

PHARMACEUTICAL INORGANIC CHEMISTRY- BP104T

UNIT: 1 (IMPURITIES IN PHARMACEUTICAL SUBSTANCES)

CLASS: 1

TOPIC: HISTORY OF PHARMACOPOEIA

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 Pharmacopoeial list' Committee under chairmanship of Sir R. N. Chopra along with other 9 members prepared The Indian Pharmacopoeial 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 Pharmacopoeia 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

BRITISH PHARMACOPOEIA

- First edition of BP was published in 1864 & consists of two sections
- Part I: Materia Medica Part II: Preparation• & compounds
- Second edition of BP was published in 1867
- Third edition of BP was published in 1885
- Fourth edition of BP was published in 1898
- Fifth edition of BP was published in 1914
- Eighth edition of BP was published in 1953
- Titles of drugs & preparations were in English instead of Latin and metric system.
- It has been published annually.
- In BP 2007 monographs has been introduced for material specifically used in preparation of Traditional Chinese Medicines.
- Term “Prolonged release” has been replaced the term “Slow” and the term “Gastroresistant” has been replaced with “Enteric coated” in number of monographs
- BP 2008 contains approximately 3100 monographs for substances, preparations and articles used in practice.
- It has been made effective from 1st January 2008. BP 2007-2009 were given in 06 Volumes i.e. Vol. I to Vol. VI.
- Volume I & II: Contains medicinal substances.
- Volume III: Contains formulated preparations, blood related products, immunological products, radiopharmaceutical preparations, surgical materials & homoeopathic preparations.
- Volume IV: Contains supplementary chapters, IR spectra etc.
- Volume V: Contains veterinary products
- Volume VI: Contains CD ROM version

BP 2010

- The Stationery Office, on behalf of BP Secretariat, part of the Medicines and Healthcare products Regulatory Agency (MHRA), has recently published the BP, 2010.
- BP is the official collection of standards for UK medicinal products and pharmaceutical substances.
- Published annually, the BP contains monographs for pharmaceutical substances, formulated preparations and other articles used in the practice of medicine.
- The standards in the BP 2010 are legally effective in the UK from 1 January 2010.
- BP has been providing authoritative, official standards for pharmaceutical substances and medicinal products since 1864.
- It is used in almost 100 countries worldwide and remains an essential reference for any individual or organization working within pharmaceutical research and development, manufacturing and testing across the globe.
- BP 2010 has 40 monographs for formulated preparations, including veterinary medicines and additional standards for widely used unlicensed formulations.
- All European Pharmacopoeia 6th edition material up to and including Supplement 6.5 is integrated into the text of the BP 2010.
- BP supports regulatory work in the fields of herbal and complementary medicines by providing additional new and revised monographs for herbal medicinal products and for homeopathic stocks and mother tinctures.
- Print edition of BP 2010 comprises 4 volumes of BP 2010 and a single volume of BP (Veterinary) 2010. 27

The BP 2013 package includes:

- 06 volume printed edition including the BP (Veterinary) 2013
- 41 new BP monographs
- 40 new European Pharmacopoeia monographs
- 619 amended monographs
- 6 new and 1 amended Infrared Reference Spectra BP 2013
- The 2014 edition includes almost 3500 monographs which are legally enforced by the Human Medicines Regulations 2012.

BP 2014

- The BP 2014 package comprises 5 volumes of BP 2014 and a single volume of BP (Veterinary) 2014, along with a fully searchable CD ROM and online access to provide you with flexible resources.
- Legally effective from 1 January 2014
- 40 new, 272 amended and 4 new BP (Vet) monographs

- 03 new Supplementary Chapters
- 01 new BP (Vet) Supplementary Chapter

BP 2018

- 35 new monographs 185 amended BP monographs
- 04 new monographs for unlicensed formulations
- 04 new monographs for herbal medicines
- 06 new monographs for veterinary medicines

UNITED STATE PHARMACOPOEIA (USP)

- 1st edition of USP was published on 15th Dec. 1820 in both Latin & English
- From 1820 to 1942 it was published at 10 years intervals
- From 1942 to 2000 it was published at 05 years intervals
- From 2002 it was published annually
- First National Formulary of the united state appeared in 1888
- USP21-NF16 has 08 supplements
- First appeared in January 1985 & last in November 1988
- USP22-NF17, 1990 is the 3rd revision that consolidates USP & NF into a single volume
Electronic version of USP-NF on floppy disks was introduced in 1992
- USP23-NF18, was published in Mumbai at the end of 1994 USP23 has 10 supplements.
- 1st supplement was published in January 1995 & Last in May 1999.
- USP24-NF19, appeared from first January 2000
- USP30-NF25 appeared from May 2007.
- It contains scientific standards for drugs, dietary substances, biological products & excipients used in dosage forms.
- It contains 4,100 monographs and 200 general chapters.
- It has been printed in 03 volume set.
- Volume I contains general chapters, while Volume II, III contains monographs.
- 1st supplement to USP30-NF25, appeared from August 2007 & 2nd supplement from November 2007 which was official from May 2008.
- From 2006, Spanish edition of USP is also being published. United States Pharmacopoeia 30 – National Formulary 25: New heavier paper stock
- Complete table of contents and index in each volume
- Special 'Using the New USP-NF Print' tutorial CD
- Convenient slipcase for easy access and storage (English edition only)

United States Pharmacopoeia 31 - National Formulary 26:

- It is a single-volume combination of two official compendia, the United States Pharmacopeia (USP) and the National Formulary (NF).
- Monographs for drug substances and preparations are featured in the USP, with monographs for dietary supplements and ingredients appearing in a separate section of the USP
- Excipients monographs are included in the NF 36

United States Pharmacopoeia 32 - National Formulary 27:

- More than 4,200 monographs
- Includes over 200 general chapters, covering general tests and assays
- Displays helpful guides and charts that make it easy to find focus specific information
- Includes information on emerging areas of science and medicine
- Helps ensure compliance with official standards
- Enables validation of test results against proven benchmarks
- Creates in-house standards for operating procedures and specifications
- Expedites new product development and approvals

United States Pharmacopoeia 33 - National Formulary 28:

- More than 4,400 monographs
- Over 200 general chapters covering general tests and assays
- A new, easy-to-read format and monograph layout
- Helpful guides and charts that make it easy to find focus-specific information
- Ensures compliance with official standards
- Establishes in-house standard operating procedures and specifications
- Facilitates new product development and approval

United States Pharmacopoeia 34 - National Formulary 29:

- Published in 2011
- USP 34-NF 29 features more than 4,500 monographs for drug substances, dosage forms, excipients, biologics, dietary supplements, and other therapeutics.
- USP 34-NF 29 also offers harmonized material and more than 230 General Chapters with current guidelines for the full range of laboratory tests and established processes for validating methods.

United States Pharmacopoeia 35 - National Formulary 30:

USP-NF is a combination of two official compendia: the 'United States Pharmacopeia (USP)' and the 'National Formulary (NF)' and is officially applicable from 1 May, 2012 to 30 April, 2013.

United States Pharmacopoeia 41 - National Formulary 36:

- Published in 2018
- 4900 monographs
- 350 chapters
- Sections of solutions, reagents, indicators
- Section on hazardous drug handling

2 MARKS QUESTIONS

1. Define Pharmacopoeia

5 MARKS QUESTIONS

1. Write a note on pharmacopoeia of India
2. Write a note on United states pharmacopoeia

10 MARKS QUESTIONS

1. Give a detailed account on history of pharmacopoeia