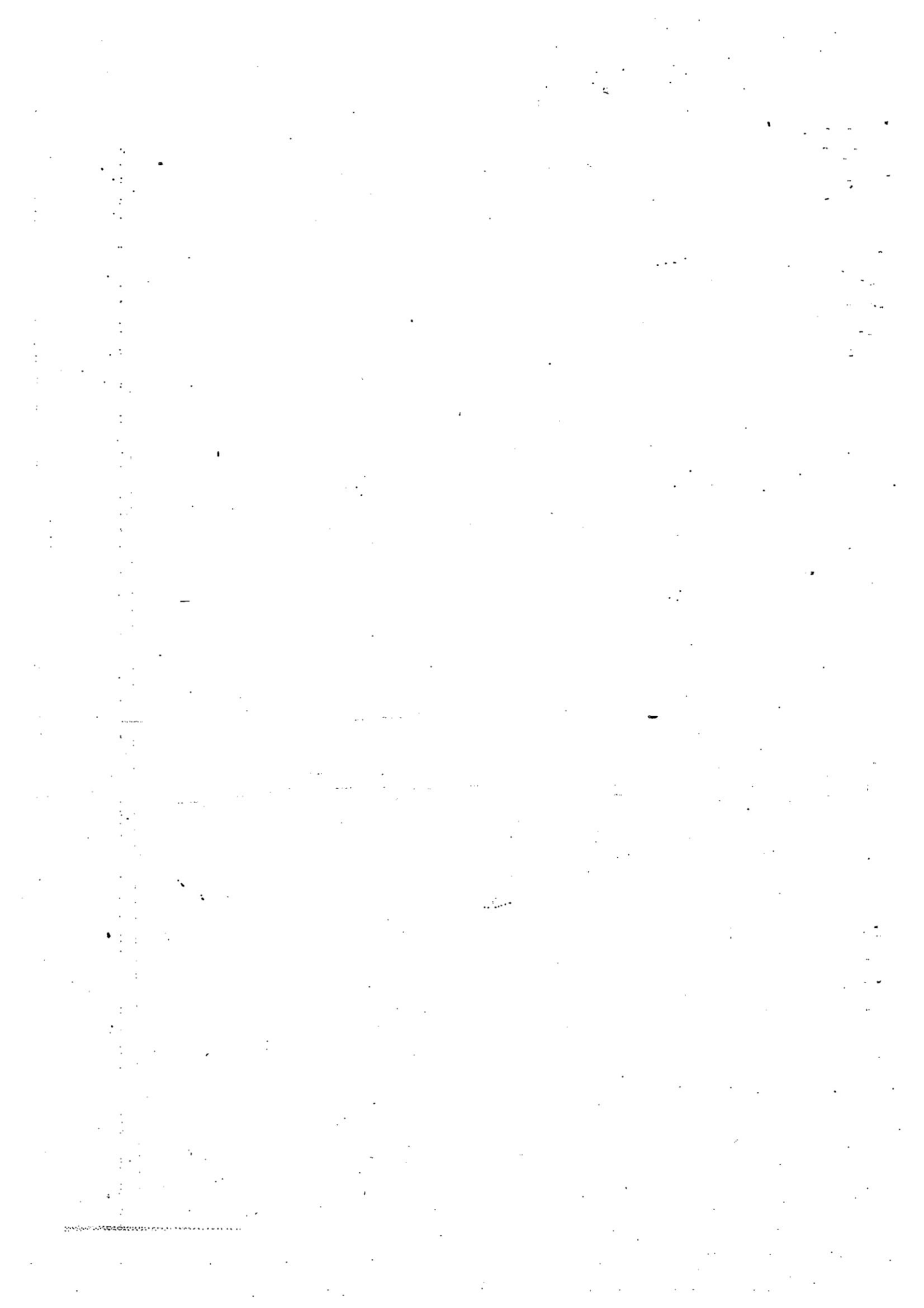


## PHARMACEUTICAL CHEMISTRY -1

S.NO.	CONTENT	PAGE NO.
1.	Definitions	3
2.	Official compounds	4-5
3.	Antioxidants	6
4.	Anti-dote	7
5.	Dental products	8
6.	Respiratory stimulants	9
7.	Gastro intestinal agents	10-13
8.	Expectorants	14
9.	Inhalant	15
10.	Topical agents	16-17
11.	Emetics	18
12.	Buffers	19
13.	Quality control	20-29
14.	Radio-pharmaceuticals	30-33
15.	Quantitative analysis	34-42
16.	Compounds with its synonym, formula & uses	43-44
17.	Storage conditions	44



## CHAPTER – 1 DEFINITIONS

### Q.1 Define the following terms

**1. OFFICIAL COMPOUNDS:** It constitutes an important section of pharmacopoeia which gives all necessary information of drugs and compounds that are official. The information includes the title, subtitle, molecular formula, molecular weight, tests for identification, tests for purity, description the official compound is one & solubility, method of assay, category & dose it applicable.

**2. ASSAY:** The quantitative estimation of the amount of drug present in a given sample constitutes as assay. The percentage purity of the sample is determined by carrying out its assay.

**3. LIMIT TEST:** Limit tests are quantitative or semi-quantitative tests designed to identify and control small quantities or impurities which are likely to present in the substance.

Limit test involves simple comparison of opalescence, turbidity or colour with standards prescribed in pharmacopoeias. If the opalescence, turbidity or colour of the test sample is less than the standard then the given sample passes the limit test and vice versa.

#### **4. ACID & BASE:**

##### Arrhenius theory:

i) **Acid:** Generates [  $H^+$  ] ion in the solution

ii) **Base:** Generates [  $OH^-$  ] ion in solution

Eg: Acid + Base  $\longrightarrow$  Salt + Water

Eg:  $HCl + NaOH \longrightarrow NaCl + H_2O$

##### Bronsted-Lowery theory:

i) **Acid:** Anything that donates a  $H^+$  {Proton donor}

ii) **Base:** Anything that accepts a  $H^+$  {Proton acceptor}

Eg: Acid + Base  $\longrightarrow$  Acid + Base

Eg:  $HNO_2 + H_2O \longrightarrow NO_2^+ + H_3O^+$

##### Lewis theory:

i) **Acid:** Accepts an electron pair. Ex. of Lewis acids are  $H^+$ ,  $Na^+$ ,  $K^+$ ,  $Al^{+3}$ .

ii) **Base:** Donates an electron pair. Ex. of Lewis acids are  $OH^-$ ,  $Cl^-$ ,  $CH_3COO^-$ .

**Buffer:** Solution which resists any change in its pH value on dilution or on addition of small quantity of an acid or alkali.

**CHAPTER - 2**  
**OFFICIAL COMPOUNDS**

**Q.1 Enumerate the official preparations of following compounds**

**ALUMINUM**

Official Compounds of aluminum are-

- i) Aluminum hydroxide gel -  $\text{Al}(\text{OH})_3$   
Use: Antacid.
- ii) Potash alum -  $\text{KAl}(\text{SO}_4)_2 \cdot 12\text{H}_2\text{O}$   
Use: Astringent
- iii) Aluminum sulphate -  $\text{Al}_2(\text{SO}_4)_3$   
Use: Astringent
- iv) Aluminum phosphate gel -  $\text{AlPO}_4$   
Use: Antacid
- v) Aluminum phosphate gel (B.P)  
Use: Antacid

**MAGNESIUM**

Official compounds of magnesium are

- i) Light Magnesium Oxide -  $\text{MgO}$   
Use:-Antacid
- ii) Heavy Magnesium Oxide -  $\text{MgO}$   
Uses: Antacid
- iii) Light Magnesium Carbonate- $\text{MgCO}_3$   
Uses: Antacid
- iv) Heavy Magnesium Carbonate- $\text{MgCO}_3$   
Uses: Antacid
- v) Magnesium Trisilicate -  $2\text{MgO} \cdot 3\text{SiO}_2 \cdot \text{XH}_2\text{O}$   
Uses: Antacid
- vi) Magnesium Sulphate -  $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$   
Use: as saline cathartic
- vii) Magnesium Hydroxide -  $\text{Mg}(\text{OH})_2$   
Use: as antacid & Laxative

**IRON**

Official compounds of Iron are:

- i) Ferrous sulphate -  $\text{FeSO}_4$
- ii) Ferrous Gluconate -  $\text{C}_{12}\text{H}_{22}\text{O}_{14}\text{Fe} \cdot 2\text{H}_2\text{O}$
- iii) Dried Ferrous Sulphate -  $\text{FeSO}_4$
- iv) Iron and Ammonium Citrate

- v) Ferrous Succinate
- vi) Ferric Chloride -  $\text{FeCl}_3$
- vii) Iron Phosphate
- viii) Iron Dextran Injection
- ix) Iron Sorbitol Injection

### **USES**

Iron Preparation is used as Haematinic.

It is used in Anemias caused due to Iron Deficiency.

---

### **Iodine:**

Official compounds of Iodine are:

i) **Sodium Iodide - NaI**

ii) **Potassium Iodide - KI**

Sod.Iodide & Pot.Iodide : Are used in Thyroid Disorders.

Used in a cough mixture as an expectorant.

iii) **Radioactive iodine and sodium Iodide.**

It is Used for Diagnosis of Thyroid disorder.

---

### **Calcium:**

Official compounds of Calcium are:

i) Calcium acetate -  $\text{C}_4\text{H}_6\text{CaO}_4$

ii) Calcium Chloride -  $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$

iii) Calcium gluconate -  $\text{C}_{12}\text{H}_{22}\text{CaO}_{14} \cdot \text{H}_2\text{O}$

iv) Calcium Hydroxide -  $\text{Ca}(\text{OH})_2$

### **USES**

It used as a Source of Calcium.

It used as a Protective agent and dentifrices.

## CHAPTER - 3

### ANTI-OXIDANTS

**Q. Define & Classify Anti-oxidants. Write its properties & uses**

**Answer-**

Antioxidants are the agents which inhibit the Process of oxidation of Ingredients used in Pharmaceutical preparations.

Ex.: Sodium bisulphate, Sodium Metabisulphate, Sulphur dioxide.

#### CLASSIFICATION

1. True antioxidants
2. Reduction agents
3. Antioxidants synergists

**1. True anti-oxidants:** These are effective against auto-oxidation but in-effective against redox reactions.

**Ex: Tocopherol.**

**2. Reducing agents:** These have lower redox potential and are more readily oxidized than the drug.

**Ex: Ascorbic acid, sodium meta- bisulphate.**

**3. Antioxidants synergists:** They enhance the action of true antioxidants.

**Ex:-Citric Acid**

#### Properties of antioxidants

- They should be effective in low concentrations.
- They must have desired redox potential.
- They should be pharmacologically inert.
- They should be easily soluble in the preparation.
- They should be physiologically and chemically compatible with ingredients in the preparation.

#### Importance/Uses

- Used in pharmaceutical preparations to prevent the oxidation of active ingredients.
- Used to prevent the rancidity of fats and oils.

## CHAPTER - 4

### ANTIDOTE

#### Q.1 Define & Classify Antidote.

##### Answer-

Antidotes are agents used to counteract the effects of poisons & toxic substances.

Poisoning may be due to heavy metals like arsenic & lead, overdose of drugs or contamination of food & water. In addition, the inhalation of toxic gases and consumption of insecticides are also common causes of poisoning.

Example: Sodium Nitrite, Activated Charcoal, Copper Sulphate.

**CLASSIFICATION:** Based on mechanism of action

**Physiological antidotes:** - they act by producing opposite pharmacological effects to that of the poison.

**Ex:** Atropine.

**Chemical antidotes:** - they combine with the poison to convert into a complex and make it ineffective.

**Ex:** EDTA in heavy metal poisoning.

**Mechanical Antidotes**

They act by absorption of the poison in the GIT, which is then expelled by emesis or eliminated through faces.

**Ex:** Activated charcoal

Commonly used in-organic antidotes are sodium nitrate ( $\text{NaNO}_2$ ) and  $\text{Na}_2\text{S}_2\text{O}_3$ .

#### Q.2 Write a note on Cyanide poisoning

##### Answer

##### CYANIDE POISONING

Cyanide poisoning normally occurs accidentally or when cyanide poison is taken intentionally for suicidal intention. In cyanide poisoning cyanide ion combines with ferric ion of cytochrome oxidase an enzyme responsible for electron transfer reactions. This leads to stoppage of cellular respiration and metabolic reaction. Cyanide poisoning is usually fatal, if not treated immediately.

In cyanide poisoning sodium nitrite and sodium thiosulphate injections are given to counteract the effects of cyanide poisons. Sodium thiosulphate reacts with cyanide ions and convert into sodium thiocyanate which is less toxic than cyanide. While sodium nitrite reacts with ferrous iron of haemoglobin and converts into ferric iron of methaemoglobin and thus reduces the concentration of cyanide ions.

## CHAPTER - 5

### DENTAL PRODUCTS

**Q. Define & Classify Dental products**

**Answer-**

#### DENTAL PRODUCTS

Drugs used in the treatments of dental disorders are called dental products they include dental caries, dentifrices, desensitizers, dental cement.

#### TYPES OF DENTAL PRODUCTS

**1. Dental caries:** Dental caries means tooth decay when food materials adhere to the surface of the teeth or get lodged between the teeth; micro-organisms grow on them and produce acid like lactic acid, these acids attached the enamel of the teeth and form small cracks on their surface. Further degradation of food by bacteria & dissolution of enamel by acid, leads to the formation of fissures & Pockets resulting in painful cavities in the teeth.

In order to prevent dental caries and to maintain clean and healthy teeth, it is necessary to use antiacaries agents like sodium fluoride, stannous fluoride.

**2. Dentifrices:** Substance used for the cleaning and polishing of teeth, in the form of the tooth paste or powder is called dentifrices. They are used to remove food particles, plaque & tartar the surface of teeth their abrasive action.

**Ex:** Dibasic calcium phosphate  $\text{CaHPO}_4$

**3. Desensitizers:** These are substance that reduces pain & sensitivity of teeth to extreme heat & cold.

**Ex:** Strontium chloride –  $\text{SrCl}_2$

Zinc Chloride –  $\text{ZnCl}_2$

**4. Dental cement:** Substance that are used as a temporary filling for dental cavities, Clipped or broken teeth.

**Ex:** Zinc oxide –  $\text{ZnO}$

Calcium sulphate –  $\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$

## **CHAPTER -6**

### **RESPIRATORY STIMULANTS**

**Q. Explain Respiratory Stimulants & write the preparation, properties & uses of ammonium carbonate**

**Answer-**

#### **RESPIRATORY STIMULANT**

Respiratory stimulants are drugs used to restore normal respiration in conditions where the lungs are un-able to sufficiently eliminate carbon-dioxide (CO<sub>2</sub>) & take up oxygen (O<sub>2</sub>).

Respiratory stimulants belong to the class of drugs known as central nervous system stimulants. One of the important features of this stimulating activity is the "respiratory stimulation". This is brought about by stimulation of chemo – receptor and the vasomotor centers.

In – organic compounds mainly act by irritating the epithelial layers of air passages, namely trachea, bronchi & Lungs which leads to respiratory stimulation.

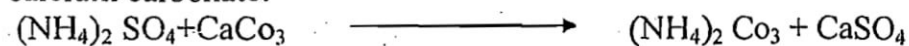
Ammonical salts & preparations are especially useful as respiratory stimulants because they give out ammonia gas which irritate the respiratory tract & act as reflex stimulant.

Ex: Ammonium carbonate

#### **Ammonium Carbonate:**

##### **Preparation:**

It is prepared by subliming a mixture of ammonium sulphate and calcium carbonate.



##### **Properties:**

White power, freely soluble in water & partly soluble in alcohol.

##### **Storage**

It is stored in well closed air tight container because it decomposes easily into ammonia and CO<sub>2</sub>.

**Uses:** Used as respiratory stimulant & expectorant.  
In the preparation of aromatic spirit of ammonia.

## CHAPTER - 7

### GASTRO INTESTINAL AGENTS

**Q.1 Define & Classify G.I.T agents with suitable examples.**

Answer-

#### G.I.T AGENTS

Drug used in the treatment of disorders of the gastro-intestinal tract are called GIT of agents.

#### Classification:

These are classified into 4 major groups depending on their action.

1. Acidifying agents : Dilute HCL
2. Antacids :  $\text{NaHCO}_3$ , MgO,  $\text{Al(OH)}_3$ .
3. GIT Protective & Adsorbents : Kaolin.
4. Saline cathartics :  $\text{MgSO}_4$ , Sodium Sulphate.

#### ACIDIFYING AGENTS

Drugs which increase acidity are known as acidifying agents. In a normal person, hydrochloric acid is secreted which helps in the digestion of food.

If due to some reason, there is no secretion of hydrochloric acid in the stomach the condition is called as **achlorhydria**.

Thus in order to counteract the effect of achlorhydria **dilute hydrochloric acid** is used.

**Uses:** dilute hydrochloric acid is used in the treatment of achlorhydria

**Q.2 Define & classify antacids and write its ideal properties**

#### ANTACIDS

These are drug or preparations which are used to neutralize excess HCl secretions (hyper chlorhydria) in the stomach. They give relief from pain due to hyper chlorhydria.

**Example:** Sodium bicarbonate, Aluminium hydroxide gel, Calcium carbonate, Magnesium trisilicate, Magnesium oxide

**Antacids are classified as follows:**

i) **Systemic antacids:** These are absorbed into systemic circulation and cause systemic alkalosis. They are used to treat systemic acidosis.

Ex:  $\text{NaHCO}_3$ .

ii) **Non-Systemic antacids:** These do not dissolve in gastric fluids & hence do not get absorbed into systemic circulation. They are considered ideal antacid. They may be further divided into.

a) Aluminum containing compounds.

Ex:  $\text{Al}(\text{OH})_3$  gel,  $\text{AlPO}_4$

b) Calcium containing antacids.

Ex:  $\text{CaCO}_3$

c) Mg Containing antacids.

Ex:  $\text{MgCO}_3$ , Heavy & Light  $\text{MgCO}_3$  & magnesium trisilicate.

**Use:** - Antacid

**Storage-** Stored in well closed container in a cool place.

**Ideal requirements of antacids are:**

- Antacids should not be absorbable or cause systemic alkalosis.
- Antacids should not be laxative or cause constipation.
- Antacids should show its effect rapidly and over a long period of time.
- The reaction between antacid and gastric hydrochloric acid should not produce large volume of gas.
- The antacid should probably inhibit pepsin, the proteolytic enzyme.

---

**Q.3 Write short note on Antacid combination therapy**

**Answer**

**COMBINATION ANTACID PREPARATION**

No any single antacids meet the ideal requirements of antacid. Calcium and Aluminium compounds have undesirable constipating effect whereas Magnesium has laxative effect.

So in market antacid preparations containing combination of above antacid is observed so as to balance the constipating effect of calcium and aluminium with the laxative effect of magnesium.

Examples:

- Aluminium hydroxide gel : Magnesium hydroxide combinations
- Aluminium hydroxide gel : Magnesium trisilicate combinations

---

**Q.4 Write a note on G.I.T protective & adsorbent**

**G.I.T PROTECTIVE AND ADSORBENT**

Protective & absorbents are a class of gastro-intestinal agents used internally to treat the disturbances in the normal functioning of the GIT which results in dysentery or diarrhea.

## PHARMACEUTICAL CHEMISTRY-I

GIT protective and adsorbents absorb gases, bacterial toxins and other poisons, excess fluids & micro-organisms from the gastrointestinal tract and also provide a protective coating on the intestinal mucosa. This gives relief from pain and weakness that result frequent watery stools with or without blood & mucous seen in amoebic dysentery and non-specific diarrhea, this loss of fluid and electrolytes can cause severe dehydration and electrolyte imbalance.

Organic compounds used as protective & absorbents are

**Kaolin** -  $\text{Al}_2\text{O}_3 \cdot 2\text{SiO}_2 \cdot 2\text{H}_2\text{O}$

**Bismuth sub-carbonates** -  $[(\text{BiO})_2\text{CO}_3 \cdot \text{H}_2\text{O}]$

### CATHARTICS

These are drugs used for the treatments of severe constipation to bring about evacuation of bowels.

Purgatives act similarly but are generally mild in their nature of action; while laxatives are milder than purgatives.

**Ex:** 1. Magnesium sulphate :  $\text{Mg SO}_4 \cdot 7\text{H}_2\text{O}$

(Epson salt)

2. Sodium potassium tartrate :

(Rochelle salt)

$\text{CHOH COON}_4$

$\text{CHOH COOK} \cdot 4\text{H}_2\text{O}$

3. Mercurous chloride :  $\text{HgCl}_2$

(Calomel)

**Cathartics or purgatives act by four different mechanisms:**

**i. Stimulant:** Act by local irritation on intestinal tract and bring stimulation of peristaltic activity. Ex: Senna, castor oil

**ii. Bulk Purgatives:** Increases the bulk of intestinal contents. Ex: Ispagol Methyl cellulose

**iii. Lubricants:** They lubricate the bowel and bring smooth clearance of the fecal material. Ex: Glycerine, Liquid Paraffin.

**iv. Saline Cathartics:** Act by increasing the osmotic load of the gastrointestinal tract by absorbing large quantity of water and thus stimulate peristalsis. Ex: Salts of Magnesium, sulphate tartrate etc.

### Mechanism of action:

When orally administered, Saline cathartics are retained in the GIT where they draw water from systemic circulation by osmosis & thereby increase the intestinal bulk. This acts as mechanical stimulus, which produces increased peristaltic movements causing evaluation of bowels. So they are also called osmotic cathartics.

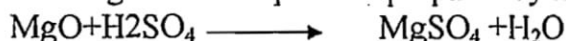
### Magnesium sulphate

**Mol. Formula** -  $MgSO_4 \cdot 7H_2O$  -

**Synonym** - Epsom salt

### Preparation :

Magnesium sulphate is prepared by neutralizing MgO by dilute  $H_2SO_4$



### Properties:

1. Colourless, odourless, bitter taste.
2. Freely soluble in a water.
3. It effloresces in warm, dry air, losing its water of crystallization.

### Storage:

It effloresces in warm dry air & should be stored in well closed air tight container uses.

**Uses:** . Used as saline cathartic in constipation.

---

## **CHAPTER - 8**

### **EXPECTORANTS**

Expectorants are drug used to remove excessive sputum from the respiratory tract. These drugs reduce the viscosity of sputum or increase the volume of secretions thereby facilitating their expulsion from the respiratory tract, by coughing.

Expectorants are used in cough preparations.

Ex- $NH_4Cl$ , KI

### Classification:

Expectorants are broadly classified as :

**i.Sedative type:** These are stomach irritants and produce their effect through stimulation of gastric reflexes.

Ex: Ipecac

Ammonium Chloride ( $NH_4Cl$ )

**ii.Stimulant type:** Produce their effect by stimulation of secretory cells of respiratory tract directly or in directly.

Ex: Eucalyptus oil, Lemon oil.

## CHAPTER - 9

### INHALANTS

Inhalants are the drugs or chemicals which are in vapour form and are inhaled in the body. Inhalation of gases cause changes in physiological functions and bring pharmacological actions.

Oxygen, carbon dioxide, nitrous oxides are the gases used as inhalants.

#### OXYGEN (O<sub>2</sub>)

Oxygen contains not less than 99.0% v/v of O<sub>2</sub>, with trace of other gases like argon, nitrogen or hydrogen.

- Uses:**
- Oxygen is required for respiration of human beings.
  - Oxygen is given by inhalation to correct hypoxemia conditions in chronic bronchitis, pneumonia, pulmonary edema etc.
  - In the treatment of carbon monoxide poisoning.
  - Used as a diluents of volatile and gaseous anaesthetics

**Storage:** Oxygen is stored in metal cylinder. The shoulder of the cylinders is painted black with a white shoulder and the name and symbol O<sub>2</sub> is stenciled on the shoulder.

#### Carbon Dioxide (CO<sub>2</sub>)

Carbon dioxide contains not less than 99.0% w/w of CO<sub>2</sub>.

- Uses:**
- CO<sub>2</sub> regulates the acid-base balance of the blood and tissues.
  - CO<sub>2</sub> is used as respiratory stimulant.
  - CO<sub>2</sub> 5 – 7 % in oxygen has been used in the treatment of carbon monoxide poisonings.

**Storage:** It is stored under compression in steel cylinders painted grey. and the name and symbol CO<sub>2</sub> is stenciled on the shoulder.

#### Nitrous Oxide (N<sub>2</sub>O)

Synonym – Laughing gas

It should not contain less than 99.0% v/v of N<sub>2</sub>O

- Uses:**
- Used as a general anaesthetic
  - It produce muscle relaxant
  - Used as anaesthetic for minor dental and surgical operations.

**Storage:** It is stored in blue metal cylinder under compression and temperature not exceeding 37<sup>0</sup> C. The metal cylinder is painted blue. The name and symbol N<sub>2</sub>O should be stenciled in paint on the shoulder of the cylinder.

## **CHAPTER - 10**

### **TOPICAL AGENTS**

Topical agents are the compounds that act locally on skin or mucous membrane to produce effects like protective, antimicrobial, astringent, emollient etc.

#### **Classification**

- 1. Topical protective & adsorbents**  
Ex – Zinc oxide (ZnO)
- 2. Anti-microbial agent**  
Ex- Hydrogen Peroxide ( $H_2O_2$ )  
Potassium Permanganate ( $KMnO_4$ )
- 3. Astringents**  
Ex- Potash alum  $KAl(SO_4)_2 \cdot 12H_2O$   
Zinc sulphate –  $ZnSO_4$
- 4. Miscellaneous compounds**  
Ex- Bees wax, lanolin.

#### **TOPICAL PROTECTIVE AND ADSORBENTS**

**Topical protective** are soothing substances that protect the skin & mucous membranes from irritation, itching & mild inflammation.

**Ex-** Dusty powders like talc, silicon polymers, and calamine.

**Adsorbents:** are chemically inert substance that absorbs secretions like sweat, excess oil, pus & Micro – organisms.

**Ex:** Purified talc, bentonite.

#### **ANTIMICROBIAL AGENTS**

**Anti-microbial** include a number of agents that act against micro – organisms they include.

- **Germicides:** It is a chemical agent which destroys pathogenic microorganisms. It is further divided into bactericide (against bacteria), virucide (against virus), fungicide (against fungi) etc.
- **Antiseptics:** These are the substances that kill or prevent the growth of microorganisms when applied on living tissue.  
**Ex:** Hydrogen peroxide ( $H_2O_2$ ) Boric acid ( $H_3BO_3$ ), Iodine ( $I_2$ )

## PHARMACEUTICAL CHEMISTRY-I

- **Disinfectants:** These are the substances that kill or prevent the growth of microorganisms when applied on non living objects. Ex: Phenol
- **Bacteriostatic:** It is a chemical agent which inhibits the multiplication of bacteria.
- **Bactericide:** It is a chemical agent which kills the bacteria but not necessarily bacteria spores.

### ASTRINGENTS

**Astringents** precipitate proteins when applied to damaged skin & mucous membranes and form a protective layer on the area to which they are applied.

**EX:** Potash alum { $KAl(SO_4)_2 \cdot 12H_2O$ }, Zinc sulphate ( $ZnSO_4$ ), Zinc chloride ( $ZnCl_2$ ).

**An astringent compounds shows following action:**

- **Styptic action:** Stopping of bleeding by constriction of small blood vessels.
- **Antimicrobial:** By precipitating superficial protein.
- **Antiperspirant:** By decreasing secretions (like sweat) by reducing pore size of the skin.
- **Anti-inflammatory:** By decreasing supply of blood to the tissues.

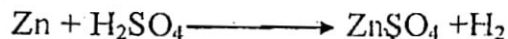
#### Zinc sulphate.

Mol. Formula:  $ZnSO_4 \cdot 7H_2O$

Synonym: **white vitrol**

#### Preparation:

It is prepared by boiling metallic zinc with dilute  $H_2SO_4$  until liberation of  $H_2O$  gas.



**Storage:** It is stored in well closed air tight container.

**Use:** Astringent, Germicidal

---

## CHAPTER - 11

### EMETICS

**Emetics:** are drugs that are used to induce vomiting or emesis, which results in the emptying of gastric contents through the oral cavity. Emetics are given in the case of ingestion of poisons.

**Ex:** Antimony potassium tatarate. Copper sulphate;

#### Antimony potassium tatarate :

**Synonym:** Tartar emetic

**Mol. Formula:**  $C_4H_4O_7SbK \cdot \frac{1}{2}H_2O$

#### Preparation

By boiling a solution of antimony trioxide & Potassium acid tartrate, the solutions filtered and evaporated to crystallization.



**Uses:** Used as an emetics

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## CHAPTER - 12

### BUFFERS

**BUFFERS:** A Solution which resists the change of PH value on the addition of a small of acid or base is called a buffer solution.

#### Classification (or) Types of Buffers Solutions

- **Acidic Buffer :** The solution containing a mixture of weak acid (ex. Acetic acid) and its salt (ex. Sodium acetate) is known as acidic buffer.
- **Basic Buffer:** The solution containing a mixture of weak base (ex. Ammonia) and its salt (ex: Ammonium chloride) is known as basic buffer.

#### Properties of Buffers Solution

- The pH of buffer solution is constant
- The pH of solution does not change on dilution.

## PHARMACEUTICAL CHEMISTRY-I

- The pH does not change even after addition of small quantity of acid or base.

### Buffer System in Pharmacy

- Hydrochloric acid buffer (pH 1.2 – 2.2 in 0.1 unit intervals)
- Acid Phthalate Buffer (pH 2.2 – 4.0 in 0.2 unit intervals)
- Neutralised Phthalate Buffer (pH 4.2 – 5.8 in 0.2 unit intervals)
- Phosphate Buffer (pH 5.8 – 8.0 in 0.2 unit intervals)
- Alkaline Borate Buffer (pH 8.0 – 10.0 in 0.2 unit intervals)

### Role of Buffer in Pharmacy

**a) Solubility:** pH plays an important role in solubility behavior of compounds. The required pH is adjusted by buffers.

**Ex:** Amines and alkaloids are soluble in acidic pH media but almost insoluble in alkaline pH media.

**b) Colour:** Colour of many dyes is pH dependent.

**Ex.** Red colour of cherry is maintained in acidic pH which becomes pale yellow to colourless in alkaline pH.

**c) Stability:** Ex. Ascorbic acid and penicillin are unstable in alkaline pH but stable acidic pH

**d) Patient comfort:** Injectables are irritating and may damage tissues, if their pH differs greatly from that of our body fluids pH.

---

## CHAPTER - 13

### QUALITY CONTROL

**Quality** of a product is the sum of all its properties and characteristics relating to its efficacy, safety and acceptability for meeting a specific therapeutic response.

**Quality control** includes inspections involved beginning with receipt of raw materials and continuing throughout the production and packaging operations, testing of finished products, documentation upto distribution.

### IMPORTANCE OF QUALITY CONTROL

- Assures purity and safety of medicines.
- Helps in preparing new drug applications and setting up of standards of drugs.
- It enables the machine settings, adjustment and modification processes and machinery.

- It helps to keep up the quality of the products during manufacturing by taking corrective steps.
- It also aids in locating and identifying the process faults and defects of products and helps to control scrap and wastes.
- It helps in continuous production of a quality product and better utilization of labour and materials.
- It may give idea to lower the cost of product, maintaining its quality.

---

## METHODS USED FOR QUALITY CONTROL

**A) ANALYTICAL CONTROL:** The Pharmacopoeas of the various countries prescribe 'Test of Purity' for the substance, so as to ensure their reasonable freedom from the undesirable impurities. Some of them are given below:

- Colour, odour and taste
- Physico-chemical constant: Determination of melting point, boiling point, refractive index, optical rotation.
- Spectral Data: Infrared(IR) absorption spectroscopy, Nuclear magnetic resonance(NMR) spectroscopy, Mass spectroscopy etc.
- Light Absorption: Measurement of light absorption in the visible and ultra-violet region.
- Viscosity, jell strength, swelling power
- Polymorphism and particle size
- Solubility
- Acidity, alkalinity, pH
- Humidity: Estimations of the moisture or humidity content of crude drug.
- Insoluble constituents: Pure substance gives a clear solution, whereas in the presence of insoluble impurities a turbidity may appear.
- Limit Test: Limit test for chloride, sulphate, iron etc.
- Assay: Titrimetric method, gravimetric method etc.
- Ash, water insoluble ash

**B) INSPECTION CONTROL:** The physical inspection of product of various intermediate stage. Ex. Packing line inspection.

**C) ENVIRONMENTAL CONTROL:** Microbiological monitoring of air and water to control the level of particulate and microbial matter in parenterals and sterile ophthalmic products.

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