As per the Drugs and Cosmetics Act 1940, the Indian Pharmacopoeia is the legally recognized book of Standards for the quality of drug substances and preparations included therein.
Introduction

This new edition of the Indian Pharmacopoeia entitled Indian Pharmacopoeia 2010 has been prepared by the Indian Pharmacopoeia Commission (IPC) in accordance with a plan and completed through the untiring efforts of its members, Secretariat and Laboratory over a period of about two years.
This is the sixth edition of the Indian Pharmacopoeia after Independence.

It supersedes the 2007 edition but any monograph of the earlier edition that does not figure in this edition continues to be official as stipulated in the Second Schedule of the Drugs and Cosmetics Act, 1940.
# Publication of IP

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Publication and Printing

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Presentation of IP 2010

IP 2010 is presented in three volumes with the following features:

Volume 1
Volume 2
Volume 3
Content of Volume I

• Notices
• Preface
• Indian Pharmacopoeia Commission
• Acknowledgements
• Introduction
• General Chapters
  o General Notices
  o Test Methods
  o Apparatus
Content of Volume II

- General Notices
- General Monographs on Dosage Forms
- Monographs on Drug substances, Dosage forms and Pharmaceutical Aids Monographs A to M
Content of Volume III

- General Notices
- Monographs on Drug substances, Dosage forms and Pharmaceutical aids
- Monographs N to Z
- Monographs on Vaccines and Immunosera for Human Use
- Monographs on Herbs and Herbal Products
- Monographs on Blood and Blood-related Products
• Monographs on Biotechnology Products
• Monographs on Veterinary Products
  o Non-Biological
  o Biological
  o Diagnostics
• Index
NEW EDITION

- New Drugs
- API’s
- Formulations
- Anticancer drugs
- Excipients
- Vaccines and Other
- Biological Products
- Herbal Products
Specific features

Adding:

(i) New monographs.
(ii) Category, Dose and Usual Strengths.
(iii) General Chapter on Liposomal Preparations.
(iv) Appendices on NMR.
(v) New Herbs and Herbal monographs.
(vi) Excipient monographs.

(vii) Anticancer monographs.

(viii) Adopted for latest drug delivery system (i.e. Amphotericin B Injection).

(ix) Drugs not in use are omitted from this edition.
The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, Veterinary vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations.

Standards for new drugs and drugs used under National Health Programmes are added in this edition and drugs as well as their formulations not in use now a days are omitted from this edition.
The number of monographs of Excipients, Anticancer drugs, Herbal products and Anti HIV drugs have been increased in this edition.

Monographs of Vaccines and Immunosera are also upgraded in view of latest technology in the field.

A new chapter on Liposomal products and a monograph of Liposomal Amphotericin B injection is an added advantage in view of latest technology adopted for drug delivery.
A chapter on NMR is also incorporated in Appendices.

The chapter on microbial contamination is also updated to great extent to harmonize with prevailing international scenario.
Format

- In an effort to make the pharmacopoeia more user-friendly, design of the texts of the monographs and of the test methods are kept the same however they are upgraded.

- Cross-referencing has been avoided to make each monograph complete in itself thus making it convenient to the analyst performing the tests and to the ones checking the results of analysis.
Basis of Pharmacopoeial requirement

- As in the past, this compendium provides a publicly available statement concerning the quality of a product that can be expected and demonstrated at any time throughout the accepted shelf-life of the article.

- The standards laid down represent the minimum with which the article must comply and it is incumbent on the manufacturer to ensure that the article is manufactured in accordance with Good Manufacturing Practices (GMPs).
It is essential that sufficiently stringent limits are applied at the time of release of a batch of a material or product so that the pharmacopoeial standards are met until its expiry date under the storage conditions specified.

It must be noted that a valid interpretation of any requirement of the Pharmacopoeia should be done in the context of the monograph as a whole, the relevant general monograph, where appropriate, the specified tests and methods of analysis including any reference to the relevant General Notices.
Familiarity with the General Notices will facilitate the correct application of the requirements.
Changes

- Keeping in view the essential requirement under the Drugs and Cosmetics Act, 1940 and Rules there in the information on category of a drug, dosage and usual available strengths of dosage forms has been re-kept in this edition.

- General chemical tests for identification of an article have been almost eliminated and the more specific infrared and ultraviolet spectrophotometric tests have been given emphasis. The concept of relying on published infrared spectra as a basis for identification has been continued.
The use of chromatographic methods has been greatly extended to cope with the need for more specificity in assays and in particular, in assessing the nature and extent of impurities in ingredients and products.

Most of existing Assays and Related substances tests are upgraded by liquid chromatographic method in view to harmonize with other international Pharmacopoeias.
The test for pyrogens involving the use of animals has been virtually eliminated.

The test for bacterial endotoxins introduced in the previous editions is now applicable to more items.

The test for abnormal toxicity is now confined to certain vaccines.
General Chapters

- Volume I is devoted mainly to test methods that are applicable to all the articles of the pharmacopoeia and general information pertaining to the quality requirements of medicinal substances.

- It also includes reference data such as reference spectra, typical chromatograms etc.
The test methods reflect the sophistication of analytical methodology and instrumentation.

Analytical methods are in general in harmony with those adopted internationally for monitoring the quality of drugs.

The steps taken for harmonization have been initiated by the need to cope with the increasing demand for drugs manufactured in the country to globally accepted standards.
The trend towards controlling the microbial quality of all medicinal products has been recognized and the requirement regarding limits of bacterial contamination even of products for oral administration and topical application so that adequate controls are exercised by manufacturers by the adoption of GMPs has been continued.
General Monographs

- The General Monographs for dosage forms of active pharmaceutical ingredients (APIs) are grouped together at the beginning of Volume II.

- They are followed by the monographs for the APIs, pharmaceutical aids and individual dosage forms, all in alphabetical order. Monographs for other articles of a special...
nature such as vaccines and immunosera for human use, herbs and herbal products, blood and blood related products, biotechnology products and veterinary products are given in separate sections in Volume III.
Thanks