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# MANUFACTURING AND MARKETING APPROVAL PROCESS FOR HERBAL FORMULATIONS IN INDIA

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**ABSTRACT**

Medicinal plants are the only source and an important contribution to primary healthcare during ancient times. Knowledge about the use of medicinal plants for treating various diseases was highly valued among ancient civilizations. In India, the history of healthcare systems goes back 5000 years B.C., i.e., noted in ancient literature like 'Rig-Veda' and 'Atharva-Veda.' Later, the literatures like 'Charak Samhita' and 'Sushruta Samhita' (about 10th century BC), where use of Plants was the highlighted for healthcare systems. Several ethnic People with diverse cultural backgrounds reside in India and practice their system of traditional medicine.

**KEYWORDS:** Medicinal plants, Charak Samhita, Sushruta Samhita, Herbal Formulations.

## 1. INTRODUCTION

Medicinal plants are the only source and an important contribution to primary healthcare during ancient times. Knowledge about the use of medicinal plants for treating various diseases was highly valued among ancient civilizations. In India, the history of healthcare systems goes back 5000 years B.C., i.e., noted in ancient literature like 'Rig-Veda' and 'Atharva-Veda.' Later, the literatures like 'Charak Samhita' and 'Sushruta Samhita' (about 10th century BC), where use of Plants was the highlighted for healthcare systems. Several ethnic People with diverse cultural backgrounds reside in India and practice their system of traditional medicine.

In ancient and medieval India, the regulation of herbal drugs was deeply rooted in traditional systems of medicine like Ayurveda, Unani, and Siddha. These systems emphasized the importance of authenticity, quality, and safety in the preparation and use of medicinal plants.

Classical texts like the Charaka Samhita and Sushruta Samhita detailed methods for identifying and verifying medicinal plants based on their appearance, habitat, and seasonal variations.

In the past, Ayurvedic education was founded on the Guru-Shishya Parampara or Teacher-Discipline Tradition. In ancient India, the Guru–Shishya Parampara (teacher– disciple tradition) was central to the regulation, preservation, and transmission of herbal medicine. This tradition was not merely an educational model but a comprehensive system that ensured the authenticity, safety, and efficacy of herbal drugs through rigorous training, ethical conduct, and experiential learning.

During British colonial rule and after India's independence, efforts were made to regulate herbal medicines. During the British Era, the British established botanical gardens and researched on Indian medicinal plants, leading to the publication of works like The Indian Materia Medica. After Post Independence, the Indian government recognized traditional medicine systems in 1959, leading to the inclusion of Ayurveda, Unani, and Siddha drugs in the Drugs and Cosmetics Act of 1940.

Although there was no centralized regulatory body in ancient India, a well-structured system based on classical texts, rigorous training, ethical conduct, and empirical validation ensured the safe and effective use of herbal drugs. These indigenous practices laid the foundation for the eventual codification and regulation of traditional medicines in modern India.

In contemporary times, the regulation of herbal drugs in India has been formalized by Drugs and Cosmetics Act 1940 and its rule in 1945 and Department of AYUSH.

Herbal drugs particularly Ayurvedic, Siddha, and Unani medicines, are regulated primarily under the Drugs and Cosmetics Act 1940 and its associated rules.

The Department of AYUSH serves as the regulatory authority for these Herbal medicines, over seeing Licensing for manufacturing and marketing. This regulation ensures quality, safety, and efficacy, while also promoting the development and standardization of herbal medicines within the Indian Tradition.

**Figure 1: Herbal Ingredients.**

**Figure 2: Mortar & Pest.**

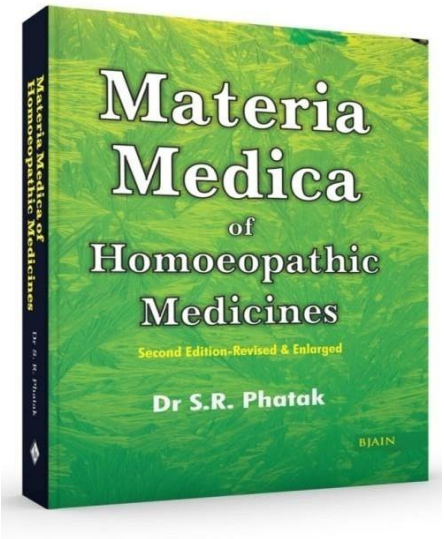



**Figure 3: Materia Medica Book.**

## 2. AUTHORITIES INVOLVED

The authorities involved in approval process of herbal drugs in India are:

- Ministry of AYUSH.
- Drugs and Cosmetics Act 1940 and its rule in 1945

### 2.1 MINISTRY OF AYUSH

The Ministry of AYUSH was founded on 9th November 2014 to ensure the optimal development and propagation of the AYUSH system of health care.

Earlier it was known as the Department of Indian System of Medicine and Homeopathy [ISM &H] which was created in March 1995 and renamed as Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy [AYUSH] in November 2003, with focused attention for the development of Education and Research in Ayurveda, Yoga, Unani, Siddha, Homeopatthy.

In India, manufacturing and marketing promotion of ASU drugs is controlled by AYUSH.

### 2.2 DRUGS AND COSMETICS ACT 1940 AND IT' S RULE IN 1945

Herbal drugs are regulated under the Drug and Cosmetic Act (D and C) 1940 and Rules 1945 in India, where regulatory provisions for Ayurveda, Unani, and Siddha medicine are laid down in Chapter IV-A. There are 18 different sections present from sections 33C to 33O. These all sections provide all the information related to ASU drugs regulations for manufacture, sale, registration, GMP certificate, licensing, and penalties.

### 2.3 OBJECTIVES

Promote the traditional and indigenous systems of medicine, such as Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa-Rigpa, and Homeopathy through policy formulation, awareness campaigns, and educational programs.

Promote research and innovation within the Ayush sector, aiming to strengthen the evidence base, enhance quality, and ensure the global relevance of traditional Indian medicine.

Guarantee access to safe and high–quality Ayush products and services, through stringent quality control measures and regulatory standards.

Focus on effective human resources development to ensure killed professionals in Ayush practices, through education, training and capacity building.

Support the growth the of medicinal plants sector and ensure widespread access to Ayush services and products, aligning with sustainability goals and enhancing public health.

| Part of Act / Rule | Chapter / Part | Nature of Activity |
|---|---|---|
| **Drugs & Cosmetics Act 1940** | Chapter IV-A (section 33-B to 33-N) | Provides provisions related to Ayurveda, Siddha and Unani Drugs |
| | The First Schedule | List of scheduled books |
| **Drugs & Cosmetics Act 1940 – Schedules** | The Second Schedule | Standards to be complied with by imported drugs and by drugs manufactured for Sale, Stocked or Exhibited for Sale or Distributed |
| **Drugs & Cosmetics Rules 1945** | Part XVI (Rule 151-160) | Manufacture for sale of Ayurvedic (including Siddha) or Unani Drugs |
| | Part XVI-A (Rule 160 A – 160 J) | Approval of institutions for carrying out tests on ASU Drugs and Raw material used in their manufacture |
| | Part XVII (Rule 161) | Labeling, Packing and Limit of Alcohol in ASU Drugs |
| | Part XVII (Rule 161-B) | Shelf life and date of expiry for ASU Medicines |
| | Part XVIII (Rule 162-167) | Government analysts and Inspectors for ASU Drugs |
| | Part XIX (Rule 168-170) | Standards of ASU Drugs |
| **Drugs & Cosmetics Rules 1945 – Schedules** | Schedule A | Different types of forms, particularly 24 D, 24 E, 25 D, 25 E, 26 D, 26 E, 26 E-1, 47, 48, 49 |
| | Schedule B-1 | Fees for the test or analysis by Pharmacopieal Laboratory for Indian Medicine or the Govt. Analyst |
| | Schedule E-1 | List of poisonous substances under ASU Systems of Medicine |
| | Schedule FF | Standards for Opthalmic Preparations |
| | Schedule T | Good Manufacturing Practices for ASU Medicines |
| | Schedule Y | Requirements and Guidelines for permission to import and / or manufacture of new drug for sale and to undertake clinical trials |
| | (Proposed) Schedule | Requirements and Guidelines for permission to Manufacture of ASU Drugs for sale or for clinical trials. |

## 3. LEGAL REQUIREMENTS

The Legal requirements for the approval process of herbal drugs in India are given below

- Documentation
- COPP certificate
- AYUSH license
- GMP certificate

### 3.1 DOCUMENTATION

#### 3.1.1 Application for license to manufacture ASU drugs

An application for the grant or renewal of a licence to manufacture for sale any ASU drugs shall be made in Form 24-D to the Licensing Authority [State] – Fees INR 1000.00 [RULE 153].

FORM 24-D

[See Rule 153]

*Application for the grant / renewal of a 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, qualification and experience of technical staff employed for manufacture and testing of Ayurvedic (including Siddha) or Unani drugs

i. ……..
ii. ……..
iii ……..
iv ……..
v ……..

4. A fee of rupees……..has been credited to the Government under the head of account……..and the relevant Treasury Challan is enclosed herewith.

*Date*…… *Signature*……..
(applicant)

**Figure 4: FORM 24D.**

### 3.1.2 Form of license to manufacture ASU drugs

Subject to the conditions of rule 157 being fulfilled, a license to manufacture for sale any ASU drugs shall be issued in Form 25-D [RULE 154].

**ANNEXURE-II**

**FORM 25-D**
[See Rule 154]

*License to manufacture for sale Ayurvedic (including Siddha) or Unani drugs*

No. of License……

1. …… is 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 (Name)
b) Names of Drugs (each item to be separately specified).

2. The license shall be in force from……to……..

3. The license 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.

*Signature*……

*Date*…… *Designation*……

*Conditions of License*

1. This license and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the expert staff named in the license shall be forthwith reported to the Licensing Authority.
3. This license shall be deemed to extend to such additional items as the licensee may intimate to the Licensing Authority from time to time, and as may be endorsed by the Licensing Authority.
4. The license shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for a maximum period of three months from the date on which the change takes

**Figure 5: FORM 25-D.**

### 3.1.3 Certificate of renewal of license

The certificate of renewal of a license in form 25-D shall be issued in form 26- D[RULE 155].

**ANNEXURE-V**

**FORM 26-D**
[See Rule 155]

*Certificate of renewal of license to manufacture for sale of Ayurvedic / Siddha or Unani drugs*

1. Certified that license No……granted on the……to Shri / Messrs…….. for the manufacture of Ayurvedic/Siddha/Unani drugs at the premises situated at …… has been renewed from…….. to……

2. Name of technical staff ……..

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

*Signature*……

*Date* …… *Designation*……

**Figure 6: FORM 26-D.**

### 3.1.4 Duration of License

An original license in Form 25-D or renewal license in Form 26- D, unless sooner suspended or canceled, shall be valid for 5 years from the date of issue or renewed [RULE 156].

### 3.1.5 Condition for the grant or renewal of a license in Form 25-D:

Conditions as specified in schedule T [RULE 157].

### 3.1.6 Condition of license

The Licensee shall keep a proper record, shall allow the inspector, appointed under the act, to enter the premises and shall maintain the inspection book Form 35[RULE 158].

### 3.1.7 The other documents required are

#### 3.1.7.1 Manufacturing License

A manufacturing license is required to produce herbal drugs.

#### 3.1.7.2 Manufacturing site details

Information about the manufacturing facility, including its location and compliance with GMP, is required.

#### 3.1.7.3 Formulations and ingredients

A detailed list of all ingredients and formulations used in the product is necessary.

#### 3.1.7.4 Product testing reports

Comprehensive testing reports, including those for heavy metals, microbial load, and stability, are required to ensure the product safety and quality.

#### 3.1.7.5 Packaging and labeling compliance

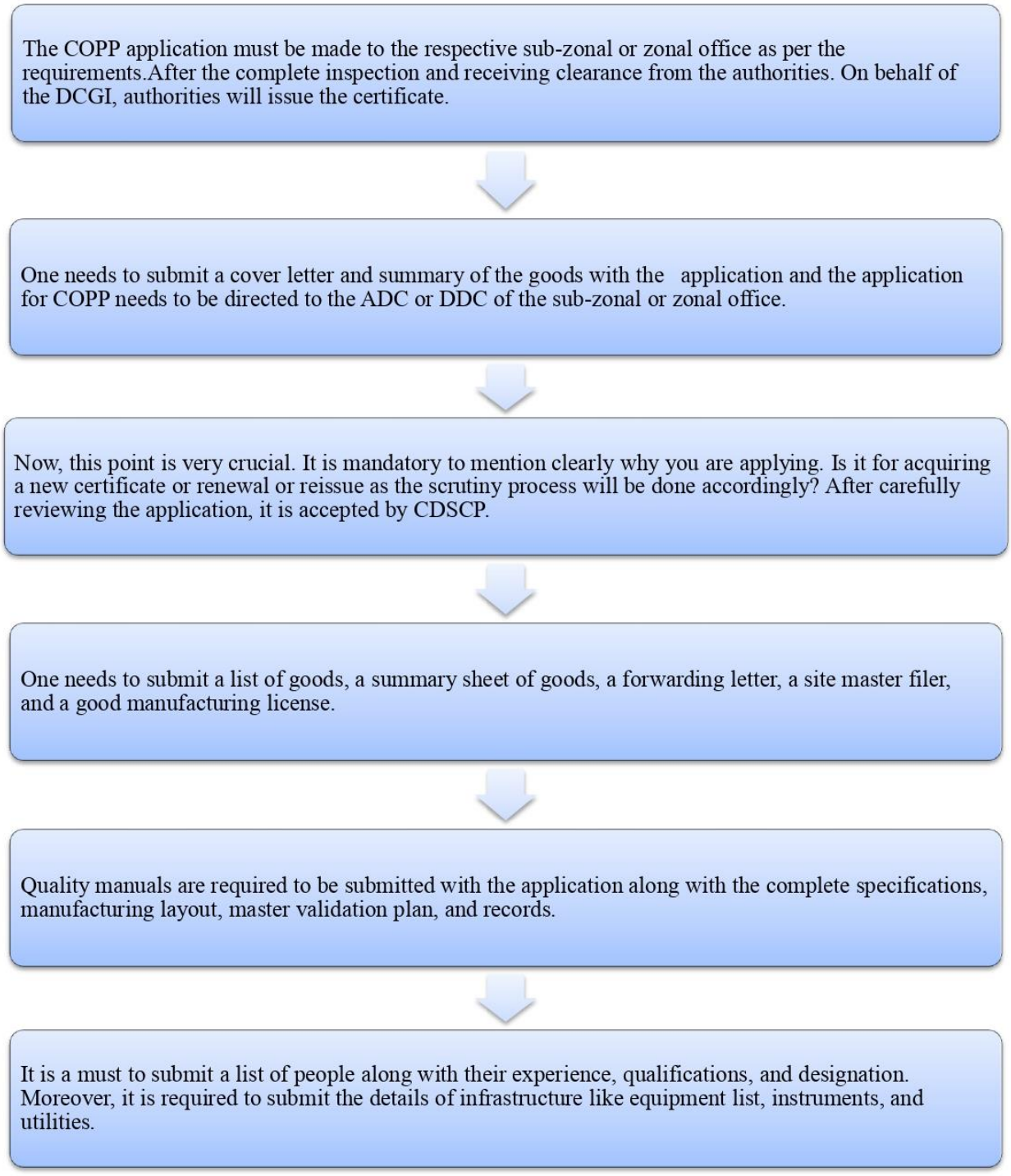
The packaging and labeling of the product must adhere to AYUSH and Food and Standards Authority of India [FSSAI] guidelines.

### 3.2 COPP

The Certificate of Pharmaceutical Product (COPP) plays a crucial role in the approval process of herbal drugs, primarily by demonstrating compliance with quality standards and facilitating international trade. It ensures that herbal drugs, like any pharmaceutical product, meet safety and efficacy requirements, enabling them to be imported and licensed in other countries.


**Figure 7: Digital COPP.**

### 3.2.1 PROCEDURE TO APPLY COPP CERTIFICATE




### 3.3 AYUSH LICENSE

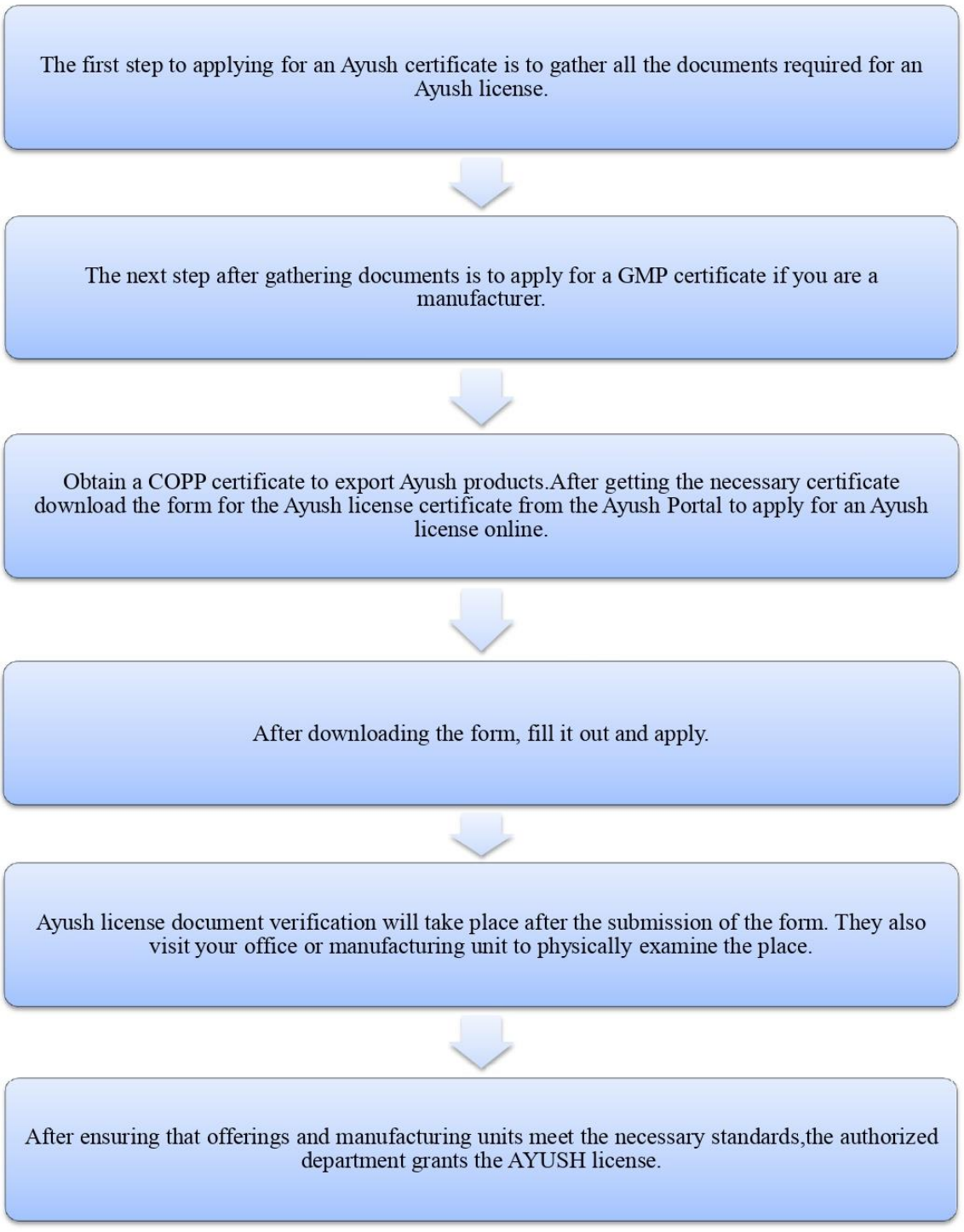
AYUSH license is a mandatory legal document for all manufacturers and distributors of Ayurvedic, Yoga, Unani, Siddha and Herbal products. This license is issued by the Ministry of AYUSH upon meeting the necessary safety, efficacy, and quality standards. AYUSH licenses are categorized based on business activities they are involved in, such as AYUSH manufacturing license and AYUSH loan license.

### 3.3.1 LIST OF DOCUMENTS REQUIRED FOR AYUSH LICENSE

1. Copy of manufacturing license.
2. Site Layout of the manufacturing facility.
3. Manufacturing formula and process.
4. Finished product specification report.
5. List of approved products for COPP certification.
6. Process Validation Report for 3 batches.
7. Details of the technical staff.
8. List of equipment used for manufacturing.
9. Water and HVAC system diagrams.
10. Proof of safety and effectiveness.
11. Self-Declaration for the absence of Non-Herbal Ingredients.
12. Self-Declaration regarding compliance with regulatory.
13. KYC details of the applicant.
14. Address proof of the premises.
15. Constitution Document of the business.


**Figure 8: Ministry of Ayush & Ayush Certification.**

### 3.3.2 PROCEDURE TO APPLY AYUSH CERTIFICATION




### 3.4 GMP REQUIREMENTS

GMP is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designated to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. GMP is intended to assure that raw materials used in the manufacture of drugs are of:

- Known quality
- Standardized quality
- Free from contamination

GMP guidelines guide for manufacturing testing and quality assurance in order to ensure that a food or drug product is safe for human consumption. GMP guidelines are not prescriptive instructions on how to manufacture products.

### 3.4.1 COMPONENTS OF GMP

GMP schedule for ISM manufacturing units is quite elaborate and broadly covers each and every component of manufacturing process. Different components of GMP are given below in order of appearance in Schedule – T.

The Good Manufacturing Practices (GMP) are prescribed as follows in Part I and Part II.

### 3.4.2 GENERAL REQUIREMENTS

#### 3.4.2.1 Factory Premises

- ✓ Location and surroundings
- ✓ Buildings
- ✓ Water Supply
- ✓ Disposal of Waste
- ✓ Containers Cleaning
- ✓ Stores (Raw materials, packing materials, Finished goods stores)
- ✓ Working Space
- ✓ Health, Clothing, Sanitation and Hygiene of Workers
- ✓ Medical Services
- ✓ Machinery and Equipment
- ✓ Batch Manufacturing Records
- ✓ Distribution records
- ✓ Record of Market Complaints

**3.4.2.2 Measurement of premises**: Manufacturing areas as per Sch –T [areas are in sq. feet]

- ✓ Office-100 Sq. feet
- ✓ Workers room -80 Sq. feet/each sex
- ✓ Raw material store-100 sq. feet
- ✓ Finished product store-100 sq. feet
- ✓ Quarantine room-100 sq. feet
- ✓ Packaging material store-100 sq. feet
- ✓ Bottle washing room -100 sq. feet
- ✓ Bottle drying room-100 sq. feet
- ✓ Packing and labeling room-100 sq. feet
- ✓ O.K. laboratories-100 -150 sq. feet[chemistry and cog nosy lab]

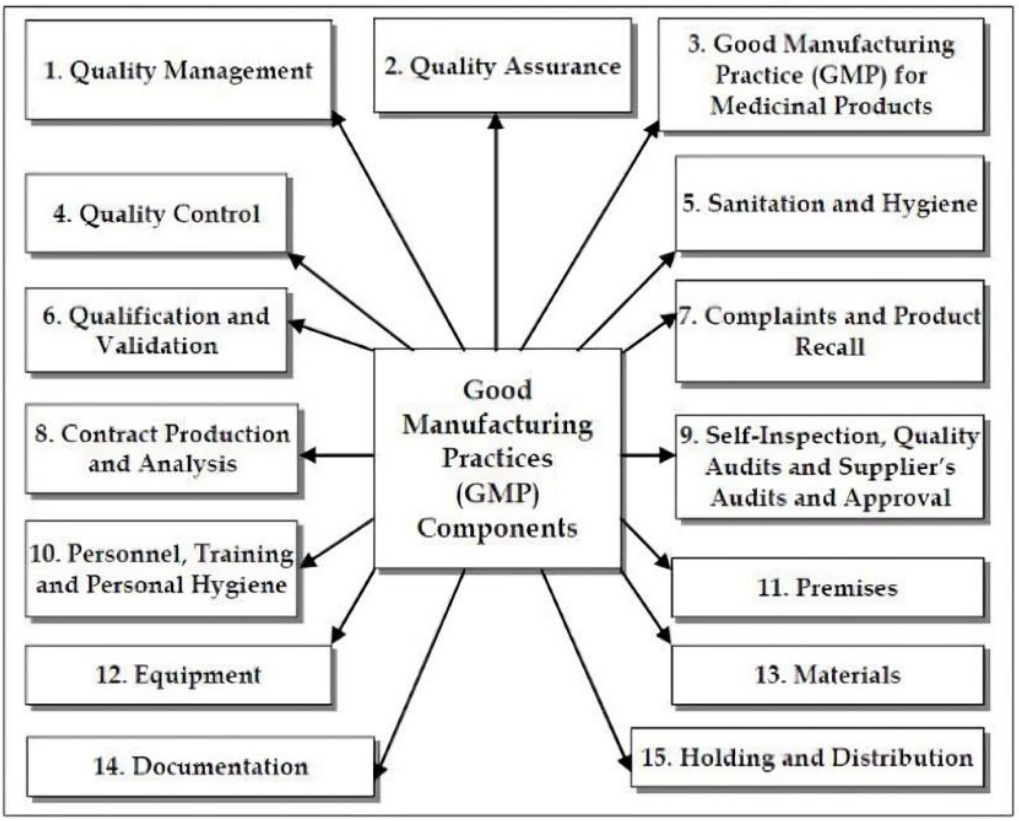



**Figure 9: Components of GMP.**

### 3.4.2.3 Location & Surroundings

The factory building for the manufacture of Ayurveda, Siddha and Unani medicines shall be so situated and shall have such construction as to avoid contamination from open sewerage, drains, or public lavatories for any factory which produces disagreeable or obnoxious odour or fumes or excessive soot, dust and smoke.

### 3.4.2.4 Buildings

The buildings used for the factory shall be such as to permit production of Drugs should be under hygienic conditions and should be free from cobwebs and insects/rodents. It should have adequate provision of light and ventilation. The floor and the walls should not be damp or Moist. The premises used for manufacturing, processing, packaging and labeling will be in conformity with the provisions of the Factory Act.

**Figure 10: Buildings in herbal industry.**

#### 3.4.2.5 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.

#### 3.4.2.6 Disposal of waste

From the manufacturing section and laboratories the waste water and the residues which might be prejudicial to the workers or public health shall be disposed off.

**Figure 12: Disposal of waste.**

#### 3.4.2.7 Container cleaner

In factories where operations involving the use of containers such as glass bottles, vials and jars are conducted, there shall be adequate arrangements separated from the manufacturing operations for washing, cleaning and drying of such containers.

#### 3.4.2.8 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.

**Figure 13: Storage area.**

### 3.4.2.9 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 systems shall decide the use of appropriate containers which would protect the quality of raw materials as well as prevent it from damage due to dampness, microbiological contamination or rodent and insect infestation, etc...

### 3.4.2.10 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**.**

**Figure 14: Packaging materials.**

### 3.4.2.11 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 finished product quality as prescribed, then it will be moved to “Approved Finished Goods Stock” area.

**Figure 15: Finished goods stores.**

### 3.4.2.12 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 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**.**

### 3.4.2.13 Health clothing, Sanitation & Hygiene of workers

All workers 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.


**Figure 16: GMP Cleaning and Sanitation.**

### 3.4.2.14 Medical services

The manufacturer shall also provide

- ✓ Adequate facilities for first aid
- ✓ 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.

**3.4.2.15 Machinery & Equipment's**

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.


**Figure 17: Machinery and Equipment's.**

**3.4.2.16 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 materials and their quantities obtained from the store, tests conducted during the various stages of manufacture like taste, color, 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 19400)**.**

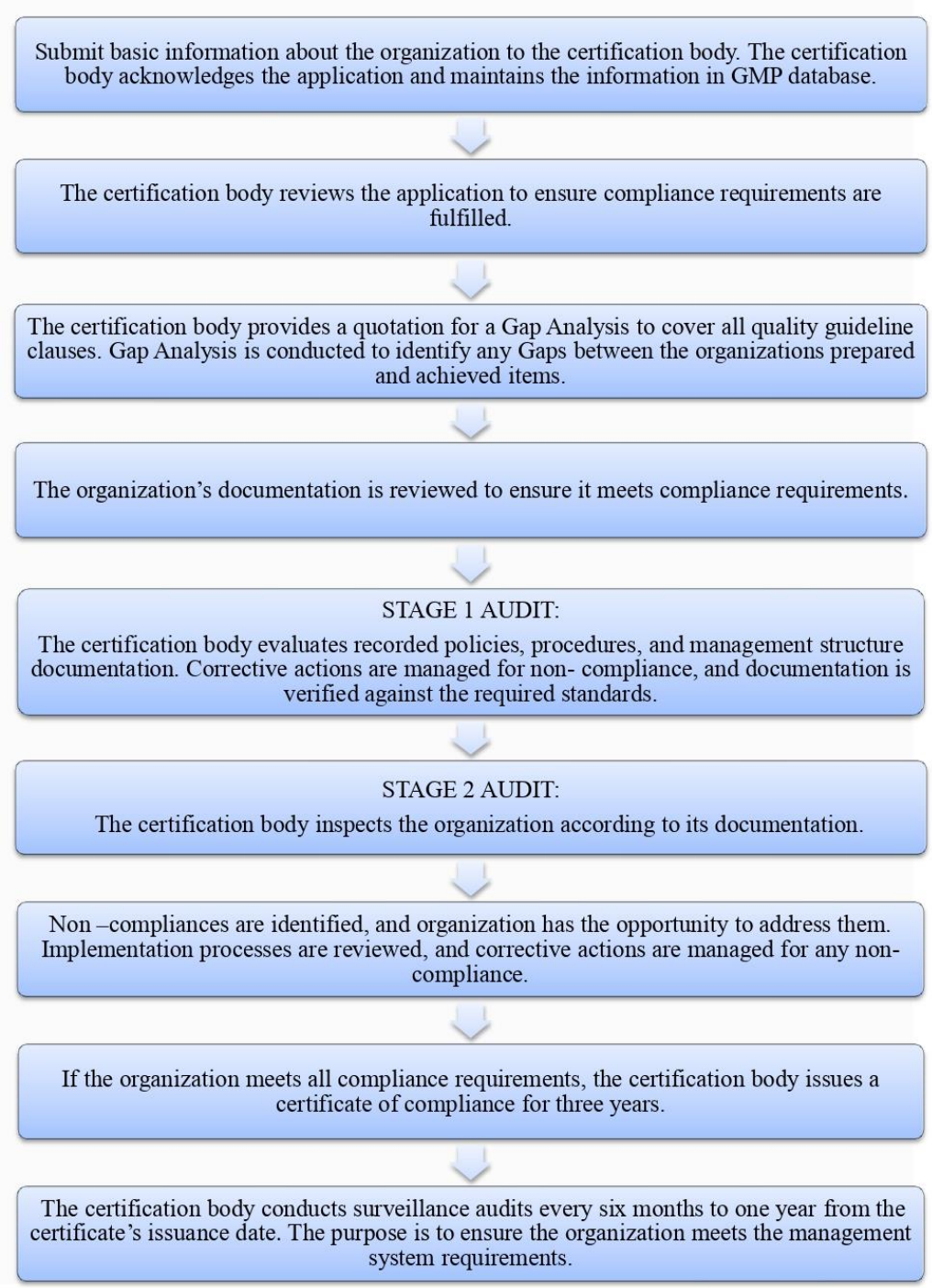
**3.4.2.17 Distribution records**

Records of sale and distribution of each batch of Ayurveda, Siddha and Kunai Drugs shall be maintained in order to facilitate prompt and complete recall of the batch, if necessary. The duration of record keeping should be the date of expiry of the batch. Certain category of Ayurvedic, siddha and Unani medicines like Bhasma, Rasa, Kupi-pakva, Parpati, Sindura, Karpu /uppu/ puram, kushta, Asava-arishta etc.

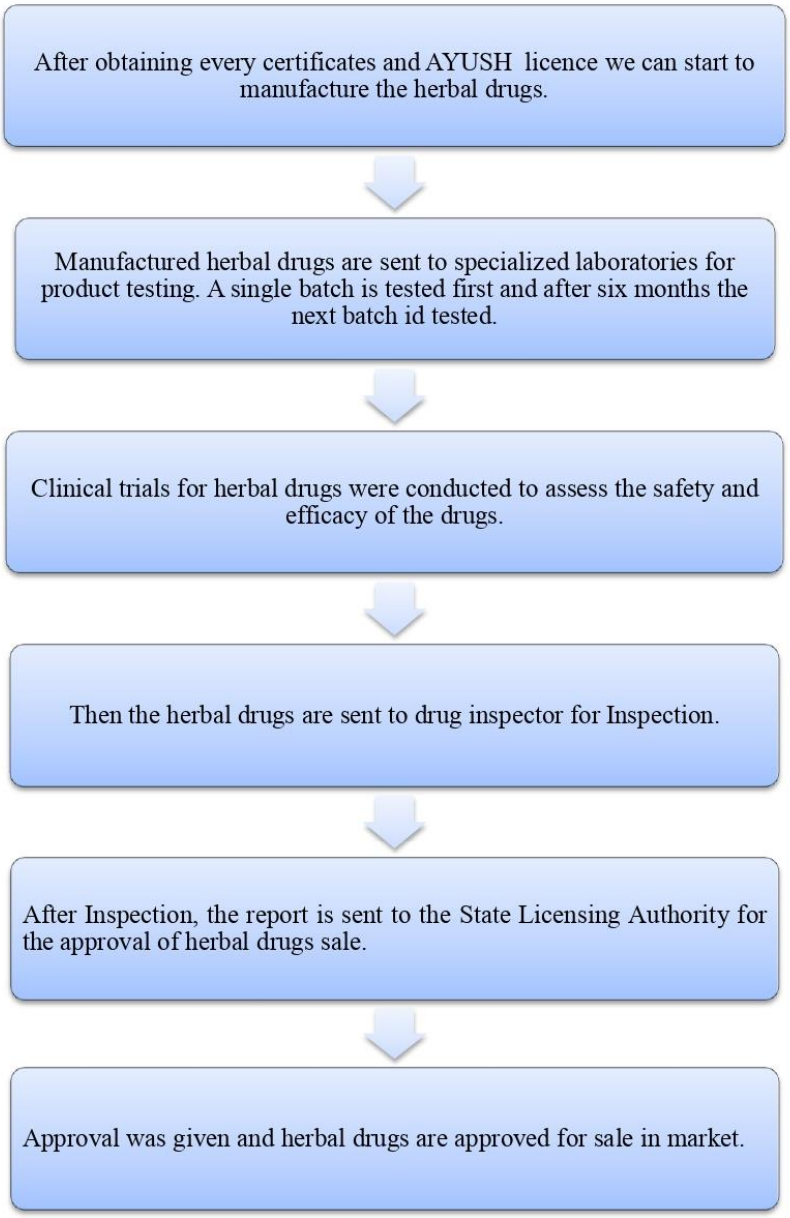
**3.4.2.18 Record of market complaints**

Manufacturers 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 577 the manufacturers regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints shall also be recorded. Once in a period of six months the manufacturer shall submit the record of such complaints to the licensing authority. The Register shall also be available for inspection during any inspection of the premises. Records 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.

### 3.5 PROCEDURE TO GET GMP CERTIFICATE



## 4. PROCEDURE FOR APPROVAL OF HERBAL FORMULATIONS




## 5. CONCLUSION

- ✓ The regulatory approval process for herbal drug preparations in India is a critical framework that ensures the safety, efficacy, and quality of these products. The process, overseen by regulatory bodies such as AYUSH and Drugs and cosmetics Act 1940 and its rule 1945, involves rigorous testing, standardization, and compliance with Good Manufacturing Practices (GMP).
- ✓ This comprehensive approach helps preserve India's rich heritage of herbal medicine while aligning with modern regulatory standards. It enables the promotion of safe and effective herbal products, both domestically and globally, and supports innovation and research in the traditional medicine sector.
- ✓ Thus, the Indian regulatory framework for herbal drug approval bridges the gap between traditional wisdom and contemporary science, ensuring public health protection and industry growth.

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