History of Pharmacopoeia

Pharmaceutical Inorganic Chemistry

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Introduction

- Derived from Greek word ‘Pharmakon’ means a drug and ‘Poiein’ means to make.
- It is a legal and official book issued by recognized authorities usually appointed by Government of each country.
- It comprises list of pharmaceutical substances, formulae along with their description and standards.

List of Pharmacopoeias

a) Argentine
b) Austrian
c) Belgian
d) Brazilian
e) British
f) Chinese
g) Egyptian
h) European
i) French
j) German
k) Hungarian
l) Indian
m) International
n) Italian
o) Japanese
p) Yugoslavian
q) Mexican
r) Netherlands
s) Nordic
t) Polish
u) Portuguese
v) Rumanian
w) Russian
x) Spanish
y) Turkish
z) United state.

Pharmacopoeial Descrition

All Pharmacopoeias consist of the three main Section-

a) Introduction
b) Monographs of the official drugs
c) Appendices

A) Introduction

It is ueful pointer to pharmaceutical progress since last edition because it summarises thevarrious changes/addition/deletions in the current edition.

B) Monograph of official drugs, preparations and substancces

The word monograph implies the written study of a subject.The pharmacopoeial monographs gives the following information about drugs:

1) **Title-**

The title is stated in english and refers to the official name of the compound.There are synonyms and could be used in place of main title.

Eg. $CaCO_3$ can also be called precipitated chalk.

2) **Formula Weight and Molecular Weight-**

It contains chemical formula with molecular wt.

Eg. $MgCl_2.6H_2O$ (Mol. Wt. 202.30)

3) **Category-**

It describe the therapeutic and pharmacological application of the compound.

Eg. Antacid – $NaHCO_3$

4) **Dose-**

These are the quantities for the guidance of the prescriber or the physician to achieve thedesired therapeutic effect.

Eg. $CaCO_3$ dose 1 to 5gm.

5) **Description**-

It give physical description of the substances like state, colour, odour, taste etc.

6) **Solubility-**

It contain information rearding solubility of drug in water/alcohol,and other organic solvents.

If exact solubility of the article is nt known, a descriptive term is use to indicate its solubility.

TABLE 1.1

Descriptive Terms	*Relative Quantities of Solvent for 1 part of Solute*
Very soluble	Less than 1 part
Freely soluble	From 1 to 10 parts
Soluble	From 10 to 30 parts
Sparingly soluble	From 30 to 100 parts
Slightly soluble	From 100 to 1000 parts
Very slightly soluble	From 1000 to 10,000 parts
Practically insoluble	More than 10,000 parts

7) **Standard-**

It is an imp. Part of monograph, which specifies the quantity purity of the title compound.

Eg. KBr is having not less than 98.0% of KBr, calculated with referene to the dried substance.

8) **Identification-**

This usually involves specific chemicl test or tests for identifying the substance.

Eg. Phenol + $FeCl_3$ gives violet colour.

9) **pH-**

pH values given in the monograph are for the guidance of pharmacist to avoid physiological complications.

Eg.- Calcium Amino salicylates (2% w/v solution gives pH 6.0/8.0

10) **Limit of Impurities-**

For different chemical different limit tests have been included to identify purity. Limit test for impurities are generally represented in ppm by weight or as a percentage.

11) **Assay-**

It is step by step description of a chemical analytical method for the active substance.

Eg. For most inorganic pharmaceuticals titrimetric and gravimetric method are used.

12) **Storage-**

This is last item under the monoraph. these directins are useful in preserving the activity of chemical.

Terms	*Pharmacopoeial meanings*
Cold	Any temperature not exceeding 8° and usually between 2°C and 8° C.
Cool	Any temperature between 8°C and 25°C. An article for which storage in a cool place is directed, may alternatively, be stored in a refrigerator (at temperature between 2°C and 8°C), unless otherwise specified in the individual monogrph.
Room Temperature	The temperature prevailing in a working area.
Warm	Any temperature between 30°C and 40°C.
Excessive Heat	Any temperature above 40°C.
Storage under non-specific	Where no specific directions are indicated in the individual monograph, it is to be understood that the storage conditions include protection from moisture, freezing and excessive heat.

c) Appendices-

The general notices and monographs are followed by a comprehensive section of appendices.

(1)	(2)	(3)
1.	Apparatus for Tests and Assays	6
2.	Biological Tests and Assays	41
3.	Chemical Tests and Assays	29
4.	Microbiological Tests and Assays	7
5.	Physical Tests and Determinations	19
6.	General Information	3
7.	Reagents and Solutions	5
8.	Reference Substances	—
9.	Tables	2

History

- In pre-independence days, British Pharmacopeia was used in India.
- The colonial addendum of BP 1898 was published in 1900 appeared as Government of India edition in 1901.
- In 1946 Government of India issued one list known as “The Indian Pharmacopoeial list”
- Committee under chairmanship of Sir R. N. Chopra along with other nine members prepared “The Indian Pharmacopoeial list”.
- It was prepared by Dept. of Health, Govt. of India, Delhi in 1946.
- In 1948 Government of India appointed an Indian Pharmacopeia committee for preparing “Pharmacopeia of India”
- Tenure of this committee was five years.

Indian Pharmacopoia Editions

First Edition (1955)

- Indian Pharmacopeia committee under chairmanship of Dr. B. N. Ghosh Published first edition of IP in 1955.
- It is written in English & official titles of monographs given in Latin.
- It covers 986 monographs.
- Supplement to this edition was published in 1960.

Second Edition (1966)

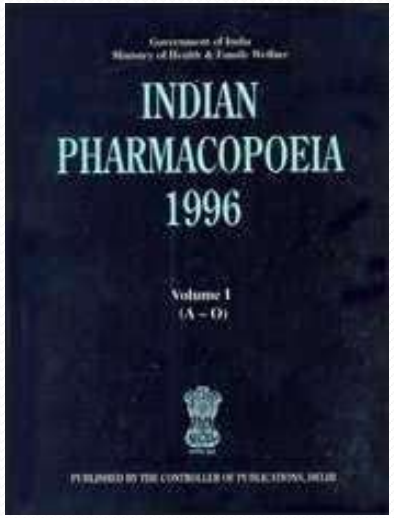
- Second edition of IP was published in 1966 under the chairmanship of Dr. B. Mukkerji.
- Official titles of monographs given in English.
- Dose were expressed in Metric system.
- For Tablets and Injections “USUAL STRENGTH” have been given.
- Formulations of the drugs were given immediately after the monograph of drugs.
- 274 monographs from IP 55 & their supplement were deleted & 93 new monographs were added.
- Supplement to this edition was published in 1975.
- 126 new monographs have been included & 250 monographs have been amended.

Third Edition (1985)

- Third edition of IP was published in 1985 under the chairmanship of P. K. Pradhan, with two volumes & nine appendices.
- 261 new monographs have been added.
- 450 monographs were deleted.
- Addendum I to IP was published in 1989 were 46 new monographs added and 126 amended.
- Addendum II was published in 1991 were 62 new monographs added and 110 amended.

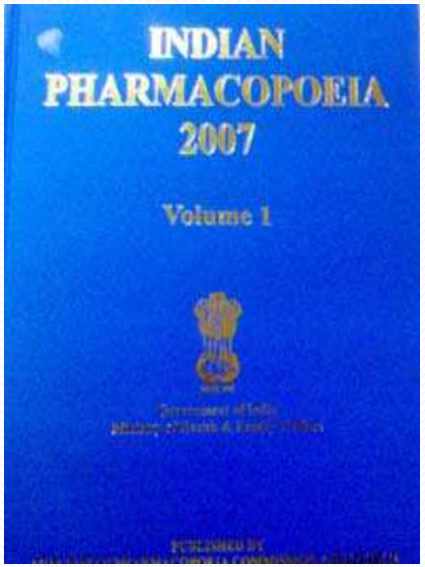
Fourth edition (1996)

- Fourth edition of IP was published in 1996 under the chairmanship of Dr. Nityanand.
- It has been made effective from 1st December 1996.
- It covered 1149 monographs and 123 appendices.
- It includes 294 new monographs & 110 monographs have been deleted.
- Addendum I has been made effective from 31st December 2000 were 42 new monographs have been added.
- Addendum II has been made effective from 30th June 2003 were 19 new monographs have been added.
- The veterinary supplement to IP 1996 contains 208 monographs & four appendices.



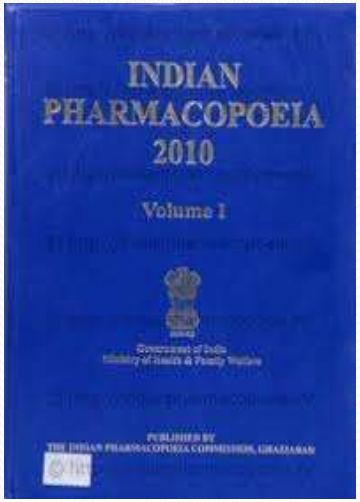
Fifth edition (2007)

- Fifth edition of IP was published in 2007 by the Indian Pharmacopoeia Commission (IPC) Ghaziabad.
- Addendum to this edition was published in 2008.
- IP 2007 is presented in Three Volumes.
- Volume One contains general notices & general chapters.
- Volume Two & Three contains general monographs on drug substances, dosage forms & Pharmaceutical aids.



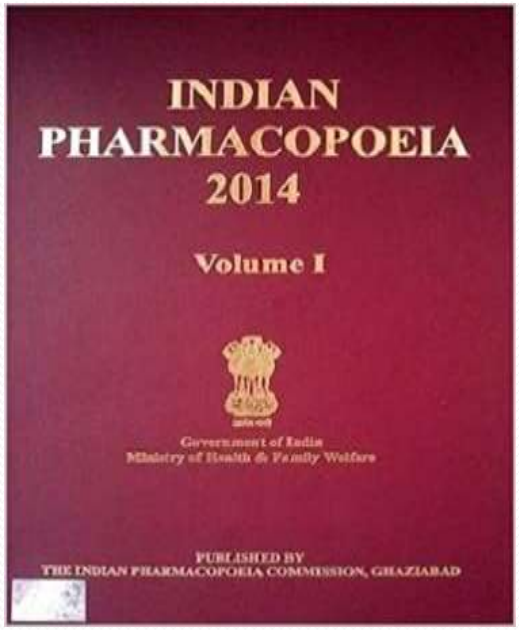
Sixth edition (2010)

- 6th editionof IP is published in 2010 by the Indian Pharmacopoeia Commission (IPC) Ghaziabad.
- The Indian Pharmacopoeia 2010 is presented in three volumes.
- Volume I contains the Notices, Preface, the Structure of the IPC, Acknowledgements, Introduction, and the General Chapters.
- Volume II contains the General Notice, General Monographs on Dosage Forms and Monographs on drug substances, dosage forms and pharmaceutical aids (A to M).
- Volume III contains Monographs on drug substances, dosage forms and pharmaceutical aids (N to Z).
- Followed by Monographs on Vaccines and Immunosera for Human use, Herbs and Herbal products, Blood and blood- related products, Biotechnology products and Veterinary products.



Seventh edition(2014)

- The seventh edition of the Indian Pharmacopoeia (IP 2014) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health & Family Welfare.
- The Indian Pharmacopoeia 2014 is presented in four volumes. The scope of the Pharmacopoeia has been extended to include additional anticancer drugs & antiretroviral drugs and formulations, products of biotechnology, indigenous herbs and herbal products, veterinary vaccines.
- The IP 2014 incorporates 2550 monographs of drugs out of which 577 are new monographs consisting of APIs, excipients, dosage forms and herbal products etc.



Eighth edition (2018)

- The eighth edition of the Indian Pharmacopoeia (IP 2018) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health & Family Welfare.
- The new edition of Indian Pharmacopoeia has been brought out in 4 Volumes incorporating 220 new monographs, 366 revised monographs and 7 omissions

British Pharmacopoeia

- British pharmacopeia is a pharmacopoeia for the United Kingdom published annually by the British Pharmacopeia commission, a nonprofit organization that owns the trademark and copyright.
- Latest edition The British Pharmacopoeia (BP) 2020 supersedes the BP 2019 and becomes legally effective on 1 January 2020.
- This edition contains 35 new and 331 amended BP monographs

- Volumes BP has six volumes as given under:
- **Volumes I and II** - Medicinal Substances
- **Volume III –**
  - Formulated Preparations
  - Blood related Preparations
  - Immunological Products
  - Radiopharmaceutical Preparations
  - Surgical Materials
  - Homeopathic Preparations
- **Volume IV**
  - Appendices
  - Infrared Reference Spectra
  - Index

- **Volume V**

  British Pharmacopoeia (Veterinary)
- **Volume VI (CD-ROM version)**

  British Pharmacopoeia

  British Pharmacopoeia (Veterinary)

- **Appendices and Indices**

  Appendix 1: Interactions

  Appendix 2: Borderline substances

  Appendix 3: Cautionary and advisory labels for dispensed medicines

  Appendix 4: Wound management products and elasticated garments Dental Practitioners' Formulary

United States Pharmacopoeia

- The United States Pharmacopoeia (USP) is a pharmacopeia for the United States published annually by the United States Pharmacopoeial Convention (usually also called the USP), a nonprofit organization that owns the trademark and copyright.
- First edition of USP was published on 15th Dec 1820 in both latin and english.
- From 1820 to 1942 it was published at ten years intervals.
- From 1942 to 2000 it was published at five year intervals.
- From 2002 it was published annually.

- Electronic version of USP-NF on flopy disk was introduced in 1992.
- The current version, **USP** 43–NF 38, will become official on November 1, 2020.
- It is published in five volume.