

# Compliance of Pharmacopoeial Quality Standards of Ayurvedic Medicine

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**ABSTRACT :** In the era of commercialization of Ayurvedic drug sector, various issues about safety and efficacy as well as quality standards of herbal and mineral drugs are being raised at global level. Therefore development of universal standards for identification, preparation and manufacturing is utmost important. The Department of AYUSH, Government of India and its various research institutes in India have published standard formularies and pharmacopoeia for Ayurvedic single as well as compound drugs. The present article reviews these publications at a glance and also directs to standardize Ayurvedic preparations to make them accepted universally.

**Key words :** Ayurveda, Pharmacopoeia, Formulary, Standardization, Quality Standards.

A customer will like to use a drug of assured quality, safety and efficacy. Quality is totality of feature and characteristic of product. Quality of medicine is most important factor for its acceptability. In earlier times, Ayurvedic physicians had been preparing medicines themselves for the use in their patients. Now, in the era of commercialization of this sector, the medicines are manufactured by different companies at different places and they are following various reference books for same medicine. Hence, the difference in the quality of formulation is obvious. The practitioners have to depend entirely on the medicines supplied by the companies. Therefore, it is essential to have scientific methods of quality production as well as testing methods of Ayurvedic medicines, to ensure clinical efficacy of these medicines.

One of the most important bottlenecks to ensure quality of Ayurvedic medicine was the non-availability of pharmacopoeial standards of these medicines. This difficulty was compounded due to the lack of infrastructure of laboratories and scientific manpower to undertake testing. Govt. of India, Ministry of Health, Department of AYUSH took this challenge of developing pharmacopoeial standards on scientific lines. Ayurveda Pharmacopoeia Committees (APC) with the help of Vaidyas, Chemists, Botanists and pharmacy experts have been constantly working to develop official Formularies and Pharmacopoeias. This is aimed to assure identity, purity and strength of Ayurvedic medicine of International standards.

Three types of official publications are most essential to achieve the goal of good quality medicines prepared and tested as per scientific parameters:

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1. **Ayurvedic Formulary of India (AFI) :** This is a book of formulae of various multiple ingredient medicines. This is essential for acquiring uniformity of the manufacturing process and ingredients of the Formulations. Various classical books have slight variations of same formulation in term of ingredients part of the herb as well as method of preparation. To achieve uniformity of a formulation with a particular name, it is essential to publish Ayurvedic Formulary of India (various volumes).
2. **Ayurvedic Pharmacopoeia of India (API) - Part-I (single drugs) :** It is essential to have the standards of identity, purity and strength of the raw-material and single drug used in the various formulations. This includes botanical and phyto-chemistry testing methods of the raw-material. Seven volumes containing 540 drugs have been published.
3. **Ayurveda Pharmacopoeia of India (API) - Part-II (Formulations) :** This is essential to develop Standards Manufacturing Procedures (SMP) for uniformity of the manufacturing process. Once a formulation is uniformly prepared, the quality standards for the identity, purity and strength are achievable. Shelf life studies for the stability of the formulation are also associated activities. So, for this purpose, two volumes containing 101 formulations have been published.

**Atlas of Ayurvedic Pharmacopoeial Drugs :** This provides pictorial description on botanical morphology and Thin Layer Chromatography (T.L.C.) of the constituents.

Two volumes of Atlas are under printing. This will be very helpful for testing purpose.

The scientific initiative on all the above four areas was taken one by one by the Ayurvedic Pharmacopoeia Committee in the last more than 40 years. This has resulted in the publication of following volumes.

**TABLE NO. 1 : AYURVEDIC FORMULARY OF INDIA (AFI)<sup>3</sup> :**

S.No.	Formulary Parts	Year	Language	Formulations
1.	AFI Part-I	1988	Hindi	
2.	AFI Part -I (Revised)	2003	English	444 formulations
3.	AFI Part-II	1990	Hindi	
4.	AFI Part-II	2000	English	192 formulations
5.	AFI Part-III	2008-editing	Bilingual	500 formulations are in draft Stage

**B. Ayurvedic Pharmacopoeia of India (API-Part-I on Single Drugs)<sup>1</sup> :**

Following Volumes of Ayurvedic Pharmacopoeia on single drugs have been published.

**TABLE NO. 2 : AYURVEDIC PHARMACOPOEIA OF INDIA PART-I:**

S. No.	Volume	Year of Publishing	Number of monographs (single drugs)
1.	API - Part - I, Vol. -I	1990	78
2.	API - Part - I, Vol.- II	1999	80
3.	API - Part - I, Vol. -III	2001	100
4.	API - Part - I, Vol.-IV	2004	68
5.	API - Part - I, Vol.-V	2006	92
6.	API - Part - I, Vol.-VI	2008	110
7.	API - Part - I, Vol.-VII	2009	21

**C. Ayurvedic Pharmacopoeia of India (API-Part-II-Formulations)<sup>2</sup> :**

Ayurvedic Pharmacopoeia of India (Formulations) contains the Standard Manufacturing Procedures (SMP) of formulations like Churna, Vati, Avaleha, Taila, Ghrita & Asava-Arishta etc. as well as their Quality Standards (Botanical and phyto-chemical) in two volumes. The following volumes on compound formulations have been prepared.

**TABLE NO. 3 : AYURVEDIC PHARMACOPOEIA OF INDIA (API) PART-II :**

S. No.	Volume	Year of Publishing	Number of monographs formulations
1.	API - Part -II, Vol. -I	2007	50
2.	API - Part - II, Vol.- II	2008	51

**A. Ayurvedic Formulary of India ( AFI ) :**

To bring uniformity among the manufacturers and to follow the same formula of ingredients, in the same proportion, two parts of Ayurvedic Formulary of India have been published in Hindi and English separately. Part III of AFI is under typing for publication (Table No. 1).

**TABLE NO. 4 : ATLAS OF AYURVEDIC PHARMACOPOEIAL DRUGS (PICTORIAL) :**

S. No.	Name of publication	Year of Publication	No. of drugs
1.	Phyto-chemistry - Chromatography Atlas of API-I Vol. I	2009	80
2.	Microscopy - Morphological - atlas of API-Part I, Vol. 5	2009	70

**Method of compliance of the official pharmacopoeial standards :**

Pharmacopoeia is a book of standards of identity, purity and strength of the medicine. With the publication of Ayurveda Formularies and Pharmacopoeias, the testing methods and protocols are available for single as well as multiple ingredients formulations. The pharmacopoeial standards of 540 single drugs have been published in seven volumes of Ayurveda Pharmacopoeia of India Part-I. These are modest standards which can be carried out by a trained botanist, and chemist. Testing laboratory require modest equipment and skill to test these materials. A master of science with Botany and Chemistry, after proper training of 1-2 years can undertake the testing methods of single drugs. The modern technique of Thin Layer Chromatography (TLC), GC-MS etc. is important tool to know the major chemical constituents as well as markers of identity of a drug.

**Heavy Metal and pesticide residue :Contamination estimation and Method of their elimination :**

The basic raw-material used for preparation of Ayurvedic formulations should be free from foreign matters and contaminants like heavy metal, pesticide

residue etc. This could be achieved by taking precautions by collecting or cultivating the raw-material at least half kilometer away from the road side at suitable time. Similarly washing and drying of the raw-material also removes the contaminants. Therefore, the practice of washing and shade-drying the raw-material in a neat and clean place is a very simple and practical step. All the starting raw material should be tested for pharmacopoeial standards before using in the formulation.

### **Compliance of Pharmacopoeial standards for compound formulations :**

The Ayurveda Pharmacopoeia Committee has successfully developed the standard to achieve uniformity and consistency of the Ayurvedic products. This can be achieved by following Standard Manufacturing Procedure (SMP)/Standard Operative procedure (SOP) of manufacturing process as described in API- Part II (on formulations).

### **Steps to prepare a multiple ingredient formulation :**

All the steps involved in the preparation of a formulation should be recorded one by one in a chronological manner. This starts with the collection of proper material, its cleaning, washing and authentication as per pharmacopoeial standards for single drugs. The various steps of grinding, sieving, boiling, filtering, cooling etc. should be chronologically recorded. Different batches of same formulations are prepared by following same Standard manufacturing procedure. This will lead to standardize the manufacturing process and product. Once the standardized product is prepared, the test for identification of constituents should be carried out. For the products like Choorna, Vati, Pills, Capsules, the use of microscope for botanical identification of the ingredients helps a lot. This is followed by the modest chemical test for chemical constituents' e.g.

1. Foreign matter
2. Total ash
3. Acid insoluble ash/water soluble ash
4. Alcohol-soluble extractives
5. Water-soluble extractives
6. Thin Layer Chromatography
7. Shelf life study
8. Estimation of Heavy metals
9. Microbial load
10. Pesticide residue etc.

Other relevant tests for various dosage forms are given in the API part II.

In case of Avaleha (Jam, Jelly), Syrup, Asava - Arishta, Taila, Ghrita most of the phyto-chemical tests are applicable. In these formulations, the TLC, HPTLC, GLC and GC/MS procedures are helpful to identify the individual constituents of the medicines. However, these tests require high skilled experts and costly equipments.

### **Compliance of standards of Rasaushadhi and Bhasma :**

The quality standards of Rasaushadhi and Bhasma, used in the various formulations are equally important. In this direction, the first and foremost requirement was the availability of quality standards of the raw-materials, ores, minerals and metals going into the formulations of Bhasma etc. Ayurveda Pharmacopoeia Committee (APC) with the help of Geo-chemist and mineral, metal experts, has published Pharmacopoeial Standards of most commonly used minerals and metals in Ayurvedic formulations. This tells us the chemical composition of these minerals and metals; not only for the major constituents but also for the minor constituents of metals in built in the ore. This has educated the Ayurvedic and manufacturing experts to give the details of the constituents as well as inbuilt other metals in the starting material (ore).

The method of preparation of Bhasmas by using specific methods of Shodhana (purification) as well as Bhasmikanrana (incineration) is also being standardized. The particle size analysis after various Putas is one of the most important features of manufacturing process of Bhasma. Similarly, the analysis of the final product for the physico-chemical characterization of the Bhasma is also needed. The Department of AYUSH has already started this activity for 8 Rasaushadhi with the help of some advanced laboratories of other organizations under Golden Triangle programme (GTP). Some CSIR labs and CCRAS have also undertaken the safety studies, which confirm that properly prepared Rasaushadhi and Bhasma are absolutely safe to be used as medicine.

The compliance on pharmacopoeial standards and SMP-SOP for Rasaushadhi and Bhasmas is feasible once we standardize the manufacturing procedure and analyze Bhasma & Rasaushadhi. The day is not far off when the manufacturers will be in a position to prepare Rasaushadhies by following scientific methods of preparations, analysis and safety measures. Similarly, the consumer will also be in a position to use these products with confidence.

### Need to change the mind set for the Compliance of Pharmacopoeial Standards :

This is a matter of mind set and acceptability of appropriate scientific tools and technology in manufacturing and standardization of Ayurvedic products. It is mandatory for the manufacturers to comply with and follow the standards SMP-SOPs prescribed in the official formularies and pharmacopoeias. To facilitate the manufacturers and laboratory personnel, the Ayurvedic Pharmacopoeia Committee has developed Atlas for botanical identification as well as phytochemistry and TLC. This Atlas will make these Pharmacopoeias more user-friendly. Twenty five Govt. Drug Testing laboratories have been strengthened by AYUSH grant of Rs. 1.5 crores for each state. In private sector more than 30 laboratories have been recognized to undertake testing of survey samples. State licensing authorities and quality control mechanism for

Ayurveda drugs has also been funded by AYUSH. The association of manufacturers and teaching institutions are supported for organizing workshops on GMP as well as training the experts for testing of Ayurvedic medicines. The manufacturing units are also supported to set up their own in-house drug testing laboratory and AYUSH is providing grant of Rs. 30 lakhs for each unit. Now this is high time for industry to change their mind set and develop units not only the GMP units but also the compliance of pharmacopoeial standards which are mandatory requirement under the provisions of Drugs and Cosmetics Act.

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3. Ayurveda Formulary of India Part I (Revised) & Part II.

## हिन्दी सारांश

### आयुर्वेदिक औषधियों के गुणवत्ता मानकीकरण की आवश्यकता

एस. के. शर्मा

आयुर्वेदिक औषधियों की गुणवत्ता के प्रमाण निर्धारित करने हेतु भारत सरकार के स्वास्थ्य मंत्रालयान्तर्गत आयुष विभाग ने अपने विभिन्न अनुसंधान केन्द्रों के साथ मिलकर कुछ औषधावली प्रकाशित की है। ये औषधावलीयाँ आयुर्वेद औषधि निर्माताओं को तथा वैद्यों को एकल तथा यौगिक औषधि की पहचान तथा उत्पादन के लिए निर्देश देती हैं। प्रस्तुत लेख में इनका विश्लेषणात्मक अध्ययन सुचारु रूप से किया गया है।

गुजरात आयुर्वेद युनिवर्सिटी