# PHARAMACEUTICS-I

SUBJECT CODE – BP103T

UNIT – 1
LESSON – 4

## Pharmacopoeia

### Introduction of Pharmacopoeia:

Pharmacopoeia has been the authoritative organization working to ensure the consistency and quality ofmedicines.

Pharmacopoeia is the formulation of drugs. It is the standard book for preparation

of drugs.The book is published in a country under the authority of its own

government.

Pharmacopoeia is derived from Greek word

**Pharmakon - Drugs**

**Copoeia - Means to**

**make**

### Type of Pharmacopoeia / List of Pharmacopeia

- We cannot call it a specific type because every country has a own Pharmacopoeia.

- Noteskarts will discuss Pharmacopoeia of some countries. First of all, let's know about our IndianPharmacopoeia. When did this book become public, Which edition of it is running now?

- **Indian Pharmacopoeia**
- **British Pharmacopoeia**
- **United States Pharmacopoeia**

## Indian Pharmacopoeia:

The Indian Pharmacopoeia is published by the Indian Pharmacopoeia commission (IPC) on behalf of theministry of health and family welfare Government of India.

- Bengal Pharmacopoeia 1844 - But this book was not made public, just this name was kept.
- Legal and official book published by IPC-1945.

- Indian Pharmacopoeia Headquarter - Ghaziabad (Uttar Pradesh)
- Indian Pharmacopoeia commission (IPC) regulated by Ministry Of Health And Family Welfare.

- Indian Pharmacopoeia is written in English and official title of monographs given in Latin.

- The Indian Pharmacopoeia is being processed to fulfill the requirement in the Drug And CosmeticsAct 1940 and rules 1945.
- In 1946 the government of India published the Indian Pharmacopoeia list which served as thesuppliment to British Pharmacopoeia.
- After publication of list the government of India constituted a parmanent Indian Pharmacopoeiacommittee in 1948.
- Indian Pharmacopoeia committee under chairmanship of Dr. B.N. Ghosh published First Edition ofIndian Pharmacopoeia in 1955.
- (Dr. B.N. Ghosh professor of pharmacology. R.Gkar medical College Kolkata who died 1958. AfterDr. B.N. Ghosh, Dr. B Mukerji Director Central Drug Research Institute Lucknow (CDRI) was appointed as chairman of the Indian Pharmacopoeia committee.)

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- Second Edition of Indian Pharmacopoeia was published in 1966. Supplement to this edition waspublished in 1975.
- (On 30 June 1978 the Indian Pharmacopoeia committee was reconstituted by the government ofIndia Ministry Of Health and Family Welfare) under the Chairmanship Dr. Nityanand Directer of Central Drug Research Institute Lucknow (CDRI).

- Third Edition of Indian Pharmacopoeia was published in 1985.
- This Pharmacopoeia include two Addendum with two Volumes.
- Addendum (Volume-1) to Indian Pharmacopoeia published in 1989. They contain legal noticeprephase acknowledgement, Introduction, General notice and monographs from A to P.
- They contain 46 new monographs added and 126 amended.
- Addendum (Volume-2) was published in 1991 contain monographs from Q to Z and they contain62 new monographs added and 110 amended.

- Fourth edition of Indian Pharmacopoeia was published in 1996 under the chairmanship of Dr.Nityanand.
- In Fourth edition addendum from veterinary product in 2002, 2005 and supplement volume -1 A toP, Volume-2 Q to Z.
- The veterinary supplement to Indian Pharmacopoeia 1996 contain 208 monographs.

- Fifth Edition of Indian Pharmacopoeia was published in 2007 and addendum to this edition waspublished in 2008.
- Fifth Edition Indian Pharmacopoeia is presented in three (3) Volume.
- Volume-1st contains general notices and general chapters.
- Volume-2nd contains general monographs on Drugs substances Dosage forms and PharmaceuticalAids.

- Sixth edition of Indian Pharmacopoeia was published in 2010.
- The 6th edition of the Indian Pharmacopoeia 2010 is published by the Indian Pharmacopoeiacommission (IPC).
- The Indian Pharmacopoeia 2010 is presented in 3 volumes.
- Volume-1st contains the notices, Preface the structure of the IPC, Acknowledgements,Introduction and the general chapters.

- Volume-2nd contains the General notice, monographs on Dosage forms and monographs on Drugsubstances, dosage forms and Pharmaceutical Aids (A to M).
- Volume-3rd contains monographs on Drug substances, dosage forms and Pharmaceutical Aids (Nto Z) followed by monographs on Vaccines and Immunosera for human use.
- Herbs and Herbal products. Blood and blood related products biotechnology product andveterinary products.

- The seventh edition of the Indian Pharmacopoeia was published in 2014 by the Indian Pharmacopoeia commission (IPC) on behalf of the Government of India Ministry of Health AndFamily Welfare.
- The Indian Pharmacopoeia 2014 is presented in four Volumes.
- The Indian Pharmacopoeia 2014 incorporates 2550 monograph of drugs out of which 577 are newmonographs consisting of APIs, Excipients, Dosage forms and herbal products etc.

- The Eight edition of Indian Pharmacopoeia was published in 2018 by the IPC on behalf of theMinistry of Health and Family Welfare, Government of India.

## Indian Pharmacopoeia 2018 salient features-

- Incorporating with 4 volume.
- 220 New monographs
- 170 New chemical monographs
- 49 API
- 64 Formulation
- 53 Fixed dose formulations
- 02 Excipients
- 02 Antibiotics
- 15 New herbs and Herbal products monographs
- 03 New Radiopharmaceutical monographs.
- 14 New veterinary Non-biological monographs.
- 18 New Biological monographs
- 02 Vaccines and Immunosera for human use
- 06 Biotechnology derived therapeutic products.
- 10 Blood and Blood related products.

## Salient features of Indian pharmacopoeia

- I.P is published in continuing pursuit of the mission of I.P.C to improve the health of thepeople through ensuring the quality, safety and efficacy of

- I.P contains procedures for analysis and specifications for the determination of quality ofpharmaceutical substances, excipients, and dosage form.
- General chapter on volumetric glassware, conductivity, dissolution test, disintegration test,dimensions of hard gelatin capsule shell etc. have been revised.
- I.P has been extended to include products of biotechnology indigenous herbs and herbals products, veterinary vaccines and additional antiretroviral drugs and formulations, inclusiveof commonly used fixed dose combinations (FDC).
- I.P contains the 170 chemical monographs, 15 herbal monographs, 10 blood and blood related products monographs, 6 biotechnology monographs, 3 pharmaceuticals monographs, 2 vaccines and immune-sera monographs, 14 veterinary and non biologicalproducts monographs.
- I.P monograph for an official substances or preparation includes the articles definition, description, identification, packaging, storage, specifications, impurities, assay and specifictests, one or more analytical procedures for each test, acceptance criteria, other requirementetc.
- General chemical tests and TLC for identification of an article have been almost eliminatedand more specific infrared, ultraviolet spectrophotometer and HPLC tests have given emphasis.
- The uses of chromatographic methods have been greatly extended to cope with the need formore specificity in assays and in particular, in assessing the nature and extent of impurities in ingredients and products.

For controlling the microbial quality of all the medicinal products- Maintenance, preservation, identification, disposal of microorganism have been revised and pyrogen tests have replaced byBacterial Endotoxin Test(BET) in parenteral preparation.

## British Pharmacopoeia (BP)

### Introduction to British Pharmacopoeia:

**British Pharmacopoeia was published by the Health ministry of the United**

**Kingdom.In is also known as National Pharmacopoeia of the United Kingdom.**

**British Pharmacopoeia**

**Headquarters : London, United Kingdom**

| Edition | Year | Addendum / Supplement | Chairmanship | Volume |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| 1st | 1955 | 1960 | D. B.N. Ghose | One |
| 2nd | 1966 | 1975 | Dr. B. Mukherjee | One |
| 3rd | 1985 | 1989/1991 | Dr. Nityanand | Two |
| 4th | 1996 | 2000/2002/2005 | Dr. Nityanand | Two |
| 5th | 2007 | 2008 | Dr. Nityanand | Three |
| 6th | 2010 | 2012 | Shri K.Chandramouli | Three |
| 7th | 2014 | 2015/2016 | Nabi Azad (HealthMinister) | Four |
| 8th | 2018 | 2019/2021 | Dr. C.K. Mishra | Four |

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## United States Pharmacopoeia

Type : Nonprofit
Founded : 1820; 201 years ago
Headquarters : North Bethesda, Maryland,United States
Key people : Ronald T. Piervincenzi (CEO)[1]Website : www.usp.org

## United States Pharmacopeia-National Formulary

The United States Pharmacopeia-National Formulary (*USP-NF*) is a book c pharmacopeialstandards. It contains standards for medicines, dosage for substances, excipients, medical devices, and dietary supplements.