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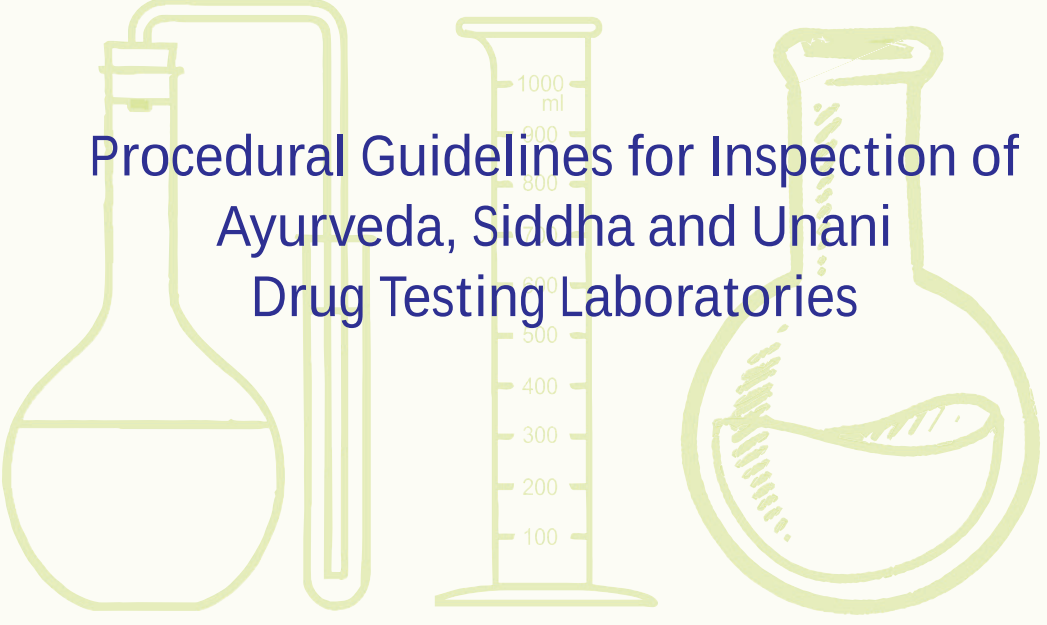
MANUAL
For
INSPECTORS



Procedural Guidelines for Inspection of Ayurveda, Siddha and Unani Drug Testing Laboratories

Department of AYUSH
(Drug Control Cell)
Ministry of Health and Family Welfare
Government of India
www.indianmedicine.nic.in

March 2013

INSPECTION MANUAL FOR APPROVAL OF DRUG TESTING LABORATORY UNDER RULE 160 A-J OF DRUGS & COSMETICS RULES-1945

Department of AYUSH
(Drug Control Cell)
Ministry of Health and Family Welfare
Government of India

March 2013

ISBN: 978-93-81458-07-5

Publisher: Department of AYUSH, Ministry of Health & Family Welfare, Government of India, New Delhi. *www.indianmedicine.nic.in*

Disclaimer: This manual has been prepared on the basis of provisions in the Drugs and Cosmetics Rules, 1945 for inspectors and drug testing institutions aimed at providing orientation and training about the procedure to be followed for approving laboratories engaged in testing of Ayurveda, Siddha and Unani drugs. The contributors and reviewers have taken due care to ensure correctness of the contents before publication and cannot be held responsible for any omission or inadvertent errors, nor can they warrant that all aspects of the subject have been covered. The manual is a guiding tool and does not have any connotation of legal binding.

Users of this manual are welcome to provide their feedback and suggestions for any improvement to Drug Control Cell, Department of AYUSH, 'B' Block, GPO Complex, INA, New Delhi-110023 by mail or by email at dcc-ayush@nic.in

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FOREWORD

Quality control of Ayurvedic, Siddha and Unani (ASU) drugs is an important task of Regulatory Authorities. Drug Testing Laboratories are required to establish the identity, purity and strength of ASU drugs and for ensuring that only good quality raw material is utilized for making ASU medicines and the quality medicines are available to the public.

A provision in the Drugs & Cosmetics (D & C) Rules, 1945 was made on 31st January 2003 for Approval of Laboratories for carrying out tests on ASU drugs and Raw materials used in their manufacture. The Inspectors designated by the Central and State Government jointly inspect such laboratories to verify that requisite regulations are complied, before recommending for approval. This Inspection Manual will facilitate better understanding amongst the Inspectors and Licensing Authorities about the provisions of Drugs & Cosmetics Rules, 1945 relating to the procedure for Approval of Drug Testing Laboratories of ASU drugs and thereby its proper implementation. It will bring uniformity, objectivity, transparency and harmonization in the procedure of inspection and approval of Laboratories as per legal provisions. The manual also brings out the provisions of D & C Rules, relating to Inspectors of ASU system in a lucid way.

I hope, the Inspectors and State Licensing Authorities for ASU drugs engaged in implementation of provisions of Drugs & Cosmetics Act 1940 and Rules made thereunder will be benefitted with the publication of this Inspection Manual. Besides, the Drug Testing Laboratories engaged in quality analysis of ASU Drugs, who wish to be recognized under the said legal provisions, will become better familiar with the procedure and requirements of approval. Suggestions and feedback from the stakeholders are welcome for Improving the caliber and contents fo the inspection manual. These guidelines are expected to help attain the objective of quality control of ASU drugs in the manufacturing units and market. The Department of AYUSH appreciates the commitment and efforts of all those involved in bringing out this document. Their efforts will be well rewarded if the document is used meaningfully by the stakeholders.

I am pleased to place on record the able guidance and motivation of our Secretary, Shri Anil Kumar for bringing out this document.

(Anil Kumar Ganeriwala)

Dated : 15th March 2013

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PREFACE

Department of AYUSH in its endeavor of making accessible quality Ayurveda, Siddha and Unani (ASU) medicines to the consumers has taken a number of regulatory and quality control steps. States have been provided financial assistance for improvement and development of ASU Drug Testing Laboratories (DTLs) and Pharmacies. However, to share the workload of State DTLs for ASU drugs and to meet the growing requirement of batch to batch testing of ASU drugs, it was decided that laboratories capable of undertaking quality analysis of ASU drugs as well as raw materials may also be involved in the task. Accordingly, a provision was made in the Drugs and Cosmetics (D&C) Rules by introduction of Rule 160 A-J for approval of laboratories from private sector for testing of ASU drugs and raw materials. Joint inspection by Inspectors appointed by the Central and State Government is necessary for according initial approval for the laboratories. The requirements in terms of area, manpower, equipment and instruments etc. for approval of laboratory are also laid down as part of the Rule 160 A-J. With this, many laboratories in the states have been recognized for the purpose of strengthening quality control and enforcement mechanism. However, many challenges are faced due to lack of adequately trained inspectors, lack of awareness and inadequate orientation of inspectors towards analytical aspects.

Therefore, a need was felt to prepare a guiding manual based on legal provisions and various aspects of inspection for awareness and capacity building amongst the regulatory staff. Present manual provides systematic information about the duties and responsibilities of inspectors, relevant provisions of D&C Act 1940 and rules thereunder in respect of required technical manpower, space, equipment, reference documents, reference samples that should be available with the laboratory and the procedural steps for making inspection and recommendation to approve a laboratory for testing ASU drugs.

It is expected that this manual will prove useful and handy for regulatory Inspectors assigned with the duty of assessing the infrastructure and functionality of Drug Testing Laboratories and for imparting necessary training to the officials engaged with quality control responsibilities. The inspection manual will also help in bringing objectivity and transparency in inspections and preventing arbitrary inspection reports. The manual may be equally useful to various stakeholder including the drug testing laboratories and regulatory personnel.

(Dr. D.C. Katoch)

15th March 2013

ACKNOWLEDGEMENT

Department of AYUSH thankfully acknowledges the contribution of all those, who were involved in preparation of the Inspection Manual.

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INTRODUCTION

Drugs and Cosmetics Act 1940 and Rules thereunder provide for appointment of Inspectors of Ayurveda, Siddha & Unani (ASU) systems of medicines who play an important role in the implementation of Drugs & Cosmetics (D&C) Act 1940 and Rules thereunder. One of the important duties of Inspectors working under the State Licensing Authority of ASU systems is inspection regarding the approval of Institutions/ Drug testing laboratories for ASU Drugs under Rule 160 A-J of D&C Rules 1945.

Training level and experience of Inspectors for the purpose of regulatory implementation varies because qualifications prescribed for Drug Inspectors of ASU drugs vary. The Inspector may be a graduate in Pharmacy/ Pharmaceutical Chemistry/ Medicine (with specialization in Clinical pharmacology or Microbiology) having undergone practical training in the manufacture of ASU drug or have a Degree/Diploma in A/S/U systems of medicines or possessing Degree in Ayurveda Pharmacy as per the provisions of the Act and Rules thereunder. Under such circumstances when the qualification and experience level of Inspector vary, it is important to impart comprehensive knowledge of the D&C Act and Rules thereunder to the Inspectors for facilitating uniform implementation of the Act. This is all more important as there is no induction training when the person with requisite qualification is made an Inspector. In many of the States due to lack of dedicated manpower for enforcement of provisions of Drugs & Cosmetics Act, ASU Doctors working in the Hospitals/ dispensaries are designated as Inspectors usually without any additional capacity building training specifically on analytical aspects. In such a situation this manual becomes even more important.

This Inspection manual covering various aspects about the qualifications, duties and responsibilities of Inspectors will be a much needed helpful guide for orientation of ASU Inspectors for proper discharge of their duties under D&C Act and Rules thereunder. The inspection manual of Drug testing laboratory is especially explained in detail for development of insight of the Inspectors regarding interpretation and implementation of the Rules. Role of State licensing Authority in facilitating such inspection is explained keeping in view essential points to be focused while forwarding the application for joint inspection to the Central Government. It also includes the list of recommended equipment required for carrying out analysis of ASU drugs and raw materials. The manual also touches upon various essential books that may be required for testing of ASU drugs. This Inspection Manual is not a substitute of the Drugs & Cosmetics Act 1940 and Rules thereunder but this manual is expected to help State Licensing Authorities to augment the regulatory capacities of Inspectors and in developing Master Trainers as well.

Chapter - I

Important points related to ASU Inspectors in Drugs & Cosmetics Act 1940 and Rules thereunder.

(1) Who is an Inspector?

In relation to Ayurvedic, Siddha or Unani drugs, an Inspector appointed by the Central Government or a State Government under section 33G of Drugs & Cosmetics Act 1940 is called as Inspector.

(2) Who can be appointed as Inspector?

A person with any of the following qualifications can be appointed as an Inspector:

(a) Degree in Pharmacy/ Pharmaceutical Sciences/ Medicine with specialization in Clinical pharmacology or Microbiology from a University established in India by law and shall have undergone practical training in the manufacture of Ayurvedic (including Siddha) or Unani drug, as the case may be;or

(b) Degree in Ayurvedic or Siddha or Unani System or a degree in Ayurveda Pharmacy, as the case may be, conferred by a University or 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) Diploma in Ayurveda, Siddha or Unani Systems, 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.

Drugs & Cosmetics Rule 167and 49 may be seen for details.

(3) Who cannot be appointed as an Inspector?

Any person having any financial interest in the manufacture or sale of any drug cannot be appointed as Inspector in spite of meeting above requirements.

(4) What are the roles and responsibilities of Inspectors?

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 powers and duties may be exercised or performed shall be such as may be prescribed in Drugs & Cosmetics Act 1940 and Rules thereunder.

(a) Powers of Inspectors (Duties regarding regulation of manufacture for sale of ASU drugs)

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, —

- Inspect, --

  (i) any premises wherein any ASU drugs is being manufactured and the means employed for standardizing and testing the ASU drugs;

(ii) any premises wherein any ASU drugs is being sold, or stocked or exhibited or offered for sale, or distributed .

- Take samples of any ASU drugs,--

  (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 ASU drugs to a purchaser or a consignee.

- 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 ASU drugs in respect of which an offence under Chapter IV-A of D&C Act has been, or is being, committed; or

  (ii) enter and search any place in which he has reason to believe that an offence under Chapter IV-A of D&C Act 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 ASU drugs in respect of which an offence under Chapter IV-A of D&C Act has been, or is being, committed, and order in writing the person in possession of the ASU drugs in respect of which the offence has been, or is being, committed, not to dispose of any stock of such ASU drugs 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 ASU drugs, seize the stock of such ASU drugs 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. (clause c of Section 22 of D&C Act 1940)

- Examine any record, register, document or any other material object found with any person, or in place, vehicle, vessel or other conveyance referred as above 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.

  A receipt by an Inspector for the stock of any ASU drugs or any record, register, document or any other material object seized by him shall be in Form 16 of Drugs & Cosmetics Rules 1945

- 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 ASU drugs in respect of which he has reason to believe that an offence under Chapter IV-A of D&C Act has been, or is being, committed.

- Exercise such other powers as may be necessary for carrying out the purposes of Chapter IV-A of D&C Act or any rules made there under.

- ❖ The provisions of the Code of Criminal Procedure, 1973 shall, so far as may be, apply to any search or seizure under Chapter IV-A of D&C Act as they apply to any search or seizure made under the authority of a warrant issued under section 94 of the said Code.
- ❖ Every record, register or other document seized or produced as above 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.
- ❖ If any person willfully obstructs an Inspector in the exercise of the powers conferred upon him by or under Chapter IV-A of D&C Act or refuses to produce any record, register or other document when so required as mentioned above, he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.

Subject to the instructions 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 of 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 send forth with to the controlling authority after each inspection a detailed report indicating whether or not the conditions of the license and the provisions of the Act and 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.

(b) Duties regarding Joint Inspection for Approval of Drug Testing laboratories under Rule 160A-J

- ❖ 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.
- ❖ Report of inspection. - The Inspectors appointed by the Central Government as stated in Rule 160-E shall forward to the approving authority a detailed report of the results of the inspection.

- The approved laboratory shall allow the Inspector appointed under the Act to enter with or without prior notice the premises where 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.

(5) Who is the reporting authority for Inspectors?

Every inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian penal Code and shall be officially sub-ordinate to such authority as the Government appointing him may specify in this behalf.

(6) What is the jurisdiction/ territorial responsibility of Inspectors?

The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it think fit, having the prescribed qualifications, 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.

(7) What is the standard procedure for drug sample collection by a Drug Inspector?

- Where an Inspector takes any sample of a ASU drugs under Chapter IV-A of D&C Act, he shall tender the fair price thereof and may require a written acknowledgement therefor.
- Where the price tendered is refused, or where the Inspector seizes the stock of any ASU drugs,he shall tender a receipt therefore in the Form 17A of Drugs & Cosmetics Rules 1945.
- Where an Inspector takes a sample of a ASU drugs for the purpose of test or analysis, he shall intimate such purpose in writing in the Form 17 of Drugs & Cosmetics Rules 1945, 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 ASU drugs are being manufactured, it shall be necessary to divide the sample into three portions only:

  Provided further that where the ASU drugs is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the ASU drugs 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.

- 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. (The Sample for test or analysis to be sent to the Government Analyst shall be sent by registered post or by hand in a sealed package, enclosed together with a memorandum in Form 18-A of Drugs & Cosmetics Rules 1945,in an outer addressed to the Government Analyst. The package as well as the outer cover shall be marked with a distinguishing number. A copy of the memorandum and a specimen impression of the seal used to seal the package shall be sent by registered post or by hand to the Government Analyst. On the receipt of the package from an Inspector, the Government Analyst or an Officer authorized by him in writing in his behalf shall open the package and shall also record the conditions of the seals on the package).

  (ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the ASU drugs;

  (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. (Section 18A – "Every person, not being the manufacturer of a ASU drugs or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.")

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

  (a) he shall use all despatch in ascertaining whether or not the ASU drugs contravenes any of the provisions of the section 33EEC and, if it is ascertained that the ASU drugs 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 the return of thestock seized;

  (b) if he seizes the stock of the ASU drugs, 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 ASU drugs, he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

- Where an Inspector seizes any record, register, document or any other material object, he shall, as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof.

Chapter - II

How to carry out laboratory Inspection?

Rule as in Drugs & Cosmetics Rules 1945 regarding approval of Institutions/ Drug testing laboratory for carrying out tests on Ayurvedic, Siddha & Unani Drugs and Raw materials.

(Part XVIA of D&C Rules 1945)

Approval of Institution for carrying out tests on Ayurvedic, Siddha and Unani Drugs and Raw Material used in the manufacture on behalf of licensees for manufacture for sale of Ayurvedic, Siddha and Unani Drugs.

160-A Application for grant of approval for testing Ayurvedic, Siddha and Unani Drugs.

Application for grant or renewal of approval for carrying out of tests for identity, purity, quality and Strength of Ayurvedic, Siddha and Unani Drugs or the raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of the said Ayurvedic, Siddha and Unani drugs, shall be made in Form-47 to the licensing authority appointed by the state Government for the purposes of Part XVI, XVII or XVIII of these rules, as the case may be, and referred to as the " approving authority " under this part and shall be accompanied by an inspection fee of six thousand rupees in respect of the Ayurvedic, Siddha,Unani drugs, specified in the books prescribed in First Schedule to the Act.

Provided that the applicant shall furnish to the approving authority such additional information as may be required by it in connection with the application in Form-47:

PROVIDED FURTHER that if the applicant applies for renewal of approval after the expiry but within six months of such expiry, the inspection fee payable shall be six thousand rupees plus an additional inspection fee at the rate of one thousand rupees per month in the case of testing of Ayurvedic, Siddha and Unani drugs specified in first Scheduled to the Act.

Explanation: For purposes of this part, the word "Ayurvedic Siddha and Unani Drugs" shall also mean and include the raw materials used in the manufacture of AYURVEDIC, SIDDHA and UNANI drugs, as the case may be.

160-B Form in which approval to be granted for carrying out tests on Ayurvedic, Siddha and Unani drugs on behalf of licensees for manufacture of Ayurvedic, Siddha and Unani drugs and conditions for grants or renewal of such approval.

1) Approval of carrying out of such tests of identity, purity, quality and strengthen of AYURVEDIC, Siddha and Unani drugs as may be required

under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha And Unani drugs shall be granted in Form-48

2) Before approval in Form-48 is granted or renewed, the following conditions shall be complied with by the applicants, namely:-

i) The premises where the tests are carried out shall be well lighted and properly ventilated excepted where the nature of tests of any Ayurvedic, Siddha and Unani drugs 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 be provided adequate space having regard to the nature and number or 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, (iv) Office-cum-Record Room, with proper partitions and minimum required area of 800 square feet.

(b) (i) Expert in Ayurveda, Siddha and Unani Medicine who possesses a degree qualification recognized under Scheduled II of Indian Medicine Central Council Act,1970;

(ii) Chemist, who shall possess at least Bachelor Degree in Science or Pharmacy or Pharmacy (Ayurveda) awarded by a recognized University; and

(iii) Botanist (Pharmacognosist), who shall possess at least Bachelor Degree in Science (Medical) or Pharmacy or Pharmacy (Ayurveda) awarded by recognized University.]

(c) The applicant shall provide adequate equipment 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 (Ostwald's, Redwood Viscometer).
8. Tablet disintegration apparatus.
9. Moisture determination Apparatus (IC filtration).
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/ part.
16. Water supply demineralized 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. GLC with FI detector.
27. Silica crucible.
28. Tablet friability tester.
29. Tablet dissolution tester.
30. Other related to equipment, reagents, Chemical glassware.

Pharmacognosy section:-

1. Microscope binocular.
2. Dissecting Microscope.
3. Microtome.
4. Chemical balance.

5. Micro slide cabinet.
6. Aluminum slide trays.
7. Hot air oven.
8. Ocular Micrometer.
9. Stage Micrometer.
10. Camera Lucida Prism type and mirror type.
11. Hot Plates.
12. Refrigerators.
13. LPG Cylinder with Burners.
14. Other related equipment, reagent, glassware 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 to 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 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 the identity, purity, quality and strength shall be carried out by person whose qualifications and experience of testing are adequate as stated in clause (b) of sub-rule (2).

(6) The applicant shall provide book 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 of 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 (Reference samples) recognized under the provisions of the Act and Rules made there under and such reference samples kept in the laboratory may be required in connection with the testing or analysis of the products of which approvals applied for.

160-C Duration of approval

An approval granted in Form-48 or renewed in Form-49 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 in application for the renewal of an approval in form 47 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 b e 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.

160-D Conditions of approval

An approval in Form-48 shall be subject to the following condition namely:-

I. The institution granted approval under this part (herein after referred to as the approved Laboratory) shall provide and maintain adequate staff and adequate premises and equipment as specified in Rule160-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 and the results thereof together with the protocols of tests showing the reading 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 date is assigned ; for a period of two years from such date of expiry and in the case 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 and changes in the person-in-charge of testing Ayurvedic, Siddha and Unani drugs or 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 drugs 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 IV-A of the Act of which the approving authority has given the approved laboratory not less than four months' notices.

IX. The approval laboratory shall maintain an inspection book to enable the inspector to record his impression of defects notices.

160-E 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 qualification of the expert staff who are or may by employed by the laboratory.

160-F Report of inspection

The inspectors appointed by the Central Government as stated in Rule 16-E shall forward to the approving authority a detailed report of the results of the inspection.

160-G 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 satisfy, 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.

160-H 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

160-I 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.

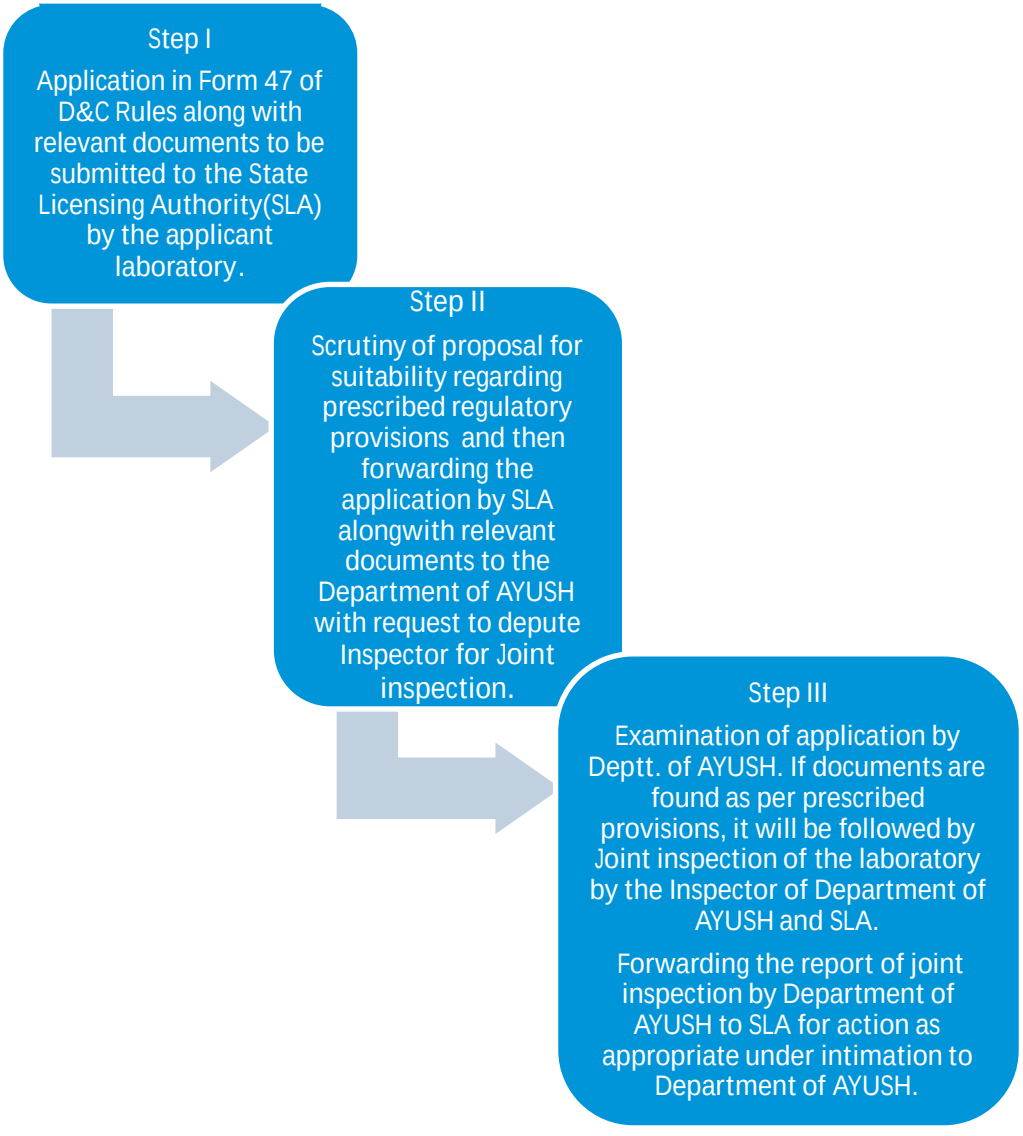
160-J Withdrawal and suspension of approvals

(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 thereof, 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 or the rules made thereunder.

2. Any approved laboratory, whose approval has been suspended or withdrawal, 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 system of Medicine and Homoeopathy, Government of India in this behalf and notified in the official Gazette.

EXPLANATORY NOTE ON RULE 160 A-J

The procedure of Approval of Institutions for carrying out tests on Ayurvedic, Siddha and Unani Drugs and Raw materials under Rule 160 A-J of D&C Rules 1945 can be broadly divided in 3 steps:



If Approval or Renewal is given by SLA to the laboratory, then SLA shall intimate to the Department of AYUSH with a copy of Approval given in Form 48 or Renewal in Form 49.

Points to be taken care by State Licensing Authority (SLA) before forwarding the application of the applicant Laboratory to Department of AYUSH in Form 47 of D&C Rules 1945

(1) The application is made in Form 47 as prescribed in Drugs and Cosmetics Rules 1945.

(2) A photocopy of Challan should be enclosed with the copy of forwarded application.

(3) The forwarded application must be accompanied with the following:

❖ List of experts employed in the Laboratory

An important point to check by the SLA before forwarding the application is whether the required numbers of experts are employed or not?

Three experts are needed:

(a) Expert in Ayurveda, Siddha or Unani possessing degree qualification recognized under SCHEDULE II OF IMCC Act, 1970.

(b) One Chemist, who shall possess at least Bachelor Degree in Science or Pharmacy or Ayurvedic Pharmacy awarded by recognized University.

(c) One Botanist (Pharmacognosist), who shall possess at least Bachelor Degree in Science (Medical) or Pharmacy or Ayurvedic Pharmacy awarded by recognized University.

❖ The attested photocopy of qualifications, appointment letter, joining letter,experience certificate and affidavits of above 3 experts employed in laboratory should accompany the application.

❖ List of equipment available with the laboratory.

An important point to check by SLA, before forwarding the application is whether the list has most of the equipment as recommended in Rule 160B of Drugs & Cosmetics Rules 1945?

Whether the lab has Instruments like HPLC, HPTLC and AAS? If not, then whether the laboratory has tie up (in the form of consent letter or MoU) with some other laboratory (NABL accredited) having these instruments to carry these tests on their behalf.

❖ An attested photocopy of Consent letter or MoU as mentioned above.

❖ A copy of layout map of laboratory.

An important point to Check by SLA is whether all the 6 sections viz. (i)Chemistry, (ii)Pharmacognosy, (iii)Ayurveda Siddha & Unani, (iv)Microbiology, (v)sample room and (vi)Office cum record room, with the required total area as mentioned in Rule 160 B is clearly demarcated in the layout plan or not? If needed for the sake of clarity the section wise area may be enclosed separately (other than map) in words.

❖ List of books of standard recognized under the provisions of the Act and the Rules made thereunder, available with the laboratory.

An important point to check by the SLA is whether the list of books includes all the Pharmacopoeias, Formularies and TLC/Microscopy/Macroscopic Atlas of Ayurveda, Siddha or Unani published by the Government of India till date? The applicant at least must have said books.

❖ List of Reference Samples of standard Ayurvedic, Siddha & Unani drugs available with the laboratory.

An important point to check by the SLA is that the list should contain reference samples of not only Herbal but also of Metal/Mineral and Animal origin, available with the laboratory.

Checklist of documents to be sent with the application

Criteria	Requirements for approval of laboratory as per Drugs & Cosmetics Rules 1945, Rule -160B	Checklist of documents to be sent with the application
Application In Form 47	Application in Form 47 of D&C Rules 1945 to the Licensing Authority with an inspection fees of six thousand Rupees in the form of Challan	(1) Copy of Application in Form 47 (2) Copy of Challan of six thousand Rupees
Experts employed by the laboratory	(1) Expert in Ayurveda, Siddha or Unanipossesing degree qualification. (2) One Chemist (Bachelor of Science/ Pharmacy/ Ayurvedic Pharmacy. (3) One Botanist/ Pharmacognosist (Bachelor in Science- Medical/ Pharmacy/ Ayurvedic pharmacy	(1) List of technical experts employed by laboratory for testing of ASU drugs with copy of their qualification and experience certificates. (2) Appointment letter and Joining letter of the technical experts (3) Affidavit by the experts regarding their employment in Laboratory.
Equipment available in the laboratory	(1) Total of 50+ equipments in the sections of chemistry, pharmacognosy& microbiology are recommended. (2) Instruments like HPLC, HPTLC, AAS could be arranged by tie up with other laboratories.	(6) List of equipment available with the laboratory. (7) Copy of MoU or consent letter of other approved or NABL accredited laboratory consenting to carry tests of HPLC/ HPTLC/AAS for the applicant laboratory (If HPLC/HPTLC/AAS are not available with the laboratory)

Provision of Separate sections in laboratory	Separate sections with total area of at least 800 square feet are required for: 1) Chemistry. 2) Pharmacognosy. 3) Ayurveda, Siddha & Unani. 4) Microbiology. 5) Sample room. 6) Office cum record room.	(1) Layout map of the laboratory clearly showing 6 sections with total area as specified.
Reference books available with the laboratory	Applicant must have: 1) Books of standard recognised under the provisions of the act & rules made thereunder. 2) Books required in connection with the testing of analysis of products for testing of which approval is required.	(9) List of Reference books available with the applicant including all the till date published Pharmacopoeias, Formularies & TLC Atlas of Ayurveda, Siddha & Unani*
Reference samples available with the laboratory	Applicant must have: 1) Reference samples of standard ASU drugs that may be required in connection with the testing or analysis of the products for which approvals applied for.	(10) List of reference samples of Herbal, Mineral/Metal and Animal origin available with the laboratory.

* List of Pharmacopoeias and Formularies published

(1) Ayurvedic Pharmacopoeia of India Pt.I –Vol. I to VIII

(2) Ayurvedic Pharmacopoeia of IndiaPt.II–Vol. I to III

(3) Atlas of Macroscopic & Microscopic Characters of Ayurvedic Pharmacopoeia Drugs (API P-I, V-I)

(4) Macroscopic & Microscopic Atlas of Pharmacopoeial Drugs (API - P-I, Vol.-V)

(5) Ayurvedic Formulary of IndiaPt. I to III

(6) Unani Pharmacopoeia of IndiaPt. I –Vol. I to VI

(7) Unani Pharmacopoeia of IndiaPt. II –Vol. I to II

(8) National Formulary of Unani MedicinePt. I to VI

(9) Siddha Pharmacopoeia of IndiaPt. I–Vol. I to II

(10) Siddha Formulary of IndiaPt. I to I

Proforma for assessment of Drug Testing Laboratory by the Inspecting Officers under Drugs & Cosmetics Rule 160E

S.No.	Points for observation	Observations of Inspection team
1	Name & full address of the laboratory with telephone, fax no. & email.	
2	Status; Autonomous/ Semi-Govt./ Private	
3	Central financial assistance	
4	Year of Establishment	
5	Years of experience in testing of Ayurveda/ Siddha/ Unani drugs	
6	Name & Designation of In-charge	
7	Whether the laboratory has been recognized for the purpose of conducting testing of drugs. If so, the date of recognition from the Central Govt. / State govt.	
8	(i) Total covered area of the building where testing of Ayurveda, Siddha & Unani drugs will be carried out. (ii) Name of Sections with space specifications (a) Chemistry, (b) Pharmacognosy, (c) Ayurveda, Siddha and Unani, (d) Microbiology, (e) SampleRoom, (f) Office-cum-Record Room (iii) Building : Old/New with remarks (iv) Whether floor, walls, roof are smooth, cracks free, tiled and plastic painted (v) Windows and doors : whether properly closing/ sealed properly/locked (vi) Rooms : Whether dust free, properly lighted, cooled/ AC, curtained (vii) Furniture : working tables/ wooden/steel, tiled/cemented, fuming cupboards, exhaust fans, electricity, generator facilities (viii) Whether fire safety measures installed.	
9	Name of the Technical experts/ Scientist/ Analyst for various section with their qualifications and experience of testing of Ayurvedic, Siddha & Unani drugs:	

	(i) Experts of Chemistry (ii) Experts of Pharmacognosy (iii) Experts of Ayurveda/ Siddha/ Unani	
10	Name and qualification of the Authorized Analyst to sign the test report.	
11	List of equipment provided for various sections with following details in tabulated form: (i) Date of purchase, (ii) Date of installation, (iii) Name of the staff operating it, (iv) Whether internal/external training to staff given (v) Number of operations per month and whether log book maintained, (vi) Calibration status (vii) Whether equipment under AMC	
12	Number of samples/product tested in the past 2 years (product wise eg. Vati, Asava, taila, churna, Syrup etc) in case of previous approval. Sample source: Internal/External/Govt. Whether the samples codified Time taken in sample testing Time taken in reporting Whether samples of raw material/ plants/ animals/ mineral/ compound formulations/ classical/P&P medicines Categories (dosage forms) of compound Ayurveda, Siddha & Unani formulation to be tested may be specified egAsava, Avaleha etc. Categories of tests carried out for raw material/ finished Ayurveda, Siddha & Unani products in the laboratory. Random checking of test reports	
13	Fees structure for various tests to be conducted in the laboratory specifically for plant, mineral/metal, and animal based drugs and other Ayurveda, Siddha & Unani formulations applicable for the approved period.	
14	Whether reference books including Formularies, Pharmacopoeias and TLC Atlas of Ayurveda, Siddha & Unani drugs are maintained in the laboratory. If so details thereof.	

15	Whether reference samples of Standard Ayurvedic, Siddha & Unani Drugs of Herbal, Metal/Mineral and Animal origin are maintained in the laboratory. If so details thereof. Whether reference samples are labeled with regard to--- Procurement details, Date of expiry, Analytical Report no. etc.	
16	Observation and recommendations of the inspecting officers, indicating the: Basis of recommendations Reasons for not recommending objectively Avenues for further improvement	
17	(i) Name and signature of State Govt. Inspector of Joint Inspection team. (ii) Name and signature of Central Govt. Inspector of Joint Inspection team.	

- Information may be provided as separate annexure in case it cannot be accommodated in the space provided.
- All the annexures should be duly signed/acknowledged by the authorized signatory of the Institute/ Laboratory.

Checklist of Verified Documents to be enclosed with the Inspection Report

1. Copy of previous license/approval if any.
2. Copy of layout map & section wise description of area in words.
3. List of Technical experts with copy of Appointment letter, joining letter, experience certificate and affidavit.
4. Original copy of specimen signature against their name of authorized signatory for issue of test certificates and reports.
5. Copy of Authorization letter to the Authorized analyst for signing the test report.
6. Copy of equipment list and relevant information in tabular form.
7. Copy of purchase bills of a few important equipment.
8. Copy of log book for operations of any 1 or 2 equipment.
9. Copy of calibration record of any 1 or 2 equipment.
10. Copy of list of product wise samples tested in last 2 years.
11. Copy of categories of ASU formulations to be tested.
12. Copy of list of tests to be done on various formulations.
13. Copy of more than 5 test reports.
14. Copy of fees structure for various tests- formulation wise if possible.
15. Copy of list of reference books.
16. Copy of list of reference samples

Format of various Forms used by the Inspectors.

FORM 16

RECEIPT FOR STOCK OF DRUGS OR COSMETICS FOR RECORD, REGISTER, DOCUMENT OR MATERIAL OBJECT SEIZED UNDERSECTION 22(1) (C) OR 22(1)(CC) OF THE DRUGS AND COSMETICS ACT,1940

The stock of drugs or cosmetics or records, registers, documents or material objects detailed below has/ have this day has seized by me under the provisions of clause (c) or clause(cc) of sub- section (1) of Section 22 of the Drugs and Cosmetics act,1940(23 of 1940) from the premises of.....Situated at.....

Date..... Inspector.....

Details of drugs, cosmetics, records, registers, documents or material objectsseized.

Date..... Inspector.....

FORM 17

INTIMATION TO PERSON FROM WHOM SAMPLE IS TAKEN

To,

…….

I have this day taken from the premise s of ……situated at ……. samples of the drugs/ cosmetics specified below for the purpose of test or analysis.

Date…… Inspector……..

Details of sample taken

Date…… Inspector……..

FORM 17-A

RECEIPT FOR SAMPLES OF DRUGS OR COSMETICS TAKEN WHERE FAIR PRICE TENDERED THEREOF UNDER SUB-SECTION (1) OF SECTION 23 OF THE DRUGS AND COSMETICS ACT, 1940 IS REFUSED

To,

Whereas I, this …… day of …….. [20]……..have taken, from the premises of ……. situated at……. samples of drugs/ cosmetics as specified below,-

Details of samples ……..

And whereas I had offered to pay you rupees …….. as the fair price of the samples of drugs / cosmetics taken:

And whereas, you have refused to accept the fair price tendered thereof;

Now, therefore, I give you this receipt as the fair price tendered for the samples of the drugs/cosmetics taken by me.

Date…… Inspector……..

FORM 18-A

MEMORANDUM TO GOVERNMENT ANALYST

Serial No……. From……...

To,

The Government Analyst

The portion of sample/ container described below is sent herewith for test or analysis under the provisions of Section 33-H of the Drugs andCosmetics 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 47

Application for grant or renewal of approval for carrying out tests 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.

(1) *I/ We ..... of..... hereby apply for the grant / renewal of approval for carrying out tests of identity, purity, quality and strength on the following categories of Ayurvedic, Siddha and Unani drugs or raw materials used in the manufacture thereof on behalf of licensee for manufacture for sale of Ayurvedic, Siddha and Unani drugs.

(2) * Categories of Ayurvedic, Siddha and Unani drugs other than those specified in the first Schedule to this Act for which testing will be carried out:

Ayurveda and Siddha	Unani
1. Asava and Arista	1. NabeezKhal (Sirka)
2. Arka-Tinir	2. Majoon and its sub-categories :- Itrifal, Jawarish, Khammera, Laooqhalwa
3. Avaleha and paka-llakam	3. Sufoof, Zuroor, Sunoon
4. KvathaCurna-KutinirCuranam	4. Namak, khar
5. Guggulu	5. Raughan
6. Ghrita-Ney	6. Zimad
7. Churna-Curanam	7. Habb (Pill)
8. Taila-Tailam	8. Shiyaf
9. Dravaka-Tiravakam	9. Qutoor (drops)
10. Lavana-Uppu	10. Kohal (Surama), Kajal
11. Kshara-Saram	11. Satt, Usara
12. Lepa-Pacai	12. Kushta
13. Vati, Gutika-Kulika	13. Joshanda(single drugs)
14. Vartti	14. Sharbat, sikanjabeen
15. Netrabindu (Aschyotan)	15. Sayyal, Arq (Distillates)
16. Ajana-Kanmai	16. Qurs (Tablet)
17. Sattva-Sattu	17. Marham, Qairoota

18. KupipakvaRasayan-Kuppi Centuram	18. Humool, Furzaja
19. Parpati	19. Bakhoor
20. Pishti	20. Nabatiadvia
21. Bhasma-Parpam	21. Maadniadvia
22. Mandura-Atai-Kutinir	22. AjsadAdvia
23. Rasayoga-Centuram	23. HaiwaniAdvia
24. Lauha	24. Jauhar
25. Ghana Sattva	25. Natool
26. KvathPravahi-kutinir	26. Nashooq, Naswar
27. Panak (Syrup)- Manappaku	27. Shamoom
28. Tablet- Mattirai	28. Saoot(Nasai drops)
29. Capsule	29. Mazoogh
30. Ointment-Kalimapu	30. Tila
31. Phalavarti	31. Lashooq
32. Dhoomravarti/ Doopan	32. Gulqand
33. Kshar sutra/ KsharVarti	33. Fateela
34. Single drugs:	34. Ghaza, Ubtan, Sabhgh
a) Plant Based b) Mineral based c) Metal based d) Animal based e) Synthetic f) Any other Ayurvedic , Siddha and Unani formulation	
35. Pushp (Phool)	35. Capsule
36. Nasya	36. Huqna
37. Swarsasa (Fresh Juice)	37. Naurah
38. KarnaBindu (Ear Drop)	38. Latookh
39. Any other dosage form of Patent and Proprietary and Ayurvedic , Siddha and 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…… Inspector……..

Delete whichever is not applicable Full address of the applicant

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 licensee s for manufacture for sale of Ayurvedic , Siddha and Unani drugs.

Number of approval and date of issue

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

(2) Name of the 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 condition s stated below and such other conditions as may be specified in the rules for the times being in force under the Act .

Date .....

Place.....

Signature .....

Designation .....

Seal of State Licensing Authority

CONDITIONS OF APPROVAL

(1) This approval and any certificated of renewal in form 49 shall be displayed in the approved 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 the any category of Ayurvedic, Siddha and Unani drugs it should apply to approving authority for necessary endorsement as provided in Rule160-B. This approval will be deemed to extend to this items so endorsed.

(3) Any change in the experts s 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 b 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 take 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 constitutions.

FORM 49

Certificate of renewal 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.

(1) Certified that approval number ……..granted on the ….day of ……2001 for carrying out tests of identity, purity , quality and strength on the following categories of Ayurvedic, Siddha and Unani drugs and the raw materials used in manufacture thereof at the premises situated at……..has been renewed from …… to…….(Date).

Categories of Ayurvedic, Siddha and Unani drugs.
……..

(2) Name of the experts and the person-in-charge of testing…….. (Experts) and…… (Person-in-charge).

Date .....

Place.....

Signature .....

Designation .....

Seal of State Licensing Authority

ISBN 978-93-81458-07-5

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