MODEL ANSWER

SUMMER– 18 EXAMINATION

Subject Title: PHARMACEUTICAL CHEMISTRY-I **Subject Code:** 0806

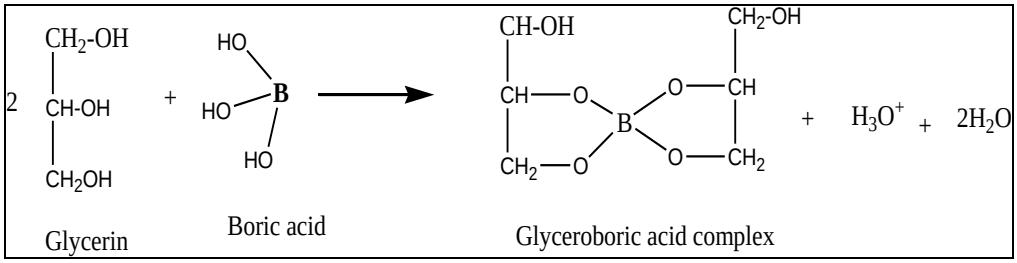
Important Instructions to examiners:

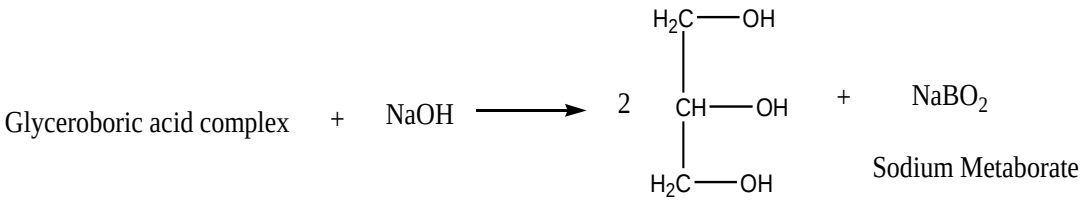
1) The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2) The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3) The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.
4) While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for anyequivalent figure drawn.
5) Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate's answers and model answer.
6) In case of some questions credit may be given by judgement on part of examiner of relevant answer based on candidate's understanding.
7) For programming language papers, credit may be given to any other program based on equivalent concept.

Q. No.	Sub Q.N.	Answer	Marking Scheme
1		**ATTEMPT ANY FIVE OF THE FOLLOWING.**	**20M (5x4)**
1	**a)**	**Define acid and base as per Arrhenius theory and write drawbacks of it.** Acid- "A Substance which when dissolved in water gives H^+ ions." e.g.- i) HCl $\longrightarrow$ $H^+ + Cl^-$ ii) $CH_3COOH \longrightarrow H^+ + CH_3COO^-$ Base- " A Substance which when dissolved in water gives OH^- ions" e.g.- i) NaOH $\longrightarrow$ $Na^+ + OH^-$ ii) $NH_4OH \longrightarrow NH_4^+ + OH^-$ **Drawbacks of Arrhenius theory-** 1) The definition of acid-base is only in terms of aqueous solution. 2) The theory does not explain acidic and basic properties of substance in non-aqueous solvents. 3) The neutralization of acid and base in absence of solvents is not explained. 4) The basic substances which do not contain hydroxide ion is not explained by theory.	**2 M def.** **2 M drawbacks**
1	**b)**	**Define Antioxidants. Explain its mechanism of action.** **Definition:** Antioxidants are the agents which inhibit oxidation and are commonly used to prevent rancidity of oil and fats or deterioration of other substances through oxidative process. **Mechanism of action-** The mechanism of action of inorganic type of antioxidants is the same as it is involved in redox chemical reaction.	**1M def.** **3M Mech.**

		• In a redox reaction, there is a transfer of electron from one compound to the other. • Since oxidation is the loss of electrons from chemical species and reduction is the gain of electrons the overall reaction can be shown as OX + e- → Red • The inorganic type of antioxidants basically acts as reducing agents. • When a substance acts as antioxidant (it being a reducing agent) it gets oxidized itself and prevents the oxidation of the active pharmaceutical species. • If the active constituent is already oxidized, the antioxidant reduces it back to its original oxidation state. • Inert gas like nitrogen displaces the oxygen in container & prevents oxidation.	
1	**c)**	**Explain mechanism of action of Antimicrobial agents.** **Mechanism of action of topical antimicrobial agents-** Inorganic compounds generally exhibit antimicrobial action by any of the three mechanisms viz. **(i) Oxidation** **(ii) Halogenation** **(iii) Protein binding or precipitation.** **1. Oxidation:** Compounds acting by this mechanism belong to class of peroxide, peroxyacids, Oxygen liberating compounds like permanganate and certain Oxo-halogen anions. Microorganisms require protein for their growth. Various reducing groups are present in proteins which are oxidized by oxidizing agents. They act on proteins containing sulfhydryl group and oxidize free sulfhydryl to Disulphide bond and inactivate its function. Hence change in molecular shape of protein leads to destruction of protein. e.g. Hydrogen peroxide, Potassium permanganate, non-metals act by this mechanism. **2. Halogenation:** Proteins are made up of different amino acids and it contains peptide linkage or peptide chain. Some antimicrobial agents like hypochlorite's or compounds containing or liberating chlorine or iodine cause chlorination or iodination at peptide linkage of primary &	**4 M.**

		secondary structures present in protein, leading to change in molecular shape of protein, and destruction of protein. E.g. Iodine & iodine preparations, Chlorinated lime, Sodium Hypochlorite **3. Protein Precipitation:** Protein structure contains many polar groups & groups having lone pair of electrons. Some antimicrobial agents containing metal ions form complexes with polar groups or groups having lone pair of electrons leading to precipitation of enzyme proteins. e.g. Silver nitrate, Mild silver protein, Mercury & Mercury compounds like Yellow Mercuric oxide, Ammoniated mercury, Boric acid, Borax, IB, IIB group metals- Cu(II), Ag(I), Zn(II), Hg(II) etc.	
1	**d)**	**Write reactions involved in Assay of boric acid with glycerine.**	**4 M**





Net reaction:

Glycerine

H_3BO_3 + NaOH ----------→ $NaBO_2$ + $2H_2O$

1	e)	**Define and classify antacids with examples.** **Definition**- Antacids are the substances which are weak bases and on ingestion react with the gastric acid, neutralize the excess of HCl and lower the acidity of gastric contents. **Classification of antacids is as follows**: A) Systemic/ Absorbable antacids- Sodium Bicarbonate B) Non systemic/ Non absorbable antacids: • Aluminium containing antacids- Aluminium Hydroxide, Aluminium Phosphate, Basic aluminium carbonate • Calcium containing antacids- Calcium carbonate, Calcium Phosphate • Magnesium containing antacids- Magnesium carbonate, Magnesium oxide, Magnesium hydroxide, Magnesium trisilicate C) Combination antacids- Aluminium Hydroxide and Magnesium hydroxide, Aluminium Hydroxide gel and Magnesium trisilicate.	**1 M def. classify 3M**
1	f)	**Write different allotropic forms of sulphur and give the properties and uses of precipitate sulphur.** **Allotropic forms of sulphur:** 1. Rhombic (α sulphur) 2. Monoclinic (β sulphur) 3. Liquid (λ sulphur) 4. Plastic sulphur 5. Amorphous sulphur **Properties –** 1) It is a pale greyish, yellowish or pale yellow soft powder free from grittiness. 2) It has no odour and taste. 3) Insoluble in water and alcohol but dissolves in carbon disulphide. 4) When heated it burns with blue flame. 5) Microscopical appearance show that it consists of amorphous particles without crystals.	**2 M allotropes** **1M Prop.** **1M Use**

		Uses – 1) It is used in ointment form as Scabicide. 2) It is used in treatment of Seborrhoea. 3) It also acts as kerotolytic agent.	
1	**g)**	**Define topical agents and classify with examples.** **Topical agents** are the compounds that act locally on skin or mucous membrane, their action is of different types depending upon the nature of compound and its chemical properties and they mainly act by mechanical or physical mechanism. The compounds have very less distinct pharmacological properties as they are not absorbed in systemic circulation. **Classification of topical agents:** Topical agents are classified according to their main action. 1) Protective : Ex: Zinc stearate, Zinc oxide 2) Adsorbent and demulcents: Ex: Talc, Silicone polymer, Titanium Dioxide, Calamine 3) Antimicrobial agents: It acts by Oxidation, Halogenation and Protein precipitation mechanism. Ex: Hydrogen peroxide, Potassium permanganate, Chlorinated lime, Iodine and its preparation, Boric acid, Borax and Silver nitrate. 4) Astringent: These compounds bring about mild protein precipitation. Ex: Alum, Zinc chloride, Zinc sulphate 5) Miscellaneous compounds. These compounds mainly contain Sulphur and Sulphur compounds. It is topically used as antibacterial. It also acts as fungicide, parasiticide, and in the treatment of various skin diseases. Ex: Sulphur Ointment, Selenium Sulphide	**1 M def. 3M classify**

1	h)	**Define Astringents. Discuss their uses.** **Definition**-Astringents are the agents which cause local or surface or mild protein precipitation when applied to damaged skin or mucus membrane. This action may be on mucosal membrane when taken internally or on skin for topical use. Astringents when applied topically cause precipitation of protein of surface cell by coagulation. The action depends upon the extent of penetration of agent and the type of chemical action resulting with protein. In general, astringents compounds have the following uses:- • It causes constriction of small blood capillaries, and promotes the coagulation of blood hence used as styptic (able to stop bleeding). • It decreases the volume of exudate from wounds & skin eruption & thus can be used in acne &pimples. • Astringent causes constriction of skin pores & destroy body odor, hence used as an antiperspirant & deodorant. • Higher concentration of astringent is used to remove warts (extra growth of cell on skin). • It promotes healing and toughens the skin. • It restricts blood flow to the surface of mucous membrane hence astringent decreases inflammation.	**1M def. 3M classify**
2		**Attempt any <u>THREE</u> of the following.**	**12M (3x4)**
2	a)	**Define the term Achlorhydria and write synonym, chemical formula, properties and uses of Muriatic acid.** **Definition of Achlorhydria :-** When due to some reasons, there is no secretion of Hydrochloric acid in gastric secretion; the condition is called as achlorhydria. **Synonym-** Hydrochloric Acid, spirits of salt, acidum hydrochloricum.	**1M def. 0.5M syn. 0.5M formul**

		Chemical Formula- HCl **Properties of HCl -** • It occurs as a colourless fuming liquid with pungent odour. • It is miscible with water, alcohol & has a specific gravity of 1.18. • It is a strong acid & attacks metals forming their hydrochlorides with the evolution of hydrogen gas. • It gets oxidized by strong oxidizing agents liberating chlorine gas. **Uses of HCl-** • The dilute hydrochloric acid is used as acidifying agent. • It is also used as a solvent in numerous industries. • Also used as laboratory reagent.	**a** **1M** **prop.** **1M** **uses**
2	**b)**	**Write mechanism action of osmotic laxatives. Classify cathartics with examples.** **Osmotic laxatives-** These are the agents that increase fluidity of intestinal contents by retention of water by osmotic forces and indirectly increase motor activity. They act by increasing osmotic load of GIT. They are salts of poorly soluble anions and sometimes cations. Ingestion of osmotic laxatives results in the hypertonic condition. The body relieves the hyper tonicity of gut by secreting additional fluid into intestinal tract. The resulting increased bulk stimulates peristalsis. The cathartics can be considered under the following class, 1**. Mild purgatives or laxatives:** Drugs included in this group are: a) Bulk –producing drugs: They promote evacuation by increasing the stools bulk-volume & water contents e.g. Isapgol, methylcellulose, sodium carboxy methyl cellulose & karaya gum. b) Stool softeners (Emollient): They penetrate, lubricate & soften the stool e.g. Di-octyl sodium sulphosuccinate, liquid paraffin. **2. Strong Purgatives**: There are two kinds of strong purgatives: a) Irritant or stimulant purgatives e.g. Phenolphthalein, Senna glycosides, aloe, cascara, rhubarb extract, castor oil, bisacodyl.	**1 M** **mech.** **3M** **classify**

		b) Saline cathartics/Purgatives (osmatic laxatives) these are further sub classified as under: i) Sodium-containing products e.g. Sodium biphosphate, sodium phosphate, Potassium sodium tartrate. ii) Magnesium-containing product e.g. magnesium hydroxide, magnesium citrate, Magnesium sulphate iii) Sulphur as cathartic iv) Non official cathartics e.g. sodium sulphate , potassium phosphate, Potassium tartrate, calomel.	
2	**c)**	**Give reasons why combination antacids are required with examples.** **Reasons**- Because no single antacid meets all the criteria for an ideal antacid several products are in the market containing mixtures of antacids. Most of these combination products are an attempt to- 1-Balance the constipative effect of calcium & aluminium with the laxative effect of magnesium. 2-Someof these products are also a mixture of an antacid with rapid onset of action and one with a longer duration of action. 3- In another type the antacids are combined with simethicone type of compounds which has antiflatulent action as they are antifoaming agents & causes dispersion of gases. **Some preparations are mixtures of two antacids are as follows:** 1.**Aluminium hydroxide gel and Magnesium hydroxide combinations:** The USP prescribes two dosage forms suspensions & tablets. **A) Suspensions:** Alumina& magnesia oral suspension Magnesia & alumina oral suspension. **B) Tablets:** Alumina & magnesia tablets. Magnesia & alumina tablets. **2.Aluminium hydroxide and Magnesium trisilicate combinations**: **3.Calcium carbonate containing antacid mixture**:	**4 M**

		4.Algenic acid-Sodium bicarbonate combination: It provides symptomatic relief of reflux esophagitis **5.Magaldrate**: It is a hydrated magnesium aluminate .It is a chemical combination of magnesium hydroxide & aluminium hydroxide. **6.Aluminium hydroxide gel and Kaolin combinations** Kaolin as adsorbent property so can be combined with aluminium hydroxide gel.	
2	**d)**	**List official preparations of buffers and write its roles in pharmacy.** **Official preparations of buffer-** • Hydrochloric acid buffer (PH 1.2-2.2) • Acid Phthalate buffer (PH 2.2-4.0) • Neutralized phthalate buffer (PH 4.2-5.8) • Phosphate buffer (PH 5.8-8.0) • Alkaline borate buffer (PH 8.0-10.0) **Role of buffer in pharmacy:** 1. Citric acid is used for stabilizing milk of magnesia. 2. Adrenaline is rapidly oxidized by dissolved oxygen to adrenochrome in an alkaline media. Hence its pH is stabilized by using a buffer of pH range 2.5 to 3.0 3. Penicillin preparations are stabilized by addition of calcium carbonate, sodium citrate or aluminium hydroxide. 4. Sulfonamide preparations are stabilized by $NaHCO_3$, sodium acetate or sodium citrate. 5. Colour of many natural dyes, present in fluid extracts or of certain synthetic drugs has been found to be pH dependent. E.g. red colour of cherry & raspberry syrups has been maintained at acidic pH which becomes pale yellow to nearly colourless at alkaline pH. 6. For patient comfort. E.g. injectable & preparations for internal or external use become irritating if their pH is different greatly from that for the particular tissues involved. An extremely acid or alkaline pH must be avoided because of tissue damage. 7. Optimum pH conditions for activity of medicinal compounds have to be maintained. E.g.	**2 M official prep. 2M role**

		buffering methenamine with phosphate buffer.	
2	**e)**	**Define 'volume Strength' and calculate volume strength of 20%W/V H_2O_2 solution.** **Definition**- Is the volume of oxygen gas obtained upon complete decomposition of one volume (ml) of hydrogen peroxide solution at normal temperature and pressure. **Calculation-** $2H_2O_2 \longrightarrow 2H_2O+O_2$ Hence 68 gm. of H_2O_2 gives 32 gm. of O_2= 22.4 litres of O_2 at NTP Hence 1gm of H_2O_2 will give 22400/68 ml of O_2= 329.4ml of O_2 Let concentration of H_2O_2=Y=20%W/V 1 ml undiluted H_2O_2 contains Y/100=20/100 gm. of O_2 = 0.2 gm. Hence Volume strength of H_2O_2= 329.41 × Y/100 = 329.41×0.2 =65.88 Therefore Volume strength of 20%W/V H_2O_2= 65.88V	**1M def. 3M cal.**

3		**Attempt any THREE of the following:**	**12M (3X4)**
3	**a)**	**Define following terms with examples.(any four)** i) Internal protectives and absorbents ii) Desensitizing agents iii) Respiratory stimulants iv) Buffers v) Inhalants vi) Expectorants **i) Internal protective and absorbents:** Internal protective-adsorbents are agents which adsorb bacteria, toxins and viruses in addition to forming protective covering over the intestinal mucosa. Internal protectives and adsorbents are used in the treatment of diarrhea.Ex. Bismuth Sub carbonate, Kaolin **ii) Desensitizing agents:** Desensitising agents are the compounds used in treatment of sensitive tooth. Sometimes teeth become sensitive to hot & cold. During teeth decay or in tooth ache, the perception to hot & cold is felt strongly. Some desensitizing agents are incorporated in dental preparations to reduce the sensitivity of teeth to hot & cold. The numbing effect is of short duration like that of local anaesthetic effect. Ex.-Strontium chloride, Zinc chloride **iii) Respiratory stimulants**: The substances which increase the rate of respiration are called as Respiratory stimulants. OR Respiratory stimulants increase Pulmonary ventilation by their effect on depth and rate of respiration by stimulating respiratory center in the medulla. Examples- Gaseous ammonia, Dilute Ammonia solution, Ammonium carbonate etc. **iv) Buffers:** Buffers are solutions or systems that resist a sudden change in pH upon addition of small quantities of acids and bases. Ex. Hydrochloric acid buffer, acid phthalate buffers, neutralized phthalate buffers, phosphate buffer, alkaline borate buffer	**1 M each**

		v) Inhalants: Inhalants are gaseous substances directly administered by nasal or respiratory route for its local or systemic effect. OR Inhalants are drugs or chemicals which in vapor form are inhaled by nasal or respiratory route in the body. Ex. Oxygen, Carbon dioxide, Nitrous oxide. **vi) Expectorants:** The drugs that remove sputum from the respiratory tract. These drugs either increase the fluidity of sputum or increase the volume of fluids that are to be expelled from the respiratory tract by coughing. Expectorants are used orally to stimulate the flow of respiratory tract secretions. Ex**.** Potassium iodide, Ammonium chloride, Antimony potassium tartrate	
3	**b)**	**Write biological role of oxygen or carbon dioxide**. **Role of oxygen:** • Oxygen is important for the living cells. • It is necessary for normal oxidative metabolic process in cell for the production of energy, to synthesize Adenosine Triphosphate (ATP). • When ATP is hydrolyzed, energy is released. • Transport of oxygen (after it has been inhaled) is carried by hemoglobin, a constituent of blood. • Concentration of hemoglobin in blood is important in transport mechanism. • Oxygen combines with hemoglobin reversibly as shown below:- • $Hb + 0_2 \rightarrow Hb0_2$ where in Hb = deoxyhemoglobin and $Hb0_2$ = oxyhemoglobin • This loose combination readily dissociates and releases oxygen in the medium of cell. • Number of factors affects the formation and dissociation of oxyhemoglobin. • These include temperature, electrolytes, effect of carbondioxide, carbon-monoxide, pH etc.	**4M**

		• Under physiological conditions, the action of electrolyte and CO_2 on the liberation of oxygen from oxyhemoglobin is important. **Role of carbon dioxide:** • Carbon dioxide plays an important role in maintaining acid base balance of the body. • It is readily absorbed and transported by blood both in the cells and in the plasma. • It is also produced in the body during the metabolic process. A large quantity of the carbon dioxide produced is eliminated by lungs in the expired air. • A large quantity of the carbon dioxide cannot remain in the dissolved from in plasma it exist in three major forms: o As carbonic acid after the combination with water. o As a carbamino bound forms in which it combines with proteins, again mainly with haemoglobin. o Carried as bicarbonate in combination with other cations. • In utilization of carbon dioxide under normal physiological conditions, the pH of blood is maintained via carbonic acid formation, its conversion into bicarbonate ions etc. It is seen that increase in bicarbonate ions results in increase in pH of body fluids while increase in carbon dioxide levels via carbonic acid decreases it. Both effects are counter balanced by excretion process.	
3	**c)**	**Define and classify dental products with examples.** The products which are used in cleaning, polishing, treating dental caries, desensitizing, or for any dental infection are called as dental products. They are also known as dentifrices. Classification : 1.Anticaries agents: Dental caries is a disease of teeth caused by acids formed by action of microorganism on carbohydrate and it is characterized by decalcification of tooth and foul mouth odour. Ex. Sodium fluoride, Stannous fluoride 2. Cleaning agents: It helps to remove stains from teeth and gives abrasiveness. Ex. Calcium phosphate dibasic ,sodium metaphosphate	**1 M def. 3M classify**

		3. Polishing agents: It gives whiteness to the teeth. Ex. Calcium carbonate, Calcium pyrophosphate 4. Desensitizing agents: It reduces the sensitivity of teeth to heat and cold. Ex. Zinc chloride, Strontium chloride	
3	**d)**	**What is slaked lime? Give its properties, uses and molecular formula?** **Slaked lime is a calcium hydroxide.** **Properties:** 1) It is a soft white powder, with an alkaline & slightly bitter taste. 2) It is very slightly soluble in water, less in boiling water, soluble in glycerin but insoluble in alcohol. 3) Its solutions are basic in nature & can neutralize acids to form salts. 4) It readily absorbs water from air forming calcium carbonate. **Uses:** 1.It is used as an antacid and astringent. 2. It is also used in the preparation of some skin lotions and oily preparations to form calcium soaps of fatty acids in various oils. 3.Calcium hydroxide solution is used as an antidote **Molecular formula:** $Ca(OH)_2$	**1M each**
3	**e)**	**Write advantages of povidone iodine over other iodine preparations and write properties and uses of povidone iodine.** **The advantages of povidone iodine over other iodine solutions are as follows:** 1. It has non-irritating effects on tissue. 2. It has comparatively low oral toxicity. 3. It is water soluble. 4. It has low iodine vapour pressure making it stable to possible iodine loss. 5. Solutions of the complex are also non-staining and can be washed clear from skin and clothing. **Povidone – iodine:** **Properties:** 1.The complex is a yellowish brown amorphous powder,	**2M advat.** **1M prop.** **1M use**

		2. It has a slight characteristic odour of iodine. 3. It is soluble in water and in alcohol, practically insoluble in organic solvents like acetone, chloroform etc. **Uses:** 1. Povidone -iodine is a broad spectrum antiseptic for topical application in the treatment and prevention of infection in wounds. 2. It is used in first aid for minor cuts and burns. 3. It has been used in gargles and mouth washes for the treatment of infections in the oral cavity. 4. It is used as a surgical scrub for pre and post-operative skin cleansing 5. It is used in gynaecology for vaginitis associated with candidal, trichomonal infection.	
4		**Attempt any THREE of the following:**	**12M (3X4)**
4	**a)**	**Write synonyms of following (any four)** i) Calcium carbonate : Precipitated chalk ii) Sodium hydroxide: Caustic soda iii) Talc: Talcum, French chalk, Purified talc iv) Boric acid: Boracic acid, Orthoboric acid, v) Aqueous iodine solution: Lugol's solution vi) Magnesium sulphate: Epsom salt	**1M each**
4	**b)**	**Write properties and uses of alum**. **Properties:** 1. It occurs as colourless, transparent or granular crystals with a sweet astringent taste. 2. When heated slowly it melts in its water of crystallization. 3. At 200°, it loses its water of crystallization and becomes anhydrous. 4. It is soluble in water but insoluble in alcohol.	**2 M each**

		Uses: 1. It is used as a topical astringent. 2. Its 0.5 to 5% solution is useful as an antiseptic and commonly used for local styptic action. 3. Alum either as a solid or as a solution is used as a haemostatic for superficial abrasions, cut an ulcers. 4. Its dilute solutions have been used as mouth-washes or gargles, but their high acidity may damage the teeth.	
4	**c)**	**Write chemical formulae for following (any four)** i) Chlorinated lime- $Ca(OCl)Cl.H_2O$ ii) Borax- $Na_2B_4O_7.10H_2O$ iii) Antimony potassium tartrate- $C_4H_4KO_7Sb$ iv) Sodium potassium tartrate- $C_4H_4O_6NaK.4H_2O$ v) Sodium thiosulphate- $Na_2S_2O_3.5H_2O$ vi) Hypophosphorus acid- HPH_2O_2	**1M each**
4	**d)**	**Explain mechanism action of sodium thiosulphate and sodium nitrite in cyanide poisoning.** 1. Cyanide ion has a high affinity for ferric ions & hence it readily combines with it. 2. Thus, cyanide poisons by combining with the ferric ion of cytochrome oxidase which stops electron transfer chain & thereby stops cellular respiration or oxidation-reduction reactions. 3. Cyanide poisoning is treated by a combination of sodium nitrite & sodium thiosulphate. 4. Injection of sodium nitrite causes the oxidation of the ferrous ion of haemoglobin to the ferric ion of methaemoglobin, which then combines with the serum cyanide that has not yet entered the cells. 5. Following the sodium nitrite injection, a slow intravenous infusion of sodium thiosulfate is given. 6. The thiosulfate anion, catalyzed by the enzyme rhodanese present in the blood reacts	**4M**

		with cyanide ion to form the relatively non-toxic thiocyanate ion which is excreted in the urine.	
4	**e)**	**Write storage and labelling condition of sulphur dioxide and oxygen gases.** **Sulphur dioxide: Storage and labelling:** Store in a cool, well-ventilated place. Store and use with adequate ventilation. Store only where temperature will not exceed 125°F (52°C). Firmly secure containers upright to keep them from falling or being knocked over. Install valve protection cap, if provided, firmly in place by hand. Store full and empty containers separately. **Oxygen: Storage and labelling:** Store under compression in metal cylinder. Valve should not be lubricated with oil or grease. Cylinder should be stored in a special room which should be cool and free from inflammable materials. The shoulder of the metal cylinder is painted WHITE and the remainder is painted BLACK. The name of the gas or symbol "O_2" is stencilled in paint on the shoulder.	**2 M each**
5		**ATTEMPT ANY <u>THREE</u> OF THE FOLLOWING**.	**12M (3X4)**
5	**a)**	**Write four sources of impurities in the pharmaceuticals with examples** **Sources of Impurities:** 1. Raw material 2. Reagents used in manufacturing process 3. Intermediate products in manufacturing process 4. Defects in manufacturing process/ manufacturing hazards 5. Solvents 6. Action of solvent and reagents on reaction vessel 7. Atmospheric contamination during manufacturing process 8. Defective storage of final products 9. Adulteration **Raw Materials-** When substances or chemicals are manufactured; the raw materials from	**1M each**

which these are prepared may contain impurities which get incorporated into final product. Example- sodium chloride prepared from rock salt contains traces of Ca & Mg compounds.

2. Reagents used in manufacturing process: Synthesis of drugs involves many chemical reactions like nitration, halogenation, oxidation and hydrolysis. Different chemicals & solvents are used in these chemical processes. When chemical reactions are carried out in reaction vessel, the material of these vessels (Iron, tin, copper, aluminium etc.) is reacted upon by the solvents, chemicals & reaction products are formed. These reaction products then occur as impurities in the final product. Thus impurities of iron, lead, and heavy metals, copper are due to the above mentioned reasons.

3. Defects in the manufacturing process: Defects such as imperfect mixing, incompleteness of reaction, non-adherence to proper temperature, pressure, pH or reaction condition etc. may result in the production of chemical compounds with impurities in them.

4. Storage condition- The chemical when prepared is stored in different types of containers. Various types of materials are used for storage purpose. Reaction of substance with material of the storage vessel may take place. The reaction may take place directly or leaching out effect on the storage vessel. This acts as impurity. Also, rodents & insects may add impurities to the products.

5. Solvents: Water is the solvent easily available & cheap and is used in the manufacture of inorganic chemicals. This can give rise to trace impurities such as sodium, calcium, magnesium, carbonate & sulphate ions.

6. Decomposition- Decomposition is caused by light, air, oxygen & causes contamination of final product. A number of organic substances get spoiled because of decomposition on exposure to the atmosphere. E.g. amines, phenol, potent drugs.

7. Atmospheric contaminants: Atmospheric contamination may take place through dust, sulphur dioxide, hydrogen sulphide & arsenic. Carbon dioxide & water vapour are possible contaminants of substances which are affected by their action.

OR

1) Raw materials used in manufacturing – Traces of impurities in raw materials may be carried to contaminate the final product. Example – NaCl prepared from the rock salt will

almost certainly contain traces of Ca & Mg compounds.

2) **Processes used in the manufacturing** – Some impurities are incorporated during the manufacturing process. This may occur due to –

a) Reagents used in the process

b) Reagents added to remove the other impurities.

c) Solvents – Water is the cheapest solvent available and widely used. Tap water has chloride ions, carbonate ions, sulphate ions, calcium ions, magnesium ions and sodium ions as impurities in very small amounts.

d) The intermediate products may come along the process in the final product as impurity.

3) Material of the plant – The vessel used in the manufacturing process is generally made of metal like iron, copper, zinc, nickel, Aluminum and steel. Due to solvent action on the plant material, the traces of material i.e impurities come in the product. The water pipe and steam pipe may contain lead and hence Pharmacopoeias prescribe limit test for Lead.

4) Storage conditions –

a) Filth- Stored product may become contaminated with dust, insects and insect excreta.

b) Decomposition of the product during storage – Many chemical substances undergoes changes and decomposition due to careless storage. E.g. – Ferrous Sulphate is slowly converted into insoluble ferric oxide by air and moisture.

5) Accidental substitution or deliberate adulteration – Accidental substitution can take place if toxic substances are stocked with other substances or compounds. Some pharmaceutical products may be adulterated with cheaper substances. Example – Honey may be adulterated with commercial sugar, acacia powder with clay and potassium bromide

with sodium bromide.

6) Manufacturing Hazards – Even in well run manufacturing companies, product contamination may arise due to existence of certain hazards.

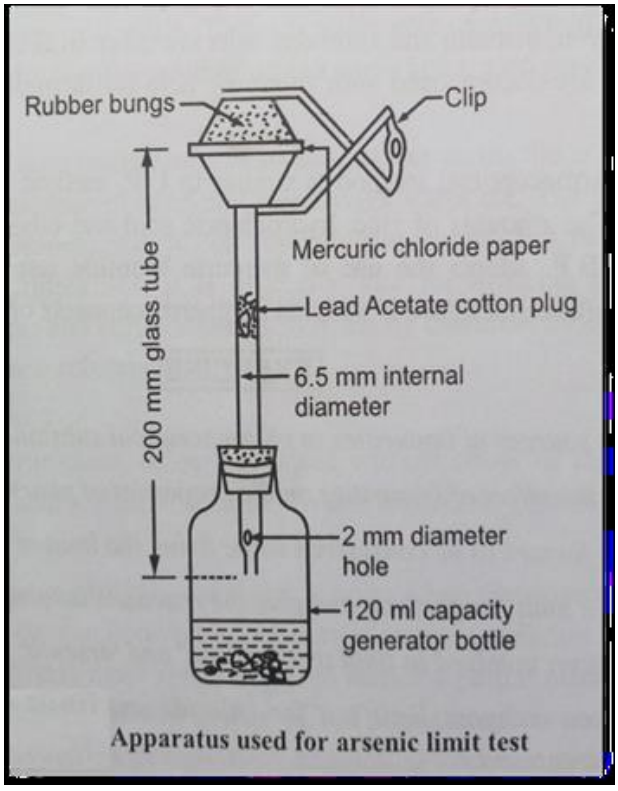
a) Particulate contamination – accidental inclusion of dirt, glass, porcelain, Metallic or plastic fragment from sieves, granulating, tableting and filling machines or even from product containers may occur.

b) Process error – Gross errors due to incomplete mixing in liquid preparations must be detected by normal analytical procedures.

c) Cross contamination – the handling of powders, granules and tablets in large quantity create considerable amount of airborne dust and may lead to cross contamination.

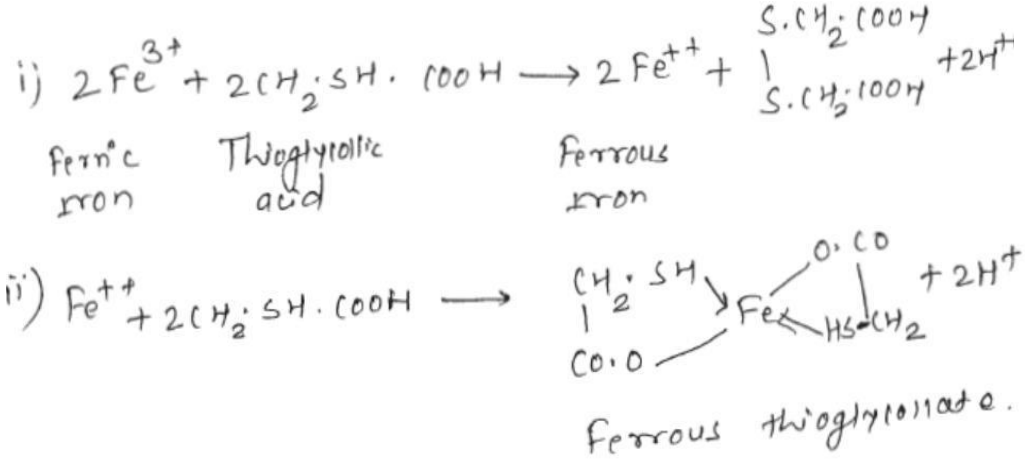
d) Microbial contamination – liquid preparations and creams for topical application are prone to bacterial, fungal and mould contamination. Special care should be taken in parenteral and ophthalmic preparation to avoid microbial contamination.

7) Packaging errors – products of similar appearance as tablets of same size, color and shape packed in similar containers may lead to mislabeling.

5	b)	**Draw well-labelled diagram of Gutzeit apparatus.** Apparatus used for limit test for Arsenic - **Gutzeit Apparatus.** Diagram-  Apparatus used for arsenic limit test	**4M**

5	c)	**Write importance of quality control and quality assurance in Pharmacy.** **Importance of Quality Control:** • The term Quality control has assumed lots of importance in pharmaceutical field. • There cannot be any compromise in this regard & one cannot think of any second quality in drugs and pharmaceuticals. • Presence of very small quantities (even few parts per million) of toxic impurities such as arsenic in drugs and pharmaceuticals can be very harmful to patient. • As drugs and pharmaceuticals are used in the treatment of diseases, therefore it is very important to maintain their quality, hence quality control becomes vital for drugs and pharmaceuticals. • Standard for drugs and methods of quality control are monographed in pharmacopoeias which are official publications made in various countries under the authorities of respective governments. • The basis of maintaining the quality of products could be seen through the following good manufacturing practices. • Since it is necessary that a good quality product should be available to the doctors to treat patients or for the users; the responsibility of pharmacist and those of pharmaceutical industry has increased considerably. • The term quality as applied to drugs and drug products include all those factors which contribute directly or indirectly to the safety, effectiveness and reliability of product. • In order to have the above referred properties in a drug it is necessary to have quality control. • To achieve Quality control a concept of total quality control is to be followed. • Total quality control will include all those aspects starting with procurement of raw material to the finished product available at the drug store and till it is consumed by the customer. • Thus, it will include not only parameters of GMP but also the storage, handling and preserving the sample till ultimate use. • The quality set for a drug is after consideration recommendations of various experts	**2 M each**

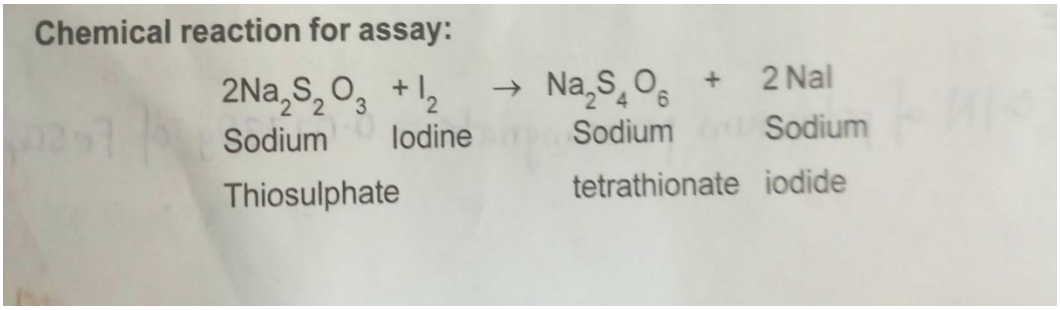
		bodies. • Various tests and procedures for analysis including finding and determining impurities are laid down in the official books. This applies both to the drugs as raw material as well in the form of finished products. **Importance of quality assurance:** • It is the responsibility of an organisation to assure that systems, facilities and written procedures are adequate and followed in order to ensure that products are controlled and will meet, in the final dosage forms, all the applicable specifications. • Prime responsibility of maintaining product quality during production tests with the manufacturing department. A systematic and effective quality assurance programme considers the variables for and includes testing for raw materials, in process, packaging material labelling and finished product.it also includes batch auditing and stability monitoring. • Quality assurance personnel must establish control or check points to monitor the quality of the product as it is processed and upon completion of manufacture. Quality assurance thus becomes a managerial function of the company, especially of high management, often coupled by auditing operations, to determine that procedures and systems are suitable for the production of completed dosage forms of the right quality. • The important parts of a quality assurance programme are: • Raw material control-the raw material used for production includes - active or therapeutic materials and inactive or inert materials.	
5	**d)**	**Write principle and reaction involved in limit test for iron.** **Limit test for Iron- Principle** • Limit test for iron depends upon the interaction of thioglycolic acid with iron in the presence of citric acid and in the ammonical alkaline medium. • This results in the formation of purple colored ferrous thioglycolate complex. • The limit test of iron is carried out in two Nessler's Cylinders, one for the Test and other for standard. The intensity of purple colour produced in the two is compared	**1 M each**

		by viewing vertically downwards. If the intensity of colour is more in the test sample than in the standard, it means that the sample contains more quantity of iron impurity than the permissible limit and hence sample is declared as not of standard quality. **Reaction:**  **Role of Thioglycolic acid-** 1. Iron impurity may be present in trivalent ferric form or in the divalent ferrous form. If it is in ferric form thioglycolic acid converts ferric form of impurity into ferrous form. 2. It produces purple colored ferrous thioglycolate complex by acting as complexing agent. **Role of Citric acid**- To prevent precipitation of iron (ferrous) with ammonia by forming ammonium citrate buffer. **Role of Ammonia**- To maintain alkaline condition.	
5	**e)**	**Write principle and reaction involved in assay of Iodine or Ferrous sulphate.** **Principle for assay of Iodine**:- Assay of iodine is based upon iodimetry (Redox) type of titration in which standard solution of iodine is used. Iodine is slightly soluble in water, it made soluble by adding potassium iodide, which forms polyiodides (KI_3). Free iodine acts as oxidizing agent; the solution is titrated against the standard solution of reducing agent, sodium thiosulphate	**2 M princi. 2M reactio n**

using starch solution as an indicator, which is added towards the end of titration. The end point is determined by colour change from blue to colourless.

These titration involve the titration of free iodine with standard sodium thiosulphate.

Reaction for assay of Iodine



Principle involved in assay of ferrous sulphate

Principle:-

Assay of ferrous sulphate depends upon oxidation-reduction type of titration where Fe^{2+} (Ferrous ions) are readily oxidized by potassium permanganate in acidic solution (H_2SO_4) in to Fe^{3+}(ferric ion). Thus ferrous sulphate acts as a reducing agent and potassium permanganate acts as an oxidising agent. The ability of potassium permanganate solution to oxidize ferrous ion is due to conversion of the MnO_4^- ion to Mn^{++} in acidic solution. Solutions containing MnO_4^- ion are purple in colour , solution of salt containing Mn^{++} ions are colourless, hence potassium permanganate in acidic solution acts as a self-indicator.

Reaction:-

$$10\ FeSO_4 + 8H_2SO_4 + 2KMNO_4 \rightarrow 5Fe_2(SO_4)_3 + 2MNSO_4 + K_2SO_4 + 8H_2O$$

$$MnO_4 + 8H^+ + 5e^- \longrightarrow Mn^{+2} + 4H_2O$$

$$Fe^{2+} \rightarrow Fe^{3+} + e^-$$

6		**Attempt any <u>THREE</u> of the following.**	**12M (3X4)**
6	**a)**	**Write acid-base balance of the body.** The acid base balance in the body is well regulated by intricate mechanism. Number of chemical reactions takes place in the cell and the activity of cell and the reactions occurring inside is greatly influenced by pH or hydrogen ion concentration. Acids are being constantly produced in process of metabolism. E.g. carbonic acid, lactic acid. Acids or alkalis produced in the body may cause change in PH Most of metabolic reactions occur between PH 7.38-7.42. Increase in acidity of body fluid & tissues means (PH < 7.38) is called as acidosis and increase in alkali reserve in blood & body fluid (PH > 7.38) is called as alkalosis. Required pH (7.38-7.42) of plasma is maintained by **1. Buffer mechanism** Three major system of buffering system occurring in the body are a) HCO_3^-/ H_2CO_3 buffer found in plasma & kidney b) HPO_4^{-2}/ H_2PO_4 buffer present in cells & kidney c) Protein or buffer system Proteins are composed of amino acids bound together by peptide linkage. However some amino acids like histidine have free acidic group which on dissociation from base and H^+ which participate in buffering of the body fluid. **2. Respiratory mechanism** The other important pH control is through the control of respiratory centre. When this is stimulated it alters the rate of breathing. Through the rate, the removal of CO_2 from body fluid leads to the changes in pH of blood. Retention of CO_2 in the body due to decrease in ventilation as a result of mechanical/muscular impairment, lung disease, pneumonia, CNS depression due to narcotic drugs, CHF etc. induces respiratory acidosis This can be overcome by renal mechanism by i) Increase in acid excretion by Na^+-H^+ exchange ii) Increase in ammonia (NH_3) formation	**4 M**

		iii) Increase in reabsorption of HCO_3^- (bicarbonate) In respiratory alkalosis there is excess loss of CO_2 from body due to over breathing or hyperventilation as a result of emotional factor, fever, hypoxia, loss of appetite, salicylate poisoning etc. This can be overcome by renal mechanism by i) Increase in bicarbonate (HCO_3^-) excretion ii) Decrease in ammonia (NH_3) formation iii) Decrease in reabsorption of HCO_3^- (bicarbonate) **3. Renal mechanism** The third mechanism is via elimination of some ions through urine by kidney. Absorption of certain ions and elimination of other control the acid-base balance of blood and thus of body fluids.	
6	**b)**	**Explain biological effect of radiation on Human body.** **Biological effect of Radiation** The effect of radiation upon biological tissue depends upon a number of factors such as: -Ability of the radiation to penetrate tissue. -The energy of Radiation -The kind of Tissue -Surface area of the tissue exposed -Dose rate of the Radiation • The radiation interacts with the molecules present in the tissue & forms abnormal chemical species like ions &/or free radicals. • These ions or free radicals can alter the local PH in the tissue & initiate the undesirable free radical chain reactions, producing peroxides & other compounds toxic to the tissue. This may lead to necrosis & ultimately destroy the tissue or organ. • Water molecules in the tissue are the most probable reactive species in the path of ionizing radiation. Other Free Radicals & Hydrogen peroxidases also formed.	**4 M**

		$\times H_2O \rightarrow \times H + \times HO$ $\downarrow \quad \downarrow$ $yH_2 \quad yH_2O_2$ • Free radicals formed from water can also abstract radicals from other molecules & produce various toxic species which can alter the DNA in cells & cause cross linking between certain amino acids in proteins. • Thus the particular tissue gets destroyed. • Alpha particles also have a potential to produce a tremendous amount of ionization or free radicals but the range & penetration of these particles are very slight. Therefore, the isotopes emitting alpha particles must be close enough to the individual for the radiation to reach the skin, in order to get observable effects. • Gamma rays have relatively low ionizing power, even though the range & penetrating power of this type of radiation are high enough to produce significant damage in the particular tissue at distances of several metres from the source.	
6	**c)**	**What is ORS. Give different formulae given by WHO and UNICEF.** **Oral rehydration salt:** ORS is used to supply water and electrolytes in amounts needed for maintenance as soon as intake of usual foods and liquids is discontinued, and before serious fluid losses occur. They are also given to replace mild to moderate fluid loses due to excessive vomiting, diarrhoea, or prolonged fever.Large number of oral rehydration preparations are available in the market which contain anhydrous glucose, NaCl, KCl and either $NaHCO_3$ or sodium citrate. These dry powder preparations are dissolved in specified amount of water and are used for oral rehydration therapy. These preparations may contain a flavouring and suitable agent for free flow of the powder. The following three formulations are usually prepared when glucose is used, sodium bicarbonate is packed separately. The quantities given below are for preparing one litre solution –	**2 M ORS** **2 M formula**

Composition of ORS recommended by WHO and UNICEF.

Ingradients	Formula-II	Formula-II
Sodium Chloride	3.5 gm	3.5 gm
Sodium bicarbonate	2.5 gm	……..
Sodium citrate	…….	2.9 gm
Potassium chloride	1.5 gm	1.5 gm
Anhydrous glucose	20 gm	20 gm
Or Glucose	22.0 gm	…….

6	d)	**Distinguish between α, β and γ rays.**	**4 M each**

α rays	**β rays**	**γ rays**
1] The alpha particles are the heaviest and slowest of the radioactive emissions. Their velocity is about 1/10 that of light which varies from element to element.	1] As these radiations are lighter, they travel with the velocity little less than that of light.	1] They are of very short wave length resembling X-rays and travel at the speed of light.
2] When a radioactive element emits alpha particles from the nucleus of the atom the resulting nucleus will have two positive charges less than the original nucleus and thus it will correspond with element having its atomic number less by two units & atomic mass number less by 4 units.	2] The emission of beta particle from element do not alter the atomic mass but alters the atomic number and is converted to element with next atomic number.	2] When gamma rays are emitted from an element there is lowering of nuclear energy level but no elementa change is noted unless other types of radiations are emitted, which is usually the case.
3] They are helium ions He with a relative +2 charge, containing two protons and two neutrons and have 4 amu mass and atomic number 2.	3] They have a mass of 1/1836 i.e. the mass of hydrogen atom and a relative charge of -1.	3] These radiations do not have any charge. These have Properties both of a wave and particle.
4] Their penetrating power is least as compared to other emissions	4] They have much more penetrating power and can penetrate aluminium sheet upto 3 mm thick.	4] They do not have mass and charge but very high energy and thus have excellent penetrating power.
5] Because of low penetrating power of alpha particles, elements which emit these do not find any use in biological applications as they cannot penetrate tissue.	5] Number of isotopes emitting beta particles are useful in biological applications because of its high penetration power as it can penetrate tissue.	5] They have many biological applications.

6	**e)**	**Solve any two of the following:-** **i) Define radio opaque contrast media with examples.** **Contrast media:-** Radio-opaque substances are those compounds both inorganic and organic that have the property of casting a shadow on X-ray films, have the ability to stop the passage of X-rays and hence appear opaque on X-ray examination. Such compounds and their preparations are called as X-ray contrast media Ex. Barium sulphate **ii) Write any four compounds official of calcium.** **Official compounds of calcium** 1. Calcium carbonate I.P. 2. Calcium Hydroxide B.P. 3. Calcium Acetate B.P. 4. Calcium Lactate I.P. 5. Calcium Levulinate I.P. 6. Calcium Dibasic Phosphate I.P 7. Calcium phosphate Tribasic. 8. Calcium gluconate I.P. **iii) Discuss role of iron in human body.** **Role of Iron:** 1. Essential part of Haemoglobin in blood (Treatment of anaemia) 2. In blood it transports Oxygen from lungs to various organs. 3. It has significant role in Oxidation-reduction reaction constantly taking place in normal metabolism. 4. It is associated with myoglobin, catalase, ferredoxin, Cytochrome P450, electron transport, enzyme cofactor etc. 5. It is required during growth, menstrual cycle, pregnancy, pathological bleeding 6. Involved in cellular respiration. 7. Production of ATP.	**2M for each**

		8. It is an essential element of several nucleoproteins. 9. Externally used as astringent **iv) Give uses of Stannous fluoride and selenium sulphide.** **<u>Uses of stannous fluoride</u>:-** • It is used to prevent dental caries, single application of 8% solution of stannous fluoride to the tooth surface sufficient for 6 month. **<u>Uses of Selenium sulphide</u> :** • As a topical agent in cream or 2.5% suspension to control dandruff and seborrheic dermatitis of the scalp. It is used as an anti seborrheic agent & also used in non-inflammatory non-exudative seborrhoea of the scalp & external glabrous skin. • It is used in form of shampoos in the treatment of dandruff & seborrheic dermatitis of the scalp, dermatitis & allergic dermatosis with seborrhoea.	