CHAPTER 2

PHARMACOPOEIAS

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Abstract

Pharmacopoeias serve as authoritative compendia of standards for pharmaceutical substances, playing a crucial role in ensuring drug quality, safety, and efficacy. These official publications provide detailed specifications for the identity, purity, and quality of drugs and excipients. The concept of pharmacopoeias dates back to ancient medical texts, evolving into standardized references for modern pharmaceutical practice. Today, major pharmacopoeias such as the United States Pharmacopeia, British Pharmacopoeia, and European Pharmacopoeia are regularly updated to reflect advances in pharmaceutical science and technology. These compendia contain monographs detailing drug descriptions, identification tests, purity criteria, assay methods, and storage requirements. Pharmacopoeias also include general chapters on analytical methods, dosage form standards, and quality control procedures. The development and revision of pharmacopoeial standards involve collaborative efforts between regulatory bodies, industry experts, and academic researchers. Efforts towards international harmonization aim to streamline global pharmaceutical trade and ensure consistent drug quality worldwide. Understanding and applying pharmacopoeial standards is essential for pharmaceutical professionals in drug development, manufacturing, and quality assurance

Keywords: *Monograph, Drug standards, Quality control, Regulatory compliance, Harmonization, Pharmaceutical analysis*

Learning Objectives

After completion of the chapter, the student should be able to:

- Define pharmacopoeia and explain its importance in pharmaceutical practice.
- Compare and contrast different national and international pharmacopoeias.
- Describe the structure and organization of a typical pharmacopoeia.
- Explain the process of creating and updating pharmacopoeial monographs.
- Identify the key information provided in pharmacopoeial monographs.
- Discuss the role of pharmacopoeias in ensuring drug quality and standardization.
- Analyze the legal and regulatory aspects of pharmacopoeias in different countries.

The books containing the standards for drugs and other related substances are known as pharmacopoeia and formularies - collectively these books are known as the drug compendia.

The pharmacopoeias or formularies contain a list of drugs and other related substances regarding their source, descriptions, standards, tests, formulae for preparing the same, action and uses, doses, storage conditions etc.

These books are prepared under the authority of the Government of the respective countries. The word "pharmacopoeia" is derived from the Greek words '*pharmacon'* meaning 'drug' and '*poieo'* means 'make'. Literally it means that it is a list of medicinal substances, crude drugs and formulae for making preparations from them.

These books are revised from time to time so as to

introduce the latest information available as early as possible after they become established. In order to keep the size of book within reasonable limit it becomes necessary to omit certain less frequently used drugs and pharmaceutical adjuvants from each new edition of the book. Therefore, in each new edition of these books certain new monographs are added while the older ones are deleted.

For the preparation of these books the expert opinion of medical practitioners, teachers and pharmaceutical manufacturers are obtained.

CLASSIFICATION

The drug-compendia are classified as:

(i) Official compendia
(ii) Non-official compendia

A. OFFICIAL COMPENDIA

Official compendia are the compilations of drugs and other related substances which are recognized as legal standards of purity, quality and strength by a government agency of respective countries of their origin.

e.g. British Pharmacopoeia (BP)
British Pharmaceutical Codex (BPC)
Indian Pharmacopoeia (IP)
United States Pharmacopoeia (USP)
National Formulary (NF)
The State Pharmacopoeia of USSR and
Pharmacopoeias of other countries

B. NON-OFFICIAL COMPENDIA

The book other than official drug compendia which are used as secondary reference sources for drugs and other related substances are known as non-official drug compendia. e.g. Merck Index
Extra Pharmacopoeia (Martindale)
United States Dispensatory etc.

Introduction to Indian Pharmacopoeia (IP)

History

The historical developments of Pharmacopoeia in India traces back to 1563 and the credit goes to Garcia da Orta a Portugese physician-cum-teacher.

The idea of indigeneous Indian Pharmacopoeia was concieved in 1837 which bore fruits in 1841 in the shape of Bengal Pharmacopoeia and Conspectus of Drugs.

The Hindustani version in Bengali and Hindi of **London Pharmacopoeia** was made available in India from 1901 onwards.

The **Indian Pharmacopoeial List**, published in 1946 formed the seeding for the true **Official Indian Pharmacopoeia** published in 1955.

The first edition of Indian Pharmacopoeia was published in 1955, but actually the process was started as early as 1944. In 1944 Government of India asked the Drugs Technical Advisory Board to prepare the list of drugs used, in India, having sufficient medicinal value to justify their inclusion in official pharmacopoeia.

The Indian Pharmacopoeial List, 1946.

The list of drugs both included and not included in the British Pharmacopoeia along with standards to secure their usefulness, tests for identity and purity was prepared by the committee and was published by the Government of India under the name '*The Indian Pharmacopoeial List 1946*'.

The committee constituted under the chairmanship of Col. Sir R.N.Chopra along with other nine members, prepared the list of drugs with the following details:

Substances included in the British Pharmacopoeia for crude drugs, chemicals and their preparations.

Substances not included in the British pharmacopoeia

a) Drugs of plant origin

b) Drugs of animal origin
c) Biological products
d) Insecticides
e) Colouring agents
f) Synthetics
g) Miscellaneous
h) Drugs for veterinary use.

The Indian Pharmacopoeial List 1946 was prepared by Department of Health, Govt. of India in 1946.

The history of development of Indian Pharmacopoeia:

Table: History of development of IP

Year	Events
1946	The Govt. of India published the *Indian Pharmacopoeial List*.
1948	The Govt. of India constituted a permanent Indian Pharmacopoeia Committee. This committee was assigned the task of preparing Indian Pharmacopoeia and to keep it up-to-date.
1955	The **first** edition of **Indian Pharmacopoeia** (IP) was published.
1960*	Supplement of IP 1955 was published.
1966*	N.B. The work of revision of the Indian Pharmacopoeia as well as compilation of new edition was taken up simultaneously under the chairmanship of Dr. B.N.Ghosh, who died in 1958. After Dr. B.N.Ghosh, Dr. B.Mukherjee, the Director of Central Drug Research Institute was appointed as the chairman of Indian Pharmacopoeia committee.
1975	The **second** edition of IP was published.
1978	A supplement of IP 1966 was published.
1985	The Indian Pharmacopoeia Committee was reconstituted by the Govt. of India, Ministry of Health and Family Welfare, under the

Year	Events
	chairmanship of Dr. Nitya Nand, Director,
1989	Central Drug Research Institute, Lucknow.
1991	The **third** edition of IP was published in two
1996*	volumes, Volume-I and Volume-II by the Controller of Publications, on behalf of Govt. of India, Ministry of Health and Family Welfare.
	Volume-I contains:
	Legal Notices, Preface, Acknowledgments, Introduction, General Notices, and Monographs from A to P.
	Volume-II contains:
	Monographs from Q to Z, Appendices, Contents of Appendices and Index.
	Addendum (I) to IP 1985 was published.
	Addendum (II) to IP 1985 was published.
	The **fourth** edition of IP was published.

For the preparation of Pharmacopoeia of India, the pharmacopoeias of other countries, like British, Europe, United States, USSR, Japan, the National Formulary (USA) and Merck Index were consulted. The persons working in pharmaceutical industry, drug control laboratories, research and teaching institutions also actively participated.

Under the Drugs and Cosmetics Act 1940, the Indian Pharmacopoeia is an official book which contains the standards for drugs and other related substances included in the pharmacopoeia. The drugs and other related substances prepared by pharmaceutical manufacturers must comply with these standards.

VARIOUS OFFICIAL PUBLICATIONS RELATED TO PHARMACY PROFESSION IN INDIA

1. NATIONAL FORMULARY OF INDIA

For the guidance of medical practitioners, medical students and pharmacists in hospitals and in sales departments National Formulary of India has been formulated.

1960 First edition was published by Govt. of India, Ministry of Health.

1966 Second edition was published.

1979 Third edition was published.

It contains information about drug interaction, resistance, cumulative effects, drug dependence, prescription writing etc.

2. SALIENT FEATURES OF THE INDIAN PHARMACOPOEIA

Under the Drugs and Cosmetics Act 1940, the Indian Pharmacopoeia is an official book which contains the standards for drugs and other related substances included in the Pharmacopoeia. The drugs and other related substances prepared by pharmaceutical manufacturers must comply with these standards.

1946	Indian Pharmacopoeial List was published by Govt. of India.
1955	First edition of Indian Pharmacopoeia was published.
1960	Supplement of IP 1955 was published.
1966	Second edition of IP was published.
1975	Supplement of IP 1966 was published.
1985	Third edition of IP was published.
1989	Addendum-I to IP 1985 was published.

1991 Addendum-II to IP 1985 was published.

1996 Fourth edition of IP was published.

Under each monograph chemical structures, molecular weight, physical description, solubility, identification tests, standards, assay method, storage etc. are given. Indian Pharmacopoeia is published by the Controller of Publications, Delhi on behalf of Govt. of India, Ministry of Health and Family Welfare

3. THE BRITISH PHARMACOPOEIA (BP)

Under the Medical Act 1858 the General Council of Medical Education and Registration was empowered to alter, amend and republish the British Pharmacopoeia (BP) as often as necessary. The first BP was published in 1964.

1864 The first BP was published.

1926 Committee of Civil Research recommended that a Pharmacopoeia Commission be formed and it should be entrusted the work of new editions of BP and also recommended that BP be revised and reissued at an interval of ten years.

1932 New edition of BP was published according to the above recommendation.

1968 Medicines Act 1968 gave the responsibility of preparing the BP to the Medicines Commission. Medicines Commission reconstituted the British Pharmacopoeia Commission and gave the responsibility to British Pharmacopoeia Committee.

1980 The **thirteenth** edition of BP was published.

1988 The 14th edition of BP was published.

1993 The 15th edition of BP was published.

BP 1988 contains two volumes with 2100 monographs:

Vol-I contains monographs on medicinal and pharmaceutical substances along with Infra-red (IR) reference spectra.