700108,  
West Bengal, India.

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details

Tel No. 033-25774055/0686

Fax No. 033-25771353

E-mail: rtc-cal@wb.nic.in

**Gun Carriage Factory**

## Address:

Metallurgical Laboratory,  
Indian Ordnance Factories,  
Jabalpur-482011, Madhya Pradesh, India.

Nature of Lab: in-house

Operations at: permanent facility

## Contact Details

Tel No. 0761-2330016-19

Fax No. 0761-2330433/2331495

**Environment Protection Training & Research Institute (EPTRI Laboratory)**

## Address:

91/4, Gachi Bowli, Serllingampally (M),  
Hyderabad-500032, A.P. India.

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details

Tel No. 040-23000489/01241

Fax No. 040-230000361

E-mail: bnmurty@eptri.com

**Regional Food Research & Analysis Centre**

## Address:

155/1, Jyothi, Subbarama Chetty Circle  
Basaranagadi, Bangalore-560004

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details

Tel No. 080-26521894

E-mail: rfrac@vsnl.net,

**Interfield Laboratories, Cochin**

## Address:

XIII/1208-A, Interprint House,  
First Floor, Kochi, Chennai-682005

Nature of Lab: Open to others

Operations at: permanent facility

## Contact Details

Tel No. 0484-2210915/2211838

E-mail: ail@interfieldlaboratories.cor

**ITC Group Research and Development Centre, Bangalore**

Address: 3, Peenya Industrial Area, 1<sup>st</sup> Phase,  
Peenya, Bangalore-560058,  
Karnakaka, India.  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 080-28394354,28391593  
Fax No. 080-28394352  
E-mail: namasivayam.palani@itc.co.in

**National Thermal Power Corpn. Ltd., Research & Development Centre, Noida**

Address: A-8A, Sec-24, Dist- Gautam Budh Nagar,  
Noida-201301, U.P., India.  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 0120-259128,2410576  
Fax No. 0120-2410311  
E-mail: goel@ntpcrd.ernet.in

**IDMA Laboratories Ltd, Panchkula**

Address: SCO 12, Sector 26, Madhya Marg  
Chandigarh-160019, India.  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 0172-2791144  
Fax No. 0172-2793041  
E-mail: idmalabs@satyam.net.in

**AVON Food Lab, Delhi**

Address: C-35/23, Lawrence Road Industrial Area,  
Delhi-110035, India,  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 011-27391116  
Fax No. 011-27392997  
E-mail: info@avonagro.com

**Geo-Chem Laboratories (P) Ltd., Mumbai**

Address: 36/37, Raja Indu. Estate, Ist Floor,  
Purushottam Kheraj Marg, Mulund (W)  
Mumbai-400080, India.  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 022-55974999  
Fax No. 02255974616  
E-mail: laboratory@gechemgroup.com

**Quality Assurance Laboratory, Synthite Indu. Chemical Lte, Kolenchery**

Address: Synthite valley, Kadayiruppu,  
Kolenchery-682311, Kerala, India.  
Nature of Lab: Partly open to others  
Operations at: permanent facility

Contact Details  
Tel No. 0484-2761181-82  
Fax No. 0484-3051351  
E-mail: synthite@synthite.com

**National Council of Cement & Building Material**

Address: 34, K.M.Stone, Delhi-Mathura Road  
(NH-2), Ballabgarh-121004, Haryana, India  
Nature of Lab: Open to others  
Operations at: permanent facility

Contact Details  
Tel No. 0129-2242051-56  
Fax No. 0129-2242100/2246175  
E-mail: nccbm@giasbi01.vsnl.net.in

**Essen and Company, Bangalore**

Address:

106, Main Road, Off, 18<sup>th</sup> Cross,  
Malleswaram West, Bangalore-560055

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel. No. 080-23341230, 23341567

Fax No. 080-23312659

E-mail: essenblr@vsnl.net

**Independent Testing Lab., National Council for Cement & Building Materials**

Address:

NCB Bhavan, Old Bombay Road,  
Hyderabad-500008, Andhra Pradesh, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 040-23000344, 23000861

Fax No. 040-23000343

E-mail: hyd2\_ncbhyd@sancharnet.in

**SGS India (P) Ltd, Visakhapatnam**

Address:

24-01-30, Ground Floor, Haroon Manzil,  
Thompson Street, Vishakapatnam-530001  
Andhra Pradesh, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 0891-2566964,

2502089, 27

E-mail: sgs\_india@sgs.com

**Aglow Quality Control Laboratory (P) Ltd, Kolkata**

Address:

38, Kabir Road, Kolkata-700026,  
West Bengal, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 033-24658305

E-mail: aqcl@rediffmail.com

**Eskaps (I) Private Ltd, Kolkata**

Address:

30, Jawaharlal Nehru Rd,  
Kolkata-700016, West Bengal, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 033-22298957/9682

Fax No. 033-22495917

E-mail: eskaps@vsnl.com

**SGS India (P) Ltd.**

Address:

Plot No. 130, Sec-8, Post Box 82,  
Near Osla Theatre, Gandhidham  
Kutch-370201, Gujarat, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 02836-21857/30185

Fax No. 02836-232883/230645

E-mail: rajesh\_chanpura@sgs.com

**ARBRO Pharmaceuticals Ltd, New Delhi**

Address:

(Analytical Division)  
4/9, Kirti Nagar, Indu. Area  
New Delhi-110015, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 011-25467228, 25457922

Fax No. 011-25463784

E-mail: arbor@vsnl.in

**ASHCO Analytical Services, Noida**

Address:

D-70, Sec-2, Noida, Delhi (NCR)-201301  
India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 0120-2534025,2533784

E-mail: aasnoida@rediffmail.com

**Central Institute of Medical & Aromatic Plants, Lucknow**

Address:

P.O. CIMAP, Lucknow-226015, U.P.  
India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 0522-2717434

Fax No. 0522-2342666

E-mail: cimap@flashmail.com

**Regional Research Laboratory, (CSIR), Jammu**

Address:

Canal Road, Jammu Tawi,  
Jammu-180001  
J & K, India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details :

Tel No. 0191-2573064, 2543829

Fax No. 0191-2543829, 2548607

E-mail: agarwalsg@yahoo.com

**Sophisticated Industrial Materials Analytical Labs. (P) Ltd, New Delhi**

Address:

C-95, Okhla Industrial Area, Phase-I,  
New Delhi-110020  
India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 011-26810444/2681555

Fax No. 011-26811777

E-mail: cmecc@vsna.com

**Bee Pharmo Labs (P) Ltd, Mumbai**

Address:

5-6-7, Kakad Estate, R.G. Thadani Marg,  
Worli, Mumbai-400018, Maharashtra,  
India.

Nature of Lab: Open to others

Operations at: permanent facility

Contact Details

Tel No. 022-24937942, 24963022

Fax No. 022-24932874

E-mail: bcepharma@vsnl.com



**Govt. of India**  
**Department of AYUSH**  
**Ministry of Health and Family Welfare**  
**Pharmacopoeial Laboratory for Indian Medicines**  
**GHAZIABAD**