

CHAPTER - 2:

PHARMACEUTICAL LITERATURE

Syllabus:

Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
History and development of Indian Pharmacopoeia.

PHARMACOPOEIA / FORMULARIES / COMPENDIA

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 '*pharmakon*' 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.

INDIAN PHARMACOPOEIA

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:

Year	Events
1946	The Govt. of India published the <i>Indian Pharmacopoeial List</i> .
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. 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.
1966*	The second edition of IP was published.

1975	A supplement of IP 1966 was published.
1978	The Indian Pharmacopoeia Committee was reconstituted by the Govt. of India, Ministry of Health and Family Welfare, under the chairmanship of Dr. Nitya Nand, Director, Central Drug Research Institute, Lucknow.
1985	The third edition of IP was published in two 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.
1989	Addendum (I) to IP 1985 was published.
1991	Addendum (II) to IP 1985 was published.
1996*	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. 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 1864.

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.

Vol-II contains formulated preparations, blood products, immunological products, radio-pharmaceutical preparations, surgical materials and appendices.

BP is the source of standards of drugs in United Kingdom and other parts of Common Wealth Countries.

4. BRITISH PHARMACEUTICAL CODEX (BPC)

It was in 1903 that the council of Pharmaceutical Society of Great Britain decided to prepare a reference book for the use of medical practitioners and dispensing pharmacists. The first edition of BPC was published in 1907.

On the request of British Pharmacopoeia Commission, the Council of the Pharmaceutical Society agreed in 1959 for the publication of Codex to coincide with that of the BP, so that BP and BPC should come into effect on the same date.

The BPC differs from BP in that :

- a) It contains many more drugs and preparations some may be included in advance to the pharmacopoeia while other drugs may have been included in the former editions of pharmacopoeia but now they are retained in the Codex because they are still commonly used.
- b) It provides information on the actions and uses of drugs, their undesirable effects, precautions and the treatment of poisoning.
- c) It contains formulae, method of preparation, container and storage conditions of most of the preparations which are still extemporaneously prepared in the pharmacy.

5. THE UNITED STATES PHARMACOPOEIA (USP)

The USP was originally published in 1820 under the authority of United States Pharmacopoeial Convention. The National Formulary (NF) was published in 1888 under the guidance of American Pharmaceutical Association.

In 1974 the NF was purchased by the United States Pharmacopoeial Convention and from 1980 onwards only one official book of drug standards was published under the heading The United States Pharmacopoeia and The National Formulary (USP-NF).

6. EXTRA PHARMACOPOEIA

The Extra Pharmacopoeia was first produced in 1883 by William Martindale and is still known as '*Martindale*'. This is an authorized reference book on drugs and is used throughout the world. It provides all sorts of latest information on drugs and medicines. It is published by the direction of the Council of the Royal Pharmaceutical Society of Great Britain and prepared in the Society's Department of Pharmaceutical Sciences.

7. THE MERCK INDEX

It is an encyclopaedia of chemicals, drugs and biologicals. The first edition was published in 1989 and the eleventh edition was published in 1989 by Merck & Co., Inc. Rahway, New Jersey, USA.

8. THE INTERNATIONAL PHARMACOPOEIA

The International Pharmacopoeia is published by the World Health Organization and is particularly used in developing countries. The first edition was published in 1951 (Volume-I) and in 1955 (Volume-II).

The object of this was to provide a uniform list which would avoid the confusion caused by different national standards, strengths and names especially for the use of travelers who might need to use the same prescription in different countries.