

# UNIT 1

## History of Pharmacopoeia

### Definition of Pharmacopoeia:

A **pharmacopoeia** is an **official compilation of drug standards**—it contains **monographs** of drugs that describe their **identity, purity, strength, quality, tests, and assay methods**. It serves as a **legal and scientific reference** for the manufacture and quality control of pharmaceutical substances and formulations.

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### Historical Development of Pharmacopoeia:

#### 1. Ancient Beginnings:

- The concept of documenting medicinal substances dates back to **ancient civilizations** like **Egypt, China, India, and Greece**.
  - **Charaka Samhita** and **Sushruta Samhita** in India (around 1000 BC) described several medicinal preparations.
  - **Hippocrates** (460–377 BC) and **Galen** (130–200 AD) of Greece were early contributors to systematic drug preparation.
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#### 2. First Pharmacopoeia (Middle Ages):

- The earliest recognized pharmacopoeia was “**Antidotarium Nicolai**” (circa 1100 AD), written by **Nicolaus Myrepsus**, a court physician in Constantinople.
  - The **first official pharmacopoeia** is considered to be the “**Nuovo Receptario**” (1498), published in Florence, Italy, authorized by the city government and prepared by the Medical College.
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#### 3. British Pharmacopoeia (BP):

- The **first edition** of the **British Pharmacopoeia** was published in **1864**, combining the pharmacopoeias of London, Edinburgh, and Dublin.
  - It is regularly revised and updated by the **British Pharmacopoeia Commission** under the UK Medicines and Healthcare products Regulatory Agency (MHRA).
  - BP serves as a standard in many Commonwealth nations and is widely respected internationally.
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#### 4. United States Pharmacopoeia (USP):

- First published in **1820** by a group of physicians in Washington, D.C.
  - It became legally enforceable in the USA under the **Federal Food, Drug, and Cosmetic Act of 1938**.
  - Published by the **United States Pharmacopeial Convention**, the USP sets standards not only for drugs but also for dietary supplements and food ingredients.
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#### 5. Indian Pharmacopoeia (IP):

- India's first official pharmacopoeia, **The Indian Pharmacopoeia**, was published in **1955** by the **Indian Pharmacopoeia Committee** under the **Ministry of Health and Family Welfare**.
  - It sets the **standards for drugs manufactured and marketed in India**.
  - **Revised editions** were published in 1966, 1985, 1996, 2007, 2010, 2014, 2018, and the **latest version in 2022**.
  - The **Indian Pharmacopoeia Commission (IPC)**, Ghaziabad, is responsible for its publication and maintenance.
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#### 6. International Pharmacopoeia (Ph. Int.):

- Published by the **World Health Organization (WHO)** since 1951.
  - Aims to provide **global standards** for quality control of medicines, especially for use in countries that do not have their own national pharmacopoeia.
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#### Other Notable Pharmacopoeias:

- **European Pharmacopoeia (Ph. Eur.):** First published in **1969**, applicable in EU member states.
- **Japanese Pharmacopoeia (JP):** First edition in **1886**, revised every five years.
- **Chinese Pharmacopoeia (ChP):** Covers both modern and traditional Chinese medicines.

## Sources and types of impurities

### Impurities:

An **impurity** is any component present in a pharmaceutical substance other than the desired **active pharmaceutical ingredient (API)** or **excipients**, that arises during **manufacture, storage, or handling**, and may affect the **safety, efficacy, or quality** of the product.

According to the Indian Pharmacopoeia and ICH guidelines, impurities can be organic, inorganic, or residual solvents.

### Sources of Impurities:

#### 1. Raw Materials Used in Manufacturing:

- Impurities in **chemicals or solvents** used for synthesis.
- Impurities in **water** (e.g., calcium, magnesium, chlorides).

#### 2. Manufacturing Process:

- **Incomplete reactions** leading to unreacted starting materials.
- **By-products** from side reactions.
- **Decomposition products** due to heat, pH, or light.

#### 3. Reagents and Catalysts:

- Traces of **acids, bases, metal catalysts** (e.g., palladium, copper).
- Use of impure **intermediate compounds**.

#### 4. Atmospheric Contaminants:

- **Dust**, carbon dioxide, and microorganisms.
- Vapors from **acids, alkalis, solvents** in the production environment.

#### 5. Storage Conditions:

- **Oxidation, hydrolysis, polymerization** during storage.
- **Reaction with container materials** (glass, plastic).

#### 6. Cross-Contamination:

- Contamination from **other products** or **inadequate cleaning** of manufacturing equipment.

#### 7. Solvents Used in Crystallization or Purification:

- **Residual solvents** may remain in the final product.

#### 8. Packaging Materials:

- Leaching of **plasticizers, lubricants, or stabilizers** into the drug from packaging.

## Types of Impurities:

### 1. Organic Impurities:

- **Process-related impurities:** starting materials, by-products, intermediates.
- **Degradation products:** formed during storage (e.g., oxidation, hydrolysis).
- Examples: aldehydes, ketones, acids, esters, amines.

### 2. Inorganic Impurities:

- Arise from the manufacturing process or raw materials.
- Examples:
  - **Reagents:** acids, bases, drying agents.
  - **Catalysts:** heavy metals.
  - **Filter aids:** silicates, carbon.

### 3. Residual Solvents:

- Volatile organic compounds used during synthesis or purification.
- Classified based on toxicity (ICH Q3C):
  - **Class I:** to be avoided (e.g., benzene, carbon tetrachloride).
  - **Class II:** limited use (e.g., methanol, acetonitrile).
  - **Class III:** low toxic potential (e.g., ethanol, acetone).

### 4. Foreign Particulate Matter:

- Physical contaminants like **fibers, glass particles, dust**, etc.

### 5. Enantiomeric Impurities:

- Undesired **optical isomers** in chiral drugs.

## Impact of Impurities:

- May **alter therapeutic efficacy**.
- Can cause **toxicity, allergic reactions, or adverse effects**.
- May affect **stability, solubility, or appearance** of the drug.

## Control of Impurities:

- **Good Manufacturing Practices (GMP)**.
- Use of **validated processes** and **analytical methods**.
- **Limit tests** (e.g., for lead, arsenic, iron).

## Principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

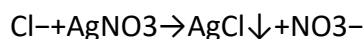
### 1. Limit Test for Chloride

#### Principle:

The test is based on the **precipitation reaction** between chloride ions ( $\text{Cl}^-$ ) and **silver nitrate** ( $\text{AgNO}_3$ ) in the presence of **dilute nitric acid** ( $\text{HNO}_3$ ), forming **silver chloride** ( $\text{AgCl}$ ) as a **white turbidity**. The acid prevents precipitation of other interfering silver salts such as carbonates or phosphates.

This turbidity is visually compared with a **standard chloride solution** that contains a known amount of chloride, usually from **sodium chloride** ( $\text{NaCl}$ ). The comparison is done in **Nessler cylinders** under similar conditions.

#### Reaction:



#### Inference:

If the test solution produces **less or equal turbidity** compared to the standard, it passes the limit test.

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### 2. Modified Limit Test for Chloride

#### Principle:

The modified method improves sensitivity by **conducting the test in a white porcelain dish** instead of a Nessler cylinder, ensuring **uniform background and better light reflection**, making visual comparison of turbidity more accurate.

The chemistry remains the same, but the **visual clarity** and **reproducibility** are improved. This is especially useful when dealing with very low chloride levels.

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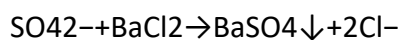
### 3. Limit Test for Sulphate

#### Principle:

This test is based on the **precipitation of sulphate ions** ( $\text{SO}_4^{2-}$ ) with **barium chloride** ( $\text{BaCl}_2$ ) in the presence of **acetic acid** ( $\text{CH}_3\text{COOH}$ ), forming **barium sulphate** ( $\text{BaSO}_4$ ) as a **white turbidity**. Acetic acid is used to maintain a slightly acidic pH, preventing interference by other ions.

The turbidity produced is compared with that of a **standard sulphate solution** (usually potassium sulphate,  $\text{K}_2\text{SO}_4$ ).

#### Reaction:



#### 4. Modified Limit Test for Sulphate

##### Principle:

In the modified method, **ethanol** is included along with **barium chloride** and **dilute hydrochloric acid** to enhance precipitation. The reaction is performed in a **white porcelain dish** to improve visualization.

Ethanol reduces the solubility of barium sulphate, promoting finer and more uniform turbidity. This makes comparison against the standard more sensitive and precise.

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#### 5. Limit Test for Iron

##### Principle:

This test detects traces of **ferric iron ( $\text{Fe}^{3+}$ )**, which forms a **purple-colored complex** with **thioglycolic acid** in the presence of **ammonia buffer** at alkaline pH. Thioglycolic acid acts both as a **reducing agent** and **complexing agent**.

At alkaline pH, ferrous ions ( $\text{Fe}^{2+}$ ) formed from the reduction of ferric ions react with thioglycolic acid to give a colored complex. The color intensity is compared with a standard solution of **ferric ammonium sulphate**.

##### Reaction:

$\text{Fe}^{3+} + \text{Thioglycolic acid}$  undergoes reduction gives

$\text{Fe}^{2+} \rightarrow \text{Purple complex}$

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#### 6. Limit Test for Arsenic

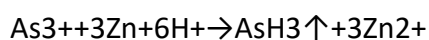
##### Principle:

The test is based on the conversion of **arsenic ( $\text{As}^{3+}$ )** in the sample into **arsine gas ( $\text{AsH}_3$ )** by reaction with **zinc and hydrochloric acid** in a specially designed apparatus. The arsine gas reacts with **mercuric chloride paper**, producing a **yellow to brown stain** due to the formation of **mixed arsenic–mercury halides**.

The intensity of the stain is compared with that of a standard arsenic solution prepared from **arsenic trioxide ( $\text{As}_2\text{O}_3$ )**.

##### Reactions:

1. Formation of arsine:



2. Arsine reacting with mercuric chloride:



This is a **highly sensitive test** and must be conducted in a **closed apparatus** to prevent toxicity.

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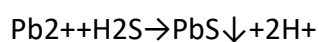
## 7. Limit Test for Lead

### Principle:

Lead is detected by **precipitating it as lead sulfide (PbS)** in the presence of **alkaline tartrate solution and hydrogen sulfide (H<sub>2</sub>S)**. This forms a **brown to black color**, which is compared with a standard lead solution of known concentration.

The test is performed in **slightly alkaline medium** using **ammonium citrate buffer**, which helps to dissolve interfering metal ions by forming soluble complexes.

### Reaction:



The intensity of color or precipitate is observed and compared visually.

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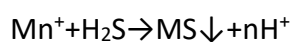
## 8. Limit Test for Heavy Metals

### Principle:

This test is designed to detect **a group of heavy metals** like **lead, mercury, cadmium, arsenic, antimony**, etc. The metal ions are precipitated as their **sulfides** in the presence of **hydrogen sulfide (H<sub>2</sub>S)** under acidic conditions (using acetic acid).

The test is done using **thioacetamide** as a sulfur source in some IP versions. The resulting **colored sulfide precipitates or turbidity** is compared with a standard solution prepared using **lead nitrate**, which serves as a reference for total heavy metal content.

### Reaction:



Where M = metal ion (e.g., Pb<sup>2+</sup>, Hg<sup>2+</sup>, Bi<sup>3+</sup>)

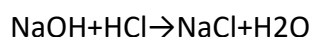
This is a **semi-quantitative test**, and different pharmacopoeias may specify limits in **parts per million (ppm)**.

## 1. Sodium Chloride (NaCl)\*

### 1. General Method of Preparation:

Sodium chloride occurs naturally in large quantities as rock salt and in sea water. It can be obtained by:

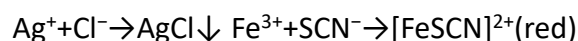
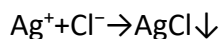
- **Evaporation of sea water**, a process widely used in coastal regions. Seawater is allowed to stand in shallow ponds and evaporate under sunlight.
- **Mining of rock salt** (halite) deposits underground.
- **Synthetic method** (rare in practice): By neutralization of **hydrochloric acid** with **sodium hydroxide**.



### 2. Assay Method: (*As per IP*)

**Volhard's method** – an indirect titration (residual silver nitrate is back-titrated).

- Sodium chloride is reacted with excess **standard silver nitrate ( $\text{AgNO}_3$ )** to form a white **silver chloride precipitate**.
- Unreacted  $\text{AgNO}_3$  is titrated with **ammonium thiocyanate ( $\text{NH}_4\text{SCN}$ )** using **ferric ammonium sulfate** as indicator.
- Endpoint: Formation of a red ferric thiocyanate complex.



### 3. Properties:

- **Physical:**
  - White crystalline powder or colorless crystals
  - Soluble in water, insoluble in alcohol
  - Neutral pH
- **Chemical:**
  - Stable under normal conditions
  - Decomposes only at very high temperatures

### 4. Medicinal Uses:

- Used in preparation of **normal saline (0.9%)** for IV fluid replacement
- Maintains **osmotic balance and electrolyte level** in the body
- Used in **oral rehydration salts (ORS)**

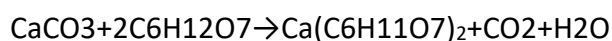


- Component of various **eye and nasal drops**
- **Flavor enhancer** in pharmaceutical formulations

## 2. Calcium Gluconate ( $C_{12}H_{22}CaO_{14}$ )

### 1. General Method of Preparation:

- Prepared by **neutralizing gluconic acid or gluconolactone** with **calcium carbonate ( $CaCO_3$ )** or **calcium hydroxide ( $Ca(OH)_2$ )**.
- The reaction is done in aqueous medium and followed by crystallization.



### 2. Assay Method: (*As per IP*)

- **Complexometric titration with disodium EDTA.**
- Medium: Alkaline buffer (pH ~12), indicator: **Murexide**
- Endpoint: Color change from pink to purple



### 3. Properties:

- **Physical:**
  - White crystalline powder or granules
  - Sparingly soluble in water
  - Odorless, tasteless
- **Chemical:**
  - Slightly hygroscopic
  - Compatible with most drugs and fluids

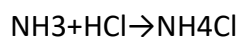
### 4. Medicinal Uses:

- Used in **treatment of hypocalcemia** and **calcium deficiency**
- Used in **tetany** caused by vitamin D deficiency
- Given orally or parenterally (10% injection)
- Also used in **cardiac resuscitation** to counteract magnesium toxicity

### 3. Ammonium Chloride (NH<sub>4</sub>Cl)\*

#### 1. General Method of Preparation:

Ammonium chloride is typically prepared by the **direct neutralization reaction** between **ammonia (NH<sub>3</sub>)** and **hydrogen chloride (HCl)**:



Alternatively, it can be obtained as a **byproduct** in the **Solvay process** during the manufacture of sodium carbonate (Na<sub>2</sub>CO<sub>3</sub>).

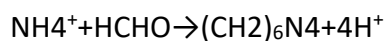
In laboratory-scale preparations, **aqueous ammonia** is reacted with **hydrochloric acid**, and the solution is then evaporated to yield crystals of ammonium chloride.

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#### 2. Assay Method: (*As per Indian Pharmacopoeia*)

Ammonium chloride is assayed by an **indirect acid-base titration** method. Here's how it works:

- Ammonium ions (NH<sub>4</sub><sup>+</sup>) do not act as bases directly.
- To make them titratable, **formaldehyde (HCHO)** is added to the solution to **fix ammonia** by forming hexamethylenetetramine.
- This reaction liberates equivalent **hydrochloric acid**, which is then titrated with standard **sodium hydroxide (NaOH)**.



The liberated acid is titrated with NaOH using **methyl red** as an indicator.

**Endpoint:** Color change from red to yellow

#### 3. Properties:

- **Physical Properties:**
  - White, crystalline powder or colorless crystals
  - Slightly hygroscopic
  - Readily **soluble in water**
  - Slightly **cooling and salty taste**
  - pH of solution: slightly **acidic**
- **Chemical Properties:**
  - On heating, it **sublimes** without melting ( $\text{NH}_4\text{Cl} \rightarrow \text{NH}_3 + \text{HCl}$ )
  - In aqueous solution, acts as a **weak acid** due to hydrolysis

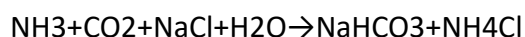
#### 4. Medicinal Uses:

- **Systemic Acidifier:** Used in conditions like **metabolic alkalosis** to acidify the body.
- **Expectorant:** Promotes the secretion or expulsion of respiratory mucus by mildly irritating the gastric mucosa, which in turn stimulates bronchial secretions via a vagal reflex.
- **Diuretic action:** Occasionally used in **edema** or **urinary alkalosis**.
- **Electrolyte replenishment:** Sometimes included in **oral rehydration** or **electrolyte replacement therapies**.

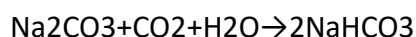
#### 4. Sodium Bicarbonate ( $\text{NaHCO}_3$ )\*

##### 1. General Method of Preparation:

Sodium bicarbonate is prepared industrially by the **Solvay process**, involving the following steps:



In the lab, it can also be prepared by bubbling  **$\text{CO}_2$  gas** through a **cold solution of sodium carbonate ( $\text{Na}_2\text{CO}_3$ )**:



##### 2. Assay Method: (*As per IP*)

###### Acid-base titration:

- Sodium bicarbonate reacts with **sulfuric acid** or **hydrochloric acid**, and the liberated  $\text{CO}_2$  is an indicator of the reaction.



- The titration is done using **methyl orange** as the indicator.
- Endpoint: Color change from yellow to pink/red

##### 3. Properties:

- **Physical:**
  - White crystalline powder
  - Slightly alkaline in aqueous solution
  - Soluble in water but insoluble in alcohol
- **Chemical:**
  - Decomposes on heating to give **sodium carbonate**,  **$\text{CO}_2$** , and **water**

- Reacts with acids to release **carbon dioxide** (effervescence)

#### 4. Medicinal Uses:

- Used as a **systemic antacid** to neutralize stomach acid in hyperacidity and GERD
- **Alkalizer** in metabolic acidosis
- Used in **effervescent granules**
- Component of **toothpastes** and **mouthwashes**
- Used in **alkaline urine therapy** and to treat **uric acid kidney stones**

#### 5. Aluminum Hydroxide Gel [Al(OH)<sub>3</sub>]

##### 1. General Method of Preparation:

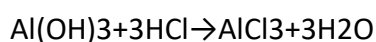
Prepared by **precipitating** aluminum ions from **aluminum salts** (such as aluminum chloride or sulfate) using an alkali like **ammonium hydroxide**:



The precipitate is washed and suspended in water to prepare the gel.

##### 2. Assay Method: (*As per IP*)

- Assayed **indirectly** by **acid-base back titration**.
- A known excess of **standard HCl** is added to dissolve Al(OH)<sub>3</sub>.
- The unreacted HCl is then titrated with **NaOH** using **methyl orange**.



##### 3. Properties:

- **Physical:**
  - White viscous gel
  - Tasteless and odorless
  - Insoluble in water and alcohol
  - Amorphous in nature
- **Chemical:**
  - Reacts with acids to form soluble aluminum salts
  - Acts as a **weak base**

##### 4. Medicinal Uses:

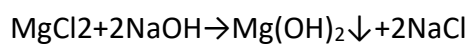
- Used as an **antacid** to relieve hyperacidity, gastritis, peptic ulcers

- **Slow-acting**, but provides **long-lasting effect**
- Also used to **bind phosphate** in chronic kidney disease to prevent hyperphosphatemia
- Component of **antidiarrheal** combinations
- May cause **constipation** with long-term use

## 6. Magnesium Hydroxide Mixture

### 1. General Method of Preparation:

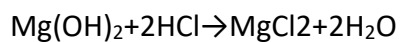
Magnesium hydroxide mixture is prepared by the **precipitation reaction** of **magnesium salt (usually magnesium sulfate or chloride)** with **sodium hydroxide**:



The precipitated **magnesium hydroxide** is washed and **suspended in purified water** to form a uniform mixture.

### 2. Assay Method: (*As per IP*)

- It is assayed **indirectly** by **acid-base back titration**.
- A known excess of **standard hydrochloric acid** is added to react with  $\text{Mg(OH)}_2$ , forming  $\text{MgCl}_2$ .
- The unreacted acid is back titrated with **sodium hydroxide** using **methyl orange** indicator.



### 3. Properties:

- **Physical:**
  - White, odorless, tasteless thick suspension
  - Practically insoluble in water
  - Settles on standing, requires shaking before use
- **Chemical:**
  - Acts as a **weak base**
  - Reacts with acids to form **magnesium salts**

### 4. Medicinal Uses:

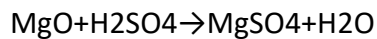
- Used as a **fast-acting antacid** to relieve heartburn and acid indigestion
- Also used as a **saline laxative** in higher doses due to osmotic water retention in intestines

- Provides **synergistic effect** when combined with **aluminum hydroxide**
- Used in **dyspepsia** and **gastritis**

## 7. Magnesium Sulphate ( $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$ )

### 1. General Method of Preparation:

Prepared by neutralizing **magnesium oxide ( $\text{MgO}$ )** or **magnesium carbonate ( $\text{MgCO}_3$ )** with **dilute sulfuric acid ( $\text{H}_2\text{SO}_4$ )**:



The solution is crystallized to obtain **heptahydrate ( $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$ )**, known as **Epsom salt**.

### 2. Assay Method: (*As per IP*)

- **Complexometric titration** using **EDTA**.
- The magnesium ions form a complex with EDTA.
- **Eriochrome Black T** is used as the indicator.
- Endpoint: Color changes from **wine red to blue**.

### 3. Properties:

- **Physical:**
  - Colorless or white crystalline powder
  - Odorless, with a cool, saline, bitter taste
  - Freely soluble in water
  - Slightly soluble in alcohol
- **Chemical:**
  - Neutral salt
  - Loses water of crystallization on heating

### 4. Medicinal Uses:

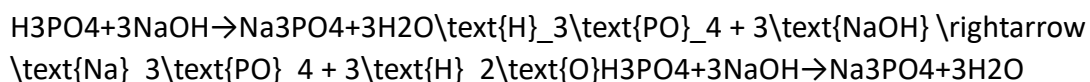
- Used as a **saline cathartic (laxative)** in constipation
- Administered intravenously in **eclampsia** and **preeclampsia** as a **CNS depressant**
- Also used to correct **magnesium deficiency**
- Externally used in **baths and compresses** for muscle relaxation
- Used as an **anticonvulsant**, **antiarrhythmic**, and **tocolytic** agent in specific clinical settings

## 8. Sodium Orthophosphate ( $\text{Na}_3\text{PO}_4$ )

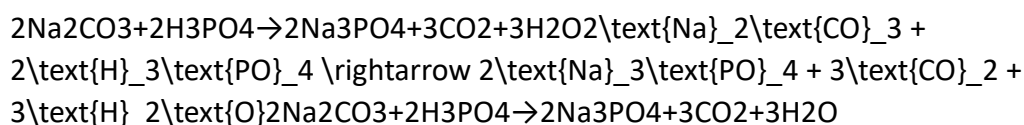
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### 1. General Method of Preparation:

Sodium orthophosphate is prepared by **neutralizing phosphoric acid ( $\text{H}_3\text{PO}_4$ )** with **sodium carbonate ( $\text{Na}_2\text{CO}_3$ )** or **sodium hydroxide ( $\text{NaOH}$ )**:



OR



The product is purified by crystallization.

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### 2. Assay Method:

- It is assayed **gravimetrically** or by **complexometric titration**.
  - One method involves precipitation of magnesium ammonium phosphate and weighing the residue after ignition.
  - Alternative titration method involves **acid-base titration** after hydrolysis.
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### 3. Properties:

- White, crystalline powder
  - Hygroscopic in nature
  - Freely soluble in water, insoluble in alcohol
  - Alkaline in nature due to hydrolysis in water
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### 4. Medicinal Uses:

- Used as a **saline cathartic**
  - Employed in **enemas** and **bowel cleansing** before diagnostic procedures
  - Sometimes used as a **buffering agent** in pharmaceutical formulations
  - In combination with sodium biphosphate in **oral phosphates** for colon cleansing
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## 9. Kaolin

### 1. General Method of Preparation:

Kaolin is a **naturally occurring hydrated aluminum silicate** clay. It is obtained from natural deposits and purified by washing with water to remove impurities like sand, iron oxide, and other soluble salts.

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### 2. Assay Method:

Kaolin is **not assayed by conventional titration methods** due to its **insolubility** and **inorganic nature**. However, it is standardized for **fineness, adsorptive power**, and **purity** as per pharmacopoeial specifications.

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### 3. Properties:

- Fine, white to greyish-white powder
  - Odorless and tasteless
  - Insoluble in water and organic solvents
  - Chemically inert and non-toxic
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### 4. Medicinal Uses:

- Acts as an **adsorbent** and **protective agent** in gastrointestinal disturbances like **diarrhea**
  - Formerly used in **anti-diarrheal mixtures** (now less common due to more effective alternatives)
  - Used externally in **dusting powders** for skin protection and to absorb moisture
  - Used as a **diluent** or **base** in pharmaceutical preparations such as **calamine lotion**
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## 10. Bentonite

### 1. General Method of Preparation:

Bentonite is a **naturally occurring colloidal hydrated aluminum silicate** derived from **volcanic ash**. It is purified by suspending it in water, decanting off impurities, drying, and milling the remaining sediment into a fine powder.

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### 2. Assay Method:



- Bentonite is not assayed by conventional titrimetric methods.
  - It is evaluated based on **swelling index**, **viscosity**, **adsorptive power**, and **pH**.
  - Quality parameters such as **grittiness**, **fineness**, and **gel-forming ability** are important as per pharmacopoeial standards.
- 

### 3. Properties:

- Greyish-white or cream-colored, odorless fine powder
  - Swells significantly in water to form a gel-like mass
  - Insoluble in water and organic solvents
  - pH is slightly alkaline
- 

### 4. Medicinal Uses:

- Acts as a **suspending agent** and **emulsifying agent** in pharmaceutical formulations
  - Used as a **bulk-forming laxative**
  - Applied externally as **protective** and **absorbent** in pastes and poultices
  - Has **adsorbent** properties and can absorb toxins and bacteria in the GIT
- 

## 11. Potassium Permanganate (KMnO<sub>4</sub>)

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### 1. General Method of Preparation:

Prepared by **oxidation of manganese dioxide (MnO<sub>2</sub>)** in an **alkaline medium (KOH)** with **air or potassium nitrate**, forming potassium manganate (K<sub>2</sub>MnO<sub>4</sub>), which is then **disproportionated** upon boiling or acidification:



### 2. Assay Method:

- Assayed by **redox titration**.
  - A known amount is titrated with a standard solution of **oxalic acid** or **sodium thiosulphate** under acidic conditions.
  - Acts as a **self-indicator** (deep purple color disappears upon reduction).
-

### 3. Properties:

- Dark purple, crystalline powder
  - Odorless, has a metallic, sweetish taste
  - Freely soluble in water forming a deep purple solution
  - Powerful oxidizing agent, especially in acidic medium
- 

### 4. Medicinal Uses:

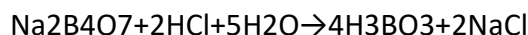
- Used as a **topical antiseptic** and disinfectant (0.01% to 0.1% solution)
- Employed in treatment of **wounds, ulcers, and fungal infections**
- Used in **gargles** and **douches** at low concentrations
- Acts by **oxidizing bacterial cell components**

## 12. Boric Acid ( $\text{H}_3\text{BO}_3$ )

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### 1. General Method of Preparation:

Prepared by **acidifying borax (sodium tetraborate)** with **hydrochloric acid** or **sulfuric acid**:



The solution is filtered and cooled to crystallize **boric acid**.

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### 2. Assay Method:

- Assayed by **acid-base titration** using **mannitol** as a complexing agent to enhance the acidity of boric acid.
  - The titration is carried out with **standard NaOH** using **phenolphthalein** as the indicator.
- 

### 3. Properties:

- White, crystalline, or granular powder
- Odorless with a slightly bitter taste
- Slightly soluble in cold water, more soluble in hot water and glycerin
- Weak monobasic acid (acts as a Lewis acid)
- pH  $\sim$  5.0 in aqueous solution

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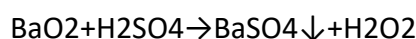
#### 4. Medicinal Uses:

- Used as a **mild antiseptic** and **antifungal** agent in eye washes, mouth rinses, and skin lotions
- Used in **dusting powders, ointments, and creams**
- Employed in **buffering** ophthalmic and otic solutions
- Overdose or prolonged use may cause **toxicity**, especially in infants

### 13. Hydrogen Peroxide (H<sub>2</sub>O<sub>2</sub>)

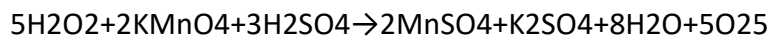
#### 1. General Method of Preparation:

Industrially prepared by the **anthraquinone process** or by **acidifying barium peroxide** with sulfuric acid:



#### 2. Assay Method:

- Assayed by **permanganate titration** in acidic medium.
- KMnO<sub>4</sub> acts as an oxidizing agent and oxidizes H<sub>2</sub>O<sub>2</sub> to oxygen.
- Endpoint: **Pink color** persists due to unreacted KMnO<sub>4</sub>.



#### 3. Properties:

- Colorless, clear liquid with a slightly acidic taste
- Miscible with water in all proportions
- Decomposes on exposure to light or heat, releasing oxygen
- Stabilizers (e.g., sodium stannate) are added to prevent decomposition

#### 4. Medicinal Uses:

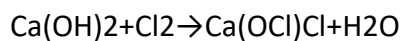
- Used as a **mild antiseptic** and **disinfectant** (3% solution)
- Applied to clean wounds, ulcers, and mouth infections
- Used in ear drops and **tooth whitening preparations**
- Higher concentrations used in laboratory or industrial disinfection

### 14. Chlorinated Lime (Ca(OCl)Cl · H<sub>2</sub>O)

Also known as **Bleaching Powder**

### 1. General Method of Preparation:

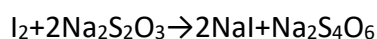
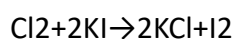
Chlorinated lime is prepared by **passing chlorine gas over dry slaked lime ( $\text{Ca(OH)}_2$ )**:



This reaction yields a **mixture of calcium hypochlorite and calcium chloride** with water of hydration.

### 2. Assay Method:

- Assayed by **iodometric titration**.
- The available chlorine content is determined by reaction with **potassium iodide** in acidic medium, liberating iodine, which is titrated against **standard sodium thiosulphate**:



### 3. Properties:

- White or grayish-white powder with a **chlorine-like odor**
- Decomposes on exposure to air and light
- Slightly soluble in water
- Strong oxidizing and bleaching agent

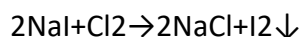
### 4. Medicinal Uses:

- Used as a **disinfectant** for water, hospital floors, and equipment
- Employed in **sanitation** during epidemics
- Acts by **liberating nascent oxygen and chlorine**
- Useful in **sterilizing surfaces, wounds, and treating infections**

## 15. Iodine and Its Preparations

### 1. General Method of Preparation:

Iodine is extracted from **natural brine** or **seaweed ashes**. It is liberated by oxidation of iodide salts (e.g., sodium iodide) using oxidizing agents like chlorine:



### 2. Assay Method:

- Assayed by **iodometric titration**.
- Iodine is titrated with **standard sodium thiosulphate** using **starch** as the indicator.

- The endpoint is the **disappearance of blue color**.

### 3. Properties:

- Shiny, violet-black crystals with a characteristic **pungent odor**
- Slightly soluble in water, more soluble in alcohol and potassium iodide solution
- Volatile and sublimates easily

### 4. Medicinal Uses:

- Used as a **topical antiseptic** in tincture or povidone-iodine forms
- Effective against **bacteria, fungi, viruses, and spores**
- Iodine preparations:
  - **Tincture of Iodine** (Iodine in alcohol)
  - **Lugol's Iodine** (Aqueous solution with potassium iodide)
  - **Povidone-Iodine** (Iodine complexed with povidone for sustained release)

## 16. Potassium Iodide (KI)

### 1. General Method of Preparation:

Prepared by **reacting iodine with hot concentrated potassium hydroxide**, followed by crystallization:



Then, potassium iodide is purified by **recrystallization**.

### 2. Assay Method:

- Assayed **iodometrically** by titrating with **standard potassium iodate (KIO<sub>3</sub>)** in presence of **acid**, which liberates iodine.
- The liberated iodine is titrated with **sodium thiosulphate** using **starch** as indicator.

### 3. Properties:

- White crystalline powder, **odorless** and **salty in taste**
- Freely soluble in water and glycerin
- Sensitive to air and light (may oxidize to iodine)
- Has good **stability in dry air**, but not in moist conditions

### 4. Medicinal Uses:

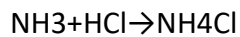
- Acts as an **expectorant** (enhances respiratory secretion)

- Used as an **iodine supplement** to prevent **goiter**
- Component of **Lugol's solution** for thyroid conditions
- Also used in **radioactive iodine prophylaxis** during nuclear exposure

## 17. Ammonium Chloride (NH<sub>4</sub>Cl)

### 1. General Method of Preparation:

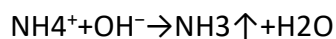
Prepared by **neutralizing ammonia** with **hydrochloric acid**:



The solution is crystallized and dried to obtain **ammonium chloride**.

### 2. Assay Method:

- Assayed by **acid-base titration**:
- Sample is dissolved in water and titrated with **standard NaOH** using **methyl red** as an indicator.
- Ammonia is liberated and titrated:



### 3. Properties:

- White crystalline powder or granules
- Odorless, **cooling saline taste**
- Soluble in water, slightly soluble in alcohol
- Slightly **acidic** solution in water

### 4. Medicinal Uses:

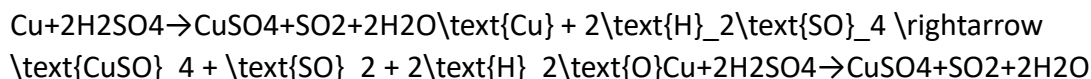
- Used as an **expectorant** (lowers surface tension of respiratory secretions)
- Acts as a **systemic acidifier** and **diuretic**
- Occasionally used as a **component in cough syrups**
- Also used in **urinary acidification**

## 18. Copper Sulphate (CuSO<sub>4</sub>·5H<sub>2</sub>O)

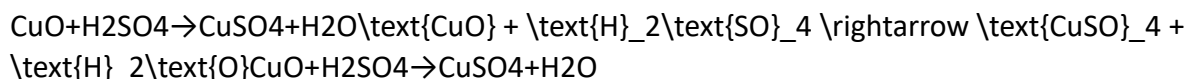
Also known as **Blue Vitriol**

### 1. General Method of Preparation:

Prepared by **dissolving copper metal** in **dilute sulfuric acid** with the help of an oxidizing agent like nitric acid or air:



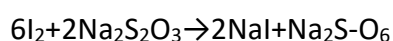
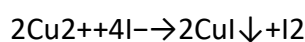
Alternatively:



The solution is concentrated and allowed to crystallize to obtain  **$\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$** .

## 2. Assay Method:

- Assayed by **iodometric titration**.
- Copper(II) ions oxidize iodide to iodine, which is then titrated with **sodium thiosulphate**:



## 3. Properties:

- Blue crystalline powder
- Efflorescent in dry air
- Soluble in water, slightly soluble in alcohol
- Turns white on heating (due to loss of water of crystallization)

## 4. Medicinal Uses:

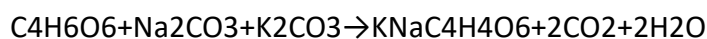
- Used as an **emetic** (induces vomiting, though rarely used now)
- Also used **externally** as an **astringent** and **antiseptic**
- Employed in **veterinary medicine** for parasitic infections

## 19. Sodium Potassium Tartrate ( $\text{KNaC}_4\text{H}_4\text{O}_6 \cdot 4\text{H}_2\text{O}$ )

Also known as **Rochelle Salt**

### 1. General Method of Preparation:

Prepared by **neutralizing tartaric acid** with equimolar quantities of **sodium carbonate** and **potassium carbonate**, then crystallizing:



## 2. Assay Method:

- Assayed by **complexometric titration** with **EDTA**, where calcium or magnesium is displaced from the tartrate complex.
- Endpoint detected using **Eriochrome Black T**.

## 3. Properties:

- Colorless or white, efflorescent crystals
- Slightly alkaline in nature
- Soluble in water, insoluble in alcohol
- Forms a **complexing agent** with metal ions

## 4. Medicinal Uses:

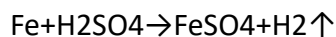
- Used as a **mild saline cathartic (laxative)**
- Acts as a **sequestering agent** in complexometric titrations
- Sometimes used in **buffered solutions** for chemical reactions

## 20. Ferrous Sulphate ( $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$ )

Also known as **Green Vitriol**

### 1. General Method of Preparation:

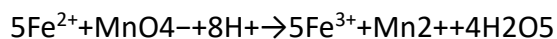
Prepared by **dissolving iron filings or granules** in **dilute sulfuric acid**, followed by crystallization:



The solution is cooled and allowed to crystallize to obtain **ferrous sulphate heptahydrate**.

### 2. Assay Method:

- Assayed by **redox titration** using **potassium permanganate ( $\text{KMnO}_4$ )** as the titrant in acidic medium.
- Reaction:



The pink color of  $\text{KMnO}_4$  disappears at the endpoint.



### 3. Properties:

- Pale green crystalline powder with **metallic astringent taste**
- Efflorescent in air, oxidizes slowly to **ferric sulphate**
- Soluble in water; aqueous solution turns brown on exposure to air

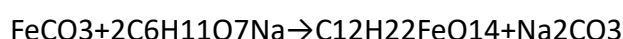
### 4. Medicinal Uses:

- Used as a **haematinic** to treat **iron-deficiency anemia**
- Also acts as a **tonic** and general iron supplement
- Commonly used in combination with folic acid or multivitamins

## 21. Ferrous Gluconate ( $C_{12}H_{22}FeO_{14} \cdot 2H_2O$ )

### 1. General Method of Preparation:

Prepared by reacting **gluconic acid or sodium gluconate** with **ferrous carbonate or ferrous sulphate**, followed by purification and crystallization.



### 2. Assay Method:

- Assayed by **complexometric titration** using **EDTA** in the presence of **ascorbic acid** to prevent oxidation of  $Fe^{2+}$  to  $Fe^{3+}$ .
- Endpoint is determined using a suitable metal indicator like **sulphosalicylic acid** or **phenanthroline**.

### 3. Properties:

- Yellowish to grey-green powder
- Slightly soluble in water, with **mild metallic taste**
- Less irritating to the gastrointestinal tract compared to ferrous sulphate

### 4. Medicinal Uses:

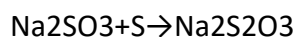
- Used as an **oral iron supplement** in iron-deficiency anemia
- Preferred over ferrous sulphate in patients with **gastric sensitivity**
- Also used in **pediatric formulations** and **iron tonics**

## 22. Sodium Thiosulphate ( $Na_2S_2O_3 \cdot 5H_2O$ )

Also known as **Hypo**

### 1. General Method of Preparation:

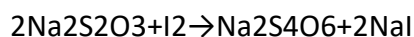
Prepared by **boiling a solution of sodium sulphite ( $\text{Na}_2\text{SO}_3$ ) with sulphur:**



Crystallization yields the **pentahydrate form**,  $\text{Na}_2\text{S}_2\text{O}_3 \cdot 5\text{H}_2\text{O}$ .

## 2. Assay Method:

- Assayed **iodometrically** by titrating with **iodine solution**.
- Reaction:



Endpoint is detected using **starch indicator** which forms a blue complex with excess iodine.

## 3. Properties:

- Colorless crystalline powder with **cooling, saline taste**
- Soluble in water, **efflorescent** in dry air
- Decomposes on heating and in acidic medium
- Acts as a **reducing agent**

## 4. Medicinal Uses:

- Used as an **antidote** in **cyanide poisoning** (converts cyanide to thiocyanate)
- Acts as an **antioxidant** and **detoxifying agent**
- Employed in **iodometric titrations** as a standard reducing agent

## 23. Activated Charcoal (Activated Carbon)

### 1. General Method of Preparation:

Prepared by **carbonizing organic substances** like coconut shells or wood at high temperature, followed by **activation** using steam or carbon dioxide at  $\sim 900^\circ\text{C}$  to increase surface area and porosity.

### 2. Assay Method:

- No standard pharmacopoeial assay.
- Quality is assessed by **adsorptive capacity tests**, such as:
  - **Decolorizing power**
  - **Adsorption of iodine or methylene blue**

### 3. Properties:

- Black, odorless, tasteless, fine powder

- Insoluble in water and most solvents
- Extremely **high surface area** and **porosity**
- Adsorbs a wide variety of substances

#### 4. Medicinal Uses:

- Used as a **universal antidote** in poisoning by adsorbing toxic substances in the GIT
- Used to **reduce flatulence and bloating**
- Employed in **filtering and purification** processes in pharmaceutical and chemical industries

### 24. Sodium Nitrite ( $\text{NaNO}_2$ )

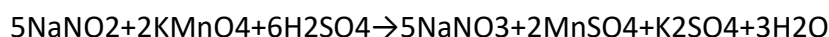
#### 1. General Method of Preparation:

Prepared industrially by **reducing sodium nitrate ( $\text{NaNO}_3$ )** using heat in the presence of **lead or other reducing agents**, or by absorption of **nitrogen oxides** in alkaline solution:



#### 2. Assay Method:

- Assayed by **redox titration**.
- Sodium nitrite is oxidized by **potassium permanganate ( $\text{KMnO}_4$ )** in acidic medium:



- Endpoint is the **permanent pink color** of  $\text{KMnO}_4$ .

#### 3. Properties:

- White to slightly yellow crystalline powder
- Hygroscopic and soluble in water
- Mildly toxic and should be handled with care
- Acts as a **reducing agent**

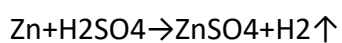
#### 4. Medicinal Uses:

- Used as an **antidote in cyanide poisoning**, often with sodium thiosulphate
- Converts hemoglobin to **methemoglobin**, which binds cyanide
- Also used as a **vasodilator** and **preservative** in some formulations (with restrictions)

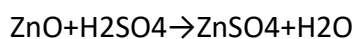
### 25. Zinc Sulphate ( $\text{ZnSO}_4 \cdot 7\text{H}_2\text{O}$ )

### 1. General Method of Preparation:

Prepared by **dissolving zinc metal** or **zinc oxide** in **dilute sulfuric acid**, followed by crystallization:

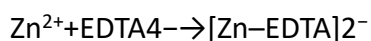


Or



### 2. Assay Method:

- Assayed by **complexometric titration** with **EDTA**, using **Eriochrome Black T** as indicator in a buffered solution:



### 3. Properties:

- Colorless or white crystalline powder
- Soluble in water, insoluble in alcohol
- Astringent and metallic taste
- Efflorescent on exposure to air

### 4. Medicinal Uses:

- Used as an **astringent** and **antiseptic**
- Commonly used in **eye drops and lotions**
- Also used as a **nutritional supplement** in zinc deficiency