PHARMACEUTICS -1 (BP 103 T)

UNIT: 1 PHARMACOPOEIAS:

CLASS:3

TOPIC: HISTORY OF PHARMACOPOEIA

PCOP

INTRODUCTION

Pharmacopoeia: the word derives from the ancient Greek (pharmakopoiia), from (pharmako-) ″drug″, followed by the verb-stem (poi-) ″make″ and finally the abstract noun ending (-ia). These three elements together can be rendered as ″drug-mak-ing″ or ″to make a drug″. A pharmacopoeia, pharmacopeia, or pharmacopoeia, in its modern sense, is a legally binding collection, prepared by a national or regional authority, of standards and quality specifications for medicines used in that country or region. A quality specification is composed of a set of appropriate tests that will confirm the identity and purity of the product, ascertain the strength (or amount) of the active substance and, when needed, its performance characteristics. Reference substances, i.e. highly-characterized, physical specimens, are used in testing to help ensure the quality, such as identity, strength and purity, of medicines. The texts cover pharmaceutical starting materials, excipients, intermediates and finished pharmaceutical products (FPPs). General requirements may also be given in the pharmacopoeia on important subjects related to medicines quality, such as analytical methods, microbiological purity, dissolution testing, stability, etc. The role of a modern pharmacopoeia is to furnish quality specifications for active pharmaceutical ingredients (APIs), FPPs and general requirements, e.g. for dosage forms. The existence of such specifications and requirements is necessary for the proper functioning or regulatory control of medicines. Pharmacopoeial requirements form a base for establishing quality requirements for individual pharmaceutical preparations in their final form. According to the information available to the World Health Organization (WHO), 140 independent countries are at present employing some 30 national as well as the African, European and International Pharmacopoeias. Compared to national and regional pharmacopoeias, The International Pharmacopoeia (Ph. Int.) is issued by WHO as a recommendation with the aim to provide international standards – including less technically demanding alternatives where needed - for adoption by Member States and to help achieve a potentially global uniformity of quality specifications for selected pharmaceutical products,

excipients and dosage forms. History and background Overwhelming empirical knowledge of mankind gained during centuries and constant effort to establish better health care possibilities have led to the creation of a list of origin, preparation and healing properties of medicines. The term Pharmacopoeia first appears as a distinct title in a work published in Basel, Switzerland in 1561 by Dr A. Foes, but does not appear to have come into general use until the beginning of the 17th century. Today's pharmacopoeias focus mainly on assurance of quality of products by various tools of analytical sciences. The aim to achieve a wide global harmonization of quality specifications for selected pharmaceutical products, excipients and dosage forms came with increased globalization and reciprocal collaboration. History of these approaches goes back to 1902–1925 when agreements established a ″Unified″ Pharmacopoeia. In 1929 the "Brussels Agreement" stipulated the League of Nations to carry out related administrative functions. Eight years later, in 1937, the first meeting of the ″Technical Commission of Pharmaceutical Experts″ was held. An important date in the history of quality assurance of medicines is 1948, when the First World Health Assembly (WHA) approved the Expert Committee on Unification of Pharmacopoeias to continue this work. One year later, the WHA renamed it the Expert Committee on International Pharmacopoeia.

INDIAN PHARMACOPOEIA

- First official IP was appeared in 1868 which was edited by Edward John Waring
- In pre-independence days, BP 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 Pharmacopeial list' Committee under chairmanship of Sir R. N. Chopra along with other 9 members prepared The Indian Pharmacopeial list
- It was prepared by Department of Health, Govt. of India, and Delhi in 1946.
- In 1948 Government of India appointed an IP committee for preparing Pharmacopeia of India " Tenure of this committee was 05 years.
- Indian Pharmacopoeia committee under chairmanship of Dr. B. N. Ghosh Published first edition of IP in 1955 First edition of IP is written in English & official titles of monographs given in Latin.
- It covers 986 monographs.
- Supplement to this edition was published in 1960.

2nd edition of IP was published in 1966 under the chairmanship of Dr. B. Mukherjee

- 274 monographs from IP 55 & their supplement were deleted.
- 93 new monographs were added.

- Official titles of monographs given in English
- Dose was expressed in Metric system For Tablets and Injections "USUAL STRENGTH" have been given.

3rd edition of IP was published in 1985 with 02 volumes & 09 appendices.

- 261 new monographs have been added.
- 450 monographs were deleted.
- Addendum I: Published in 1989, 46 new monographs added and 126 amended.
- Addendum II: Published in 1991 were 62 new monographs added and 110 amended.

4th edition of IP was published in 1996 under the chairmanship of Dr. Nityanand.

- It covered 1149 monographs and 123 appendices.
- It includes 294 new monographs & 110 monographs have been deleted.
- Addendum I: Effective from 31st December 2000, 42 new monographs have been added.
- Addendum II: Effective from 30th June 2003, 19 new monographs have been added.
- The veterinary supplement of IP 1996 contains 208 monographs & 04 appendices.

5th edition of IP was published in 2007 & addendum to this edition was published in 2008.

- IP 2007 is presented in 03 Volumes.
- Volume 1: contains general notices & general chapters.
- Volume 2 & 3: Contains general monographs on drug substances, dosage forms & Pharmaceutical aids.

6th edition of IP is published in 2010 by the Indian Pharmacopoeia Commission (IPC), Ghaziabad

- This edition would be effective from 1st September, 2010.
- The Indian Pharmacopoeia 2010 is presented in 03 volumes.
- Volume I: contains the Notices, Preface, and 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).
- Monographs on vaccines and immunosera for human use, herbs and herbal products, blood and blood-related products, biotechnology products and veterinary products.
- Products of biotechnology, indigenous herbs and herbal products, veterinary vaccines and additional antiretroviral drugs and formulations, fixed-dose combinations.
- Standards for new drugs and drugs used under national health programme are added

- Monographs of excipients, anticancer drugs, herbal products and antiretroviral drugs have been increased in this edition.
- Monographs of vaccines and immunosera are also upgraded in view of development 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 incorporated in Appendices.
- The chapter on microbial contamination is also updated to a great extent to harmonize with prevailing international requirements

7th Edition of IP (2014)

- 313 New monographs on drug substances, dosage forms & pharmaceutical aids (A to Z) 43 New drugs substances monographs 10 Antibiotic monographs
- 31 Herbal monographs 05 Vaccines & immunosera for human use
- 06 Insulin products, 07 biotechnology products etc. along with the 19 new general chapters
- 19 New radiopharmaceutical monographs & 1 general chapter is first time being included in this edition

8th Edition of IP (2018)

- 04 Volumes 170 Chemical Monographs 15 herbal monographs
- 10 monograph on blood and related products
- 06 monographs on biotechnology derived products
- 02 monographs on vaccine and immune sera

IMPORTANAT QUESTIONS

1. Write any four salient features of the Indian Pharmacopoeia ?
2. Write any four salient features of the Indian Pharmacopoeia ?

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