Guidance Document

Compliance with Indian Pharmacopoeia Standards

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Disclaimer

This Guidance Document is compiled by the Indian Pharmacopoeia Commission (IPC) after consultations with the 'Core Expert Committee' constituted by the IPC for this purpose. The information contained herein represents the current best practices in the field of pharmacopoeial sciences to demonstrate compliance with the existing regulatory requirements. The guidance provided in this document is not intended to alter or modify or supplement or in any other way change the contents of the Indian Pharmacopoeia (IP), but is intended to provide general guidance to all users of the IP to help in ensuring proper compliance with the IP requirements when standards of drugs are to be determined. The content of this document shall be treated as non-mandatory guidance and the information contained herein is subject to review by the IPC. Approaches and methods other than those described in this Guidance Document may be adopted if found suitable and justified. Where provisions of the law exist, the law as prevailing at the relevant time shall apply.

Introduction

Indian Pharmacopoeia (IP) contains an account of the General Chapters and Individual Monographs on Active Pharmaceutical Ingredients (APIs), dosage forms, excipients etc. IP text may be broadly classified into the following four sections with each section having a specific scope. In order to comply with IP standard, the scope and role of each of these sections should be clearly understood.

1. General Notices

General Notices of IP provide the basic guidelines for the interpretation and application of the standards, tests, assays, and other specifications of the IP, as well as to the statements made in the monographs and other texts of the IP. They apply to all monographs and texts contained in the IP and provide required information to understand texts and conventional expressions before starting to use monographs. General Notices must be read and understood before proceeding to use monographs.

2. General Chapters

General Chapters provide a comprehensive account of analytical tests and methods that are common to majority of monographs and are cross referred through the citation provided as appendices in the individual monographs. General Chapters are meant to avoid repeated mention of standard methods in each monograph. General Chapters, when referred to in an individual monograph, become part of the standard. General Chapters are mentioned in Volume I of the IP under following categories:

- General Notices
- Test Methods
  - Apparatus
  - Biological Methods
  - Chemical Methods
  - Physical and Physicochemical Methods
  - Pharmaceutical Methods
  - Herbal Products
  - Vaccines
  - Blood and Blood-related Products
- Reference Data
- Reagents and Solutions
- General Tests
- Primary Packages for Pharmaceuticals
- Tables

General Chapters to be referred for non-pharmacopoeial drugs; however, in such cases, the methods specified in the General Chapters need to be validated, wherever applicable. Some General Chapters are not referred to in any monograph (e.g. Raman Spectrometry, IP Reference Substances, Residual Solvents); however, they provide useful information and guidance for regulatory compliance.

3. General Monographs

General Monographs on dosage forms include requirements of general application and shall apply to all preparations within the scope of the Introduction section of the monographs, except where a preamble limits the application. The requirements are not necessarily comprehensive for a given specific preparation and additional requirements, if any, may be given in the individual monograph. Examples of few General Monographs are as follows:

- Dosage form
  - Tablets
  - Capsules
  - Parenteral Preparations,
  - Oral Liquids etc.
- Vaccine-General Requirements
- Antisera
- Herbs and Herbal Products
- Blood and Blood Related Products
- Immunosera for veterinary use
- Biotechnology Derived Therapeutic Products
- Allergen Products
- Radiopharmaceutical Preparations

4. Individual Monographs

Individual monographs are the specific monographs either of APIs, Pharmaceutical Aids, and Dosage Forms. Individual monographs of IP detail about synonym, molecular structure, molecular formula, molecular weight, definition of article, category, dose, description, potency of the article, identification, tests, assay, specifications of tests, storage, and labelling requirements.

IP Monograph

IP Monograph is the written standard of the quality parameters of a drug (or article) in the IP. It comprises of the name and synonym of the drug (where appropriate) the chemical, empirical and structural formulae of the molecule, its molecular weight, production (in the case of biological products), definition, category, dose, usual strength, description, solubility, tests for identity, related substances, and assay or potency in general, and in the case of injectables, tests for pyrogen, sterility, and in the cases of certain biological products abnormal toxicity, and storage. All the parameters of quality set out in a monograph are designed to determine the quality of a drug. The usual strength, storage conditions as may be mentioned are of known or recommended ones and the requirements as specified in the Drugs and Cosmetics Rules shall prevail in the event of dispute. Where any specific labelling requirement is specified in the IP, the requirements shall be in addition to what is specified in the Rules. A product is not of standard quality unless it complies with all the requirements of the monograph.

IP Reference Substances (IPRS)

IPRS are mentioned in the Individual Monographs or General Chapters, as the case may be, and therefore are part of the IP standard. IPRS are specifically required for establishing conformance to the IP standard. An IPRS, being an integral and essential component of the IP standard, is an official standard that alone is authoritative in case of doubts or disputes.

Compliance with IP Standard

A drug that is included in IP is considered to comply with the IP standard when it meets all of the requirements stated in the Individual Monograph, applicable General Monographs, General Chapters, General Notices, and any other relevant requirements, if applicable. However, in any case where requirements differ, the requirements of Individual Monograph shall supersede those of the General Chapters and General Notices. A drug shall comply with the IP standard throughout its shelf-life.

Alternative Methods

The tests and assays described in IP are the official methods upon which the standards of the pharmacopoeia are based. Alternative methods of analysis may be used if they demonstrate advantages over the official IP method e.g. accuracy, sensitivity, precision, selectivity, adaptability to automation or any other suitably justified reasons. Wherever applicable, such alternative methods shall be validated based on the intended purpose of use and should be able to give equivalent or better results. When a difference appears, or in the event of dispute, the results obtained by using the official methods described in the IP shall be authoritative and legally valid.

Reference

1. The Indian Pharmacopoeia, 2018