Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as

BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.

Pharmacopoeias

A **Pharmacopoeia** is an **official book of standards** that contains **monographs of drugs, excipients, and dosage forms**, describing their:

- **Identity** (tests to confirm the substance)
- **Purity** (limits of impurities allowed)
- **Strength / Potency** (amount of active drug)
- **Quality standards** (methods of analysis, reference materials, specifications)

It serves as an **authoritative guide** for the **quality control of medicines** and is legally enforceable in many countries.

Functions of a Pharmacopoeia

- Provides **official standards** for drugs and formulations.
- Ensures **safety, efficacy, and quality** of medicines.
- Guides **manufacturers, pharmacists, analysts, and regulators**.
- Helps in **harmonisation of drug standards** across countries.
- Protects patients from **adulterated or substandard drugs**.

Types of Pharmacopoeias

Pharmacopoeias can be **national (country-specific)** or **international**:

A. International Pharmacopoeias

- **International Pharmacopoeia (Ph. Int.)** – Published by **WHO** (since 1951), used globally to harmonise standards.
- **European Pharmacopoeia (Ph. Eur.)** – Council of Europe.

B. National Pharmacopoeias

- **Indian Pharmacopoeia (IP)** – Published by **Indian Pharmacopoeia Commission (IPC)**, Govt. of India.
- **United States Pharmacopoeia (USP)** – USA.
- **British Pharmacopoeia (BP)** – UK.
- **Japanese Pharmacopoeia (JP)** – Japan.
- **Chinese Pharmacopoeia (ChP)** – China.

Structure of a Pharmacopoeia

- **General Notices** (legal status, scope, instructions).
- **General Chapters** (test methods, e.g., sterility test, dissolution test).
- **Monographs on individual drugs** (name, chemical structure, molecular formula, identification tests, assay methods, impurity limits).
- **Appendices** (reagents, reference standards, analytical methods).

Examples

- *Paracetamol monograph* in Indian Pharmacopoeia describes:
  - Physical appearance.
  - Identification tests (melting point, IR spectrum).
  - Purity tests (limit of impurities, sulphated ash, heavy metals).
  - Assay (titration / HPLC method).
  - Storage conditions.

Introduction to Pharmacopoeias

Pharmacopoeias are **official publications** containing **standards for drugs and medicines**. They are recognized legally by governments and are used by **manufacturers, regulators, pharmacists, and analysts** to ensure **quality, safety, and efficacy** of medicines.

1. Indian Pharmacopoeia (IP)

- **Official drug standard of India**.
- First published in **1955** under the guidance of the **Indian Pharmacopoeia Committee**.
- Now published by the **Indian Pharmacopoeia Commission (IPC), Ghaziabad**, under the Ministry of Health & Family Welfare, Govt. of India.
- Revised periodically (latest edition: **IP 2022**).
- **Contents**:
  - General notices.
  - Monographs of drugs (allopathic, herbal, veterinary, biotechnology-based).
  - General chapters (tests like sterility, dissolution, microbiological assays).
  - Appendices (analytical methods, reference standards).
- **Legal status**: Enforceable under the **Drugs and Cosmetics Act, 1940** in India.

2. British Pharmacopoeia (BP)

- **Official drug standard of the United Kingdom**.
- First published in **1864** (combined the London, Edinburgh, and Dublin pharmacopoeias).
- Published annually by the **British Pharmacopoeia Commission**, under the **Medicines and Healthcare products Regulatory Agency (MHRA)**.
- Recognized not only in the UK but also in many **Commonwealth countries**.
- **Contents**:

  - Monographs on active drugs, excipients, herbal preparations, radiopharmaceuticals.
  - Appendices with test methods.
  - Supplementary information about quality assurance.
- **Legal status**: Officially recognized in the **Medicines Act, 1968** (UK).

3. United States Pharmacopoeia (USP)

- **Official drug standard of the USA**.
- First published in **1820**.
- Published by the **U.S. Pharmacopeial Convention**, a nonprofit scientific body.
- Combined with **National Formulary (NF)** → published together as **USP–NF**.
- Updated every year.
- **Contents**:
  - Monographs for drugs, excipients, dietary supplements, biologics.
  - General chapters on tests (e.g., dissolution, chromatography, sterility).
  - Reference standards used globally.
- **Legal status**: Recognized in the **Federal Food, Drug, and Cosmetic Act (1938)**.

4. Extra Pharmacopoeia (Martindale)

- Unlike IP, BP, USP → this is **not an official pharmacopoeia**, but a **reference book**.
- Full name: **Martindale: The Extra Pharmacopoeia**.
- First published in **1883** by Dr. William Martindale in London.
- Now known as **Martindale: The Complete Drug Reference**, published by **Pharmaceutical Press (Royal Pharmaceutical Society, UK)**.
- **Contents**:
  - Information on **drugs and medicines used worldwide** (both official & unofficial).
  - Pharmacological actions, clinical uses, adverse effects, international nonproprietary names (INN).
  - Covers drugs not included in official pharmacopoeias.
- Used as a **global drug reference** by clinicians, pharmacists, researchers.
- **Legal status**: Not official, but highly authoritative.

Summary Table

Pharmacopoeia	First Published	Published By	Legal Status	Key Features
IP	1955	Indian Pharmacopoeia Commission (India)	Official (Drugs & Cosmetics Act, 1940)	Standards for Indian drugs (allopathic, herbal, biotech, veterinary)

BP	1864	British Pharmacopoeia Commission (MHRA, UK)	Official (Medicines Act, 1968)	Widely recognized in UK & Commonwealth countries
USP	1820	U.S. Pharmacopeial Convention	Official (Federal Food, Drug & Cosmetic Act, 1938)	Global reference, includes USP–NF
Martindale (Extra Pharmacopoeia)	1883	Pharmaceutical Press, UK	Not official	Comprehensive global drug reference, includes unofficial drugs

Reference Books for Pharmacopoeias

1. **Remington: The Science and Practice of Pharmacy** – 22nd Edition, Pharmaceutical Press.
   - Standard reference for drug standards, history of pharmacopoeias, and global practices.
2. **Pharmaceutical Jurisprudence** – C.K. Kokate, A. Gokhale, S.B. Gokhale.
   - Contains chapters on Indian Pharmacopoeia, Drugs and Cosmetics Act, and official books.
3. **Textbook of Forensic Pharmacy** – B.M. Mithal.
   - Detailed notes on IP, BP, USP, and Extra Pharmacopoeia (Martindale).
4. **Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems** – Loyd V. Allen.
   - Provides background on compendia like USP–NF, BP, IP.
5. **Indian Pharmacopoeia (latest edition, 2022)** – Published by **Indian Pharmacopoeia Commission (IPC), Ghaziabad**.
6. **British Pharmacopoeia (BP 2024)** – Published by the **British Pharmacopoeia Commission, UK**.
7. **United States Pharmacopeia (USP 2024) – National Formulary (NF)** – Published by the **U.S. Pharmacopeial Convention**.
8. **Martindale: The Complete Drug Reference (40th Edition)** – Pharmaceutical Press (Royal Pharmaceutical Society, UK).