**WINTER– 2023 EXAMINATION**

**Subject Title: PHARMACEUTICS- THEORY** Subject Code: **20111**

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 any equivalent 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.
8) As per the policy decision of Maharashtra State Government, teaching in English/Marathi and Bilingual (English + Marathi) medium is introduced at first year of AICTE diploma Programme from academic year 2021-2022. Hence if the students write answers in Marathi or bilingual language (English +Marathi), the Examiner shall consider the same and assess the answer based on matching of concepts with model answer.

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| 1 | | **Answer any SIX of the following:** | **30M** |
| 1 | a | **Define parenterals. State any 3 ideal properties of parenterals. Differentiate between small volume parenterals and large volume parenterals.**<br><br>**Marking Scheme:**<br>**Definition: 1M**<br>**3 ideal properties: 0.5 mark for each property × 3= 1.5M;**<br>**Difference between small volume parenteral and large volume parenteral- 0.5M for each point of differentiation × 5 points= 2.5 marks**<br><br>**Answer:**<br><br>**Definition:**<br>Parenteral preparations are sterile solutions, suspensions, emulsions, powders, gels or implants intended to be administrated directly into the tissue or the systemic circulation in humans or animals.<br><br>**Ideal properties of parenterals**<br>• These must be free from microorganism (Sterile).<br>• These must be free from pyrogens.<br>• These must be isotonic with blood or body fluids.<br>• These must be free from fibers, dust and other foreign particles.<br>• These must have optimum pH.<br>• These must be chemically and physically stable. | **5M**<br><br>**1M**<br><br>**1.5M (0.5M for each)** |

| Small Volume Parenterals | Large volume parenterals |
|---|---|
| These are sterile solutions, suspensions, or emulsions of drug or medicament in a suitable vehicle. | These are aqueous solutions of drugs or medicaments. |
| May be pyrogen free. | Must be pyrogen free. |
| May be isotonic with blood or body fluids. | Must be isotonic with blood or body fluids. |

**2.5M (0.5M for each point)**

| Q. No. | Sub No. | Answers | | Marking Scheme |
|---|---|---|---|---|
| | | Commonly administered in volume up to 10 ml | Commonly administered in volume more than 10 ml | |
| | | May contain antimicrobial preservatives. | Must not contain antimicrobial preservatives. | |
| | | May not provide basic nutrition. | May provide basic nutrition. | |
| | | Not used for maintenance or replacement therapy. | May be used for maintenance or replacement therapy. | |
| | | Cannot be used as vehicle for other drug substances. | Can be used as vehicle for other drug substance. | |
| | | Can be administered by all injection routes like SC, IM, IV etc. | Mostly administered by IV route. | |
| | | Example: Morphine HCl Injection | Dextrose Injection IP, Sodium Chloride and Dextrose Injection IP, Mannitol injection, Ringer injection IP | |

**1 b Define** **5M**

**i) Filtration ii) Filter media**

**State and explain Darcy's Equation for theory of filtration.**

**Marking Scheme:**
**Definition: 1 M for each × 2= 2M**
**State Darcy's equation: 1M**
**Explanation of Darcy's equation: 2 M**

**Answer:**

**Definition of Filtration:** **1M**

Filtration is the process where solid particles are separated from the fluid (liquid or gas), by passing it through a porous medium that retains solids and allows the fluid to pass.

**Definition of Filter media:** **1M**

The surface on which solids are retained in the process of filtration is known as filter media or filter medium.

**Darcy's Equation**

$$= \frac{\Delta}{}$$ **1M**

Where Q = Volumetric flow rate

K = Permeability coefficient (Depends upon nature of precipitate to be filtered and filter medium)

A = Area of the filter bed

Δ = Pressure difference on the liquid and below the filter medium

η (eta) = Viscosity of the fluid

= Thickness of filter cake

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| | | **Darcy's law explains us that Filtration rate is:**<br>• Dependent upon the nature of precipitate to be filtered.<br>• Dependent upon porosity of filter media and size of pores of filter media.<br>• Directly proportional to area of filter media used.<br>• Directly proportional to the pressure difference across the filter media.<br>• Inversely proportional to viscosity of fluid/slurry to be filtered.<br>• Inversely proportional to thickness of filter cake formed on the surface of filter media. | **2M (0.5M for each point)** |
| **1** | **c** | **List out salient features of Fifth edition of IP. Write importance of pharmacopoeia with respect to i) Pharmaceutical industry, ii) Drug administration, iii) Academics**<br>**Marking Scheme:**<br>**Listing salient features of Fifth Edition of IP: Any four × 0.5 = 2M**<br>**Importance of pharmacopoeia with respect to Pharmaceutical industry (1M), Drug administration (1M), Academics (1M)**<br>**Answer:**<br>**Salient Features of Fifth Edition of Pharmacopoeia of India (2007)-**<br>1. Labelling and storage are featured at the end of a monograph.<br>2. Limit of bacterial contamination has been introduced for controlling the microbial quality of all medicinal products.<br>3. Test methods for determining compliance with quality standards of the drug, information on the category of a drug, dosage and usual available strengths of dosage forms have been omitted.<br>4. Solubility was previously given in the informatory section of a monograph. But now a separate section listing solubility of all active pharmaceutical ingredients and pharmaceutical aids has been included.<br>5. The main titles for monographs of formulated preparations are given in the terms of the active moiety rather than of the salt (with few exceptions).<br>6. Classical chemical tests for the identification of an article have been almost eliminated and the more specific infrared and ultraviolet spectrophotometric tests have been given. The concept of relying on published infrared spectra as a basis for identification has been continued.<br>7. The use of chromatographic methods has been greatly extended for more specificity in assays and in assessing the nature and extent of impurities in ingredients and products.<br>8. The test for pyrogen involving the use of test animals has been virtually eliminated. The test for bacterial endotoxins introduced in the previous edition is now applicable to more items.<br>9. The test for abnormal toxicity is now confined to certain vaccines. | **5M**<br>**2M (0.5M for each point)** |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| | | **Importance of Pharmacopoeia with respect to-**<br>**1. Pharmaceutical industry:**<br>Pharmacopoeia provide detailed information of drug substances and products which can be used as a standard reference in pharmaceutical industry that helps to detect adulteration in raw materials. Pharmacopoeia helps to identify and maintain quality of drugs and products.<br>Pharmacopoeia gives various evaluation tests to make safe dosage forms.<br>**2. Drug administration:**<br>Pharmacopoeia provide detailed information of drug substances and products along with their identification test to quality control tests. These can be act as reference for regulatory authorities to check quality and adulteration in drugs and products.<br>**3. Academics:**<br>Pharmacopoeia is considered a standard reference of drug substances and products for academics. Pharmacopoeia helps in research activities to the academics. | **1M**<br><br><br><br><br><br>**1M**<br><br><br><br><br>**1M** |
| **1** | **d** | **Define i) Immunity, ii) Immunological products. Write a note on BCG vaccine highlighting its i) Method of preparation, ii) Description, iii) Storage, iv) Use, v) Dose**<br>**Marking Scheme:**<br>Definition of Immunity: 1M<br>Definition of Immunological products: 1M<br>BCG vaccine Information:<br>i) Method of preparation: 1M<br>ii) Description: 0.5M<br>iii) Storage: 0.5M<br>iv) Use: 0.5M<br>v) Dose: 0.5 M<br>**Answer:**<br>**Immunity:**<br>The power of the body to resist the effects of the invasion of pathogenic microorganisms is called as Immunity.<br>**Immunological Products:**<br>Immunological products are the preparations that improves immunity of our body for the prevention, treatment and diagnosis of various microbial diseases.<br>**Information of BCG Vaccine:**<br>**Method of Preparation:**<br>• The bacilli are grown in a suitable culture media (Suitable growth-1 mg plated out culture media when grown on suitable medium shows NLT 20 million colonies within NMT 14 days).<br>• Then they are separated in the form of cake. | **5M**<br><br><br><br><br><br><br><br><br><br><br><br>**1M**<br><br><br><br>**1M**<br><br>**1M** |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| | | • The cake is homogenized in a grinding flask and suspended in a sterile liquid medium which preserves its antigenicity and viability.<br>• Suspension is Freeze-dried after transferring into the final sterile container. It contains no anti-microbial agent.<br>**Description:**<br>Available as white pellets which give opalescent suspension after reconstitution.<br>**Storage:**<br>Between 2-8°C. A reconstituted vaccine should be used immediately.<br>**Use:**<br>As an immunizing agent against tuberculosis.<br>**Dose:**<br>0.05 ml immediately after birth. 0.1 ml after 1 year by Intradermal route | **0.5M**<br>**0.5M**<br>**0.5M**<br>**0.5M** |
| **1** | **e** | **Differentiate between hard and soft gelatine capsules. Explain the method of manufacturing of soft gelatine capsule by rotary die process.**<br>**Marking Scheme:**<br>**Each point of differentiation 0.5 × any four points= 2M**<br>**Manufacturing of soft gelatine capsule by rotary die process:**<br>• **Construction: 1M**<br>• **Working: 1M**<br>• **Diagram: 1M**<br>**Answer:** | **5M** |

| HARD GELATIN CAPSULES | SOFT GELATIN CAPSULE |
|---|---|
| The hard gelatin capsule shell has two parts viz. Body & Cap | The soft gelatin shale is a single unit. |
| The hard gelatin capsules have a cylindrical shape only. | The soft gelatin capsules are available in oval, round and oblong shapes. |
| The hard gelatin capsules are used for filling solids only like powders, granules, etc. | The soft gelatin capsules are used for filling solids, liquid as well as semisolid substances. |
| The hard gelatin capsule shells are made up of Gelatin, color, and Titanium oxide. | The soft gelatin capsule shells are made up of Gelatin, color & plasticizers like glycerin or sorbitol. |
| The hard gelatin capsules are less flexible. | The soft gelatin capsules are more flexible. |
| In a hard gelatin capsule filling of capsule and sealing of the capsule takes place at two different stages. | In a soft gelatin capsule filling & sealing takes place at a single stroke. |
| In a hard gelatin capsule, hand-filling is possible. | In a soft gelatin capsule, hand-filling is not possible only mechanical filling is possible. |

**2M (0.5M for each point)**

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|

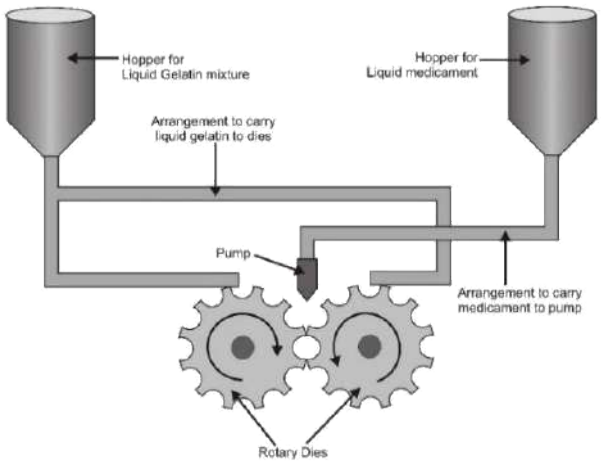
**Construction:** **1M**

The rotary machine has the following parts:

1. Two hoppers:
   a) One hopper: Liquid gelatin mixture is kept in one hopper.
   b) Another hopper: Liquid or semisolid medicament which is to be filled is kept in another hopper.
2. Two rotating dies that move in opposite directions and are arranged close to each other. Each rotary plate has sufficient width, and, on the periphery, dies are embossed with sufficient depth to hold gelatin liquid.
3. Short tubes to carry liquid gelatin from the hopper to the rotary dies.
4. Short tube to carry liquid medicament from hopper to the pump.
5. A pump is attached at the end of tubes carrying liquid medicament and it can be adjusted so that a predetermined dose of a medicament can be released after each stroke.

**Working:**

1. From the gelatin hopper hot liquid gelatin is transferred to the two rotary dies through two pipes in the form of a gelatin ribbon. **1M**
2. At the same time, the liquid medicament is transferred to the pump through the pipe.
3. Each die forms a half shell of a soft gelatin capsule. Each half moves towards the other because of the opposite movement of the die.
4. A predetermined dose of medicament is introduced into the capsule with a stroke of the pump.
5. With the movement of dies both the halves of the capsule shell fuse with each other.
6. Sealing takes place because of the heat of liquid and the pressure of rotating dies.
7. The capsules formed are washed thoroughly and dried.
8. The capacity of the rotary machine is ranging from 25000 to 30000 capsules per hour.




ROTARY SOFT GELATIN CAPSULE FILLING MACHINE **1M**

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| 1 | f | **Explain the detail components of suspension formulation. Add a note on methods of preparation of suspension.** | **5M** |
| | | **Marking Scheme:**<br>**Explanation of component of suspension in details (any four)- 4M**<br>**Method of preparation of suspension: 1M** | |
| | | **Answer:** | |
| | | **Components / Formulation ingredients / Additives in suspension:** | |
| | | For the preparation of stable suspension following additives may be used in suspension as-<br>A. Flocculating agents<br>B. Thickening agents<br>C. Wetting agents<br>D. Preservatives<br>E. Organoleptic additives | |
| | | **A. Flocculating agents:** | |
| | | Flocculating agents are used for the stability of deflocculated suspensions. These decrease strong interparticle bonding between solid particles and stabilize the suspension. Thus, flocculating agents help to re-disperse the solid particles uniformly in the vehicle or a dispersion medium. A flocculating agent is a surfactant or protective colloid. Some of the commonly used flocculating agents are sodium lauryl sulfate, tweens, span, carbonates, etc. | **1M** |
| | | **B. Thickening agent:** | |
| | | These are hydrophilic colloids, and they form colloidal dispersion when they are mixed with water which increases the viscosity of the continuous phase and the solid particles remain suspended for a prolonged period and uniform accurate dosage is possible.<br>Some commonly used thickening agents can be classified as follows.<br>a. Polysaccharides: Gum acacia, Tragacanth, Starch, Sodium alginate<br>b. Inorganic agents: Clay, Aluminium hydroxide<br>c. Synthetic agents: Carbomer, Colloidal silicon dioxide | **1M** |
| | | **C. Wetting agents:** | |
| | | Wetting agents are used to reduce the interfacial tension between suspended solid particles and liquid medium. It helps to produce the suspension of desired quality. Wetting agents when added to the formulation get adsorbed at the solid or liquid surface thus it helps to increase the affinity of solid particles towards the liquid medium. This is achieved by decreasing inter-particular forces. Some of the commonly used wetting agents are alcohol, glycerin, alginate, polysorbate, etc.<br>If the wetting agent is used in excess it may produce foaming and development of bad taste and odor in the preparation. | **1M** |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| | | **D. Preservatives:** Suspensions are susceptible to bacterial growth. To prevent deterioration of suspension suitable preservative is added to the suspension. The preservative used must have a broad spectrum of antibacterial activity. Some of the preservatives used in suspension are Benzoic acid, sodium benzoate, methylparaben propylparaben, etc. | 1M |
| | | **E. Organoleptic additives:** To increase the acceptability of the suspension and to improve the aesthetic value of the suspension coloring agent, a flavoring agent and sweetening agent are used in internal suspensions. Whereas suitable flavoring agents and coloring agents are added to the suspension for external use. | |
| | | **Method of Preparation of Suspensions:**<br>a. Weigh the powders to be added in suspension. Make them fine.<br>b. In a mixer take vehicle. Add required quantity of suspending agent or flocculating agent or wetting agent if needed.<br>c. Transfer the powder mixture in vehicle mixture and mix well.<br>d. Pass the suspension through a homogenizer or mill. | 1M |
| 1 | g | **Classify granulation techniques and describe the wet granulation method with advantages and disadvantages.** | 5M |
| | | **Marking Scheme:**<br>**Classification of granulation techniques: 1M**<br>**Description of wet granulation method: 2M**<br>**Advantages of wet granulation method (Any two): 1M**<br>**Disadvantages of wet granulation method (Any two): 1M** | |
| | | **Answer:** | |
| | | **Classification of Granulation techniques:**<br>**1. Wet Methods**<br>a. Paste or Mass method<br>b. Fluid bed method<br>**2. Dry Methods**<br>a. Using roll compactor<br>b. Slugging | 1M |
| | | **Wet granulation method description:** | |
| | | **Paste or mass method:**<br>It is one of the basic and widely used wet methods. In this method, the first drug and excipients are mixed and the resulting powder mixture is then moistened with a granulating agent to form a dough mass or paste. | 2M |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| | | Then this mass or paste is passed through a screen or sieve of desired mesh size to produce the desired size of granules. Generally, a 6-12 mesh screen is used for this purpose. The granules are placed on drying trays and are dried by air or under heat. The granules are periodically moved during drying to prevent adhesion into a large mass. The dry granules are then screened through a 14-20 mesh screen. These granules are then mixed with glidants, lubricants, and disintegrants and used for compression.<br>On a large scale instead of mortar & pestle, various types of blending equipment are used for mixing the powders. Mixing of powder with the granulating agent to form dough mass is done in various equipment like sigma mixer, planetary mixer, etc. For screening of dough mass to form granules, dough mass is passed through an oscillating granulator having desired sized sieves.<br>**Fluid bed processing:**<br>Here a fluid bed processor is used for the preparation of granules. In this method, the drug and excipient powder mixture is placed in a conical piece of equipment having a perforated base. Then hot air is allowed to pass from the bottom of the conical piece so that all the powder gets fluidized in the upper chamber. At the same time, a fine spray of granulating liquid is sprayed on the fluidized powders. Due to liquid droplets, particles get bind to one another forming granules. Then granules are collected and dried.<br>**Advantages of Wet granulation:**<br>• Wet granulation enhances the cohesiveness and compressibility of powders.<br>• Wet granulation leads to uniform distribution of powders and produces granules of uniform composition. Thus, it assures content uniformity in tablets.<br>• Granules prepared by wet granulation have good flow properties. Thus, it ensures uniformity of the weight of tablets. | **1M (0.5M for each point)** |
| | | **Disadvantages of wet granulation:**<br>• It is an expensive method with respect to labor, equipment, and space requirements.<br>• It is a time-consuming method.<br>• It cannot be employed for moisture-sensitive drugs or medicaments.<br>• If dough mass has color or dye, during drying of granules, chances of migration of dye take place. Thus, at one end granules become dark-colored and at another end, these become faint-colored. | **1M (0.5M for each point)** |

**WINTER– 2023 EXAMINATION**

**Subject Title: PHARMACEUTICS- THEORY** Subject Code: **20111**

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| 2 | | **Answer any TEN of the following:** | **30 M** |
| 2 | a | **Describe the steps involved in sugar coating with suitable examples of ingredients used in each step.**<br>**Marking Scheme: ½ marks for each step with one example. Consider any six methods.**<br>**Answer:**<br>**Sugar coating:** The process involves the deposition of aqueous sugar solutions onto the surface of the core tablet.<br>**Steps involved in sugar coating process are:**<br>**A. Sealing:**<br>Sealing or water proofing step involves coating core of tablet with polymer solution to give protection against moisture penetration. Common materials used as sealants include shellac, zein, Hydroxypropyl Methylcellulose (HPMC), Cellulose Acetate Phthalate (CAP), or Polyvinyl Acetate Phthalate (PVAP).<br>**B. Sub-Coating:**<br>In this step tablet core is coated with sugar coating in large quantities leading to increase in weight of tablet. It is performed by lamination or suspension method.<br>Eg. Gum (acacia/gelatin) based solution or sugar solution followed by dusting with Talc or calcium carbonate powder<br>**C. Smoothing:**<br>It is used to make the tablet surface smooth. The irregularity in tablet surfaces are filled with concentrated sucrose solution to make it smooth. E.g. Simple syrup solution<br>**D. Colouring:**<br>Color is applied by mixing it in sucrose solution. E.g. Titanium dioxide, Iron oxide, and D&C certified lakes (Aluminium lakes, Brilliant Blue Lake, Sunset yellow lake, Amaranth lake, Indigo lake, carmine lake) etc.<br>**E. Polishing:**<br>It is used to give shining lustre to the tablets. For polishing carnauba wax in organic solvent is sprayed over tablets. E.g. mixture of carnauba wax and beeswax<br>**F. Printing:**<br>Tablets are printed using edible ink which contains safflower, gardenia, squid ink, etc. | **3M**<br>**0.5M for each step** |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| 2 | b | **Discuss any three types of glass used as a packaging material in pharmaceuticals.**<br>**Marking Scheme: Each type of glass – 1M; For any three types – 3M.**<br>**Answer:**<br>**1. Type-I:**<br>Also known as highly resistant borosilicate glass, composed of silica and boric acid with small amounts of aluminium oxide and sodium oxide. It is ideal for packing of preparations with acidic, neutral and alkaline pH because of its high resistant nature due to the presence of boric oxide. Further has good resistance to thermal shocks and can be sterilized before or after filling.<br>**2. Type-II:**<br>Also known as treated soda lime glass, where the soda lime glass is treated with sulfur to increase its hydrolytic resistance. It is appropriate for packing of acidic and neutral parenteral preparations. Type-II glass containers can be sterilized before or after filling.<br>**3. Type-III:**<br>Also known as soda lime glass with average hydrolytic and chemical resistance. It is suitable for packaging of non-aqueous injectable preparations, powdered form parenteral and non-parenteral preparations. Type-III glass containers be sterilized by dry heat before filling.<br>**4. Type-IV:**<br>Also Known as non-parenteral glass/ general-purpose soda lime glass with low hydrolytic resistance. It is used to store topical products and oral dosage forms. This type of glass container cannot be autoclaved as it will increase erosion reaction rate of the glass. | **3M**<br>**1M for each type. Consider only 3 types** |
| 2 | c | **Define**<br>**i) Liniment ii) Lotion**<br>**Compare liniment with lotion in respect of**<br>**i) Type of preparation**<br>**ii) Application method**<br>**iii) Labelling instructions**<br>**iv) Example**<br>**Marking Scheme: Each definition - 0.5M; Each point of comparison - 0.5M.**<br>**Answer:**<br>**Liniment:**<br>Liniment are liquid & semi-liquid preparation meant for external application to the skin with friction.<br>Or | **3M**<br>**0.5M** |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| | | Liniments are solutions or mixture of various substances in oil, alcoholic solution of soap or emulsion or occasionally semi-solid preparations intended for external application to the skin with rubbing or massaged.<br>**Lotion:**<br>Lotions are liquid suspension or dispersions meant for external application to the skin or body without friction or rubbing.<br>Or<br>Lotion is medium to low viscous topical formulations meant for external application to the skin without friction or rubbing with the help of some absorbent material for medical and non-medical use. | **0.5M**<br>**2M (0.5M for each point of comparison** |

| Sr. No | Liniment | Lotion |
|---|---|---|
| 1 | **Types:**<br>1. Alcoholic liniments<br>2. Oleaginous liniments | **Types:**<br>1. Medicated lotion<br>2. Non-medicated lotion |
| 2 | **Application method:**<br>Liniments are usually applied to the skin with friction and rubbing. | **Application method:**<br>They are applied direct to the skin without friction with the help of some absorbent material (Cotton wool, cloth or cotton gauze). |
| 3 | **Labelling instructions:**<br>• For external use only.<br>• Shake the bottle before use.<br>• Avoid broken skin | **Labelling instructions:**<br>• For external use only.<br>• Shake the bottle before use.<br>• Can be applied to broken skin. |
| 4 | **Examples:**<br>• Camphor liniment<br>• Turpentine Liniment<br>• Soap liniment | **Examples:**<br>• Calamine lotion<br>• Salicylic acid & mercuric chloride lotion |

| | | | |
|---|---|---|---|
| **2** | **d** | **Classify Novel drug delivery systems on approach of Novel drug delivery system with one example of each.**<br>**Marking Scheme: One type with example – 1M; Any three types with examples – 3M**<br>**Answer:**<br>**Based on technical sophistication, NDDS are divided into four categories including**<br>**1. Rate pre-programmed DDS**<br>**2. Activation-modulated DDS**<br>**3. Feedback-regulated DDS**<br>**4. Site-targeted DDS**<br>**1. Rate pre-programmed DDS**<br>They are further divided into following types:<br>a. 1. Dissolution Controlled DDS E.g. Ambien CR ER tablet | **3M**<br>**1M for each class with example** |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|

b. 2. Diffusion Controlled DDS E.g. Wellbutrin XL ER tablet
c. 3. Erosion Controlled DDS E.g. Acutrim tablet
d. Combination of dissolution, diffusion and/or erosion-controlled DDS – E.g. CATAPRES-TTS® transdermal patch

**2. Activation-modulated DDS**

Based on the nature of stimuli, they are further classified into:

**A. Based on physical mean**

a. Osmotic pressure activated - E.g. Acutrium tablet, Adalat (OROS), Alpress LP, Alzet osmotic pump
b. Hydrodynamic pressure activated - E.g. Valrelease Capsule
c. Vapor pressure activated - E.g. Implantable infusion (Infusaid) pump for insulin, Heparin & morphine
d. Mechanically activated - E.g. Metered dose inhalers/ nebulizers (Buserelin)
e. Magnetically activated - E.g. Hemisphere (bovine serum albumin) Magnetic microsphere, magnetic liposomes
f. Sonophoresis activated - E.g. Topical anesthesia coupled with ultrasound
g. Iontophoresis activated - E.g. Phoresor by motion control
h. Hydration activated - E.g. Valrelease tablet (Valium)

**B. Based on chemical mean**

a. pH activated DDS - E.g. Enteric coated tablet
b. Ion activated DDS - E.g. BETOPTIC-S ophthalmic suspension
c. Hydrolysis activated DDS - E.g. Tegretol XR tablet

**C. Based on biochemical means**

a. Enzyme-activated DDS E.g. 5-fluorouracil loaded albumin microspheres
b. Biochemical activated DDS

**3. Feedback-regulated DDS**

They are further classified into three types:

a. Bioerosion regulated DDS - E.g. Hydrocortisone triggered insulin DDS
b. Bioresponsive regulated DDS - E.g. Glucose triggered insulin DDS
c. Self- regulated DDS - E.g. Self- regulated insulin delivery system

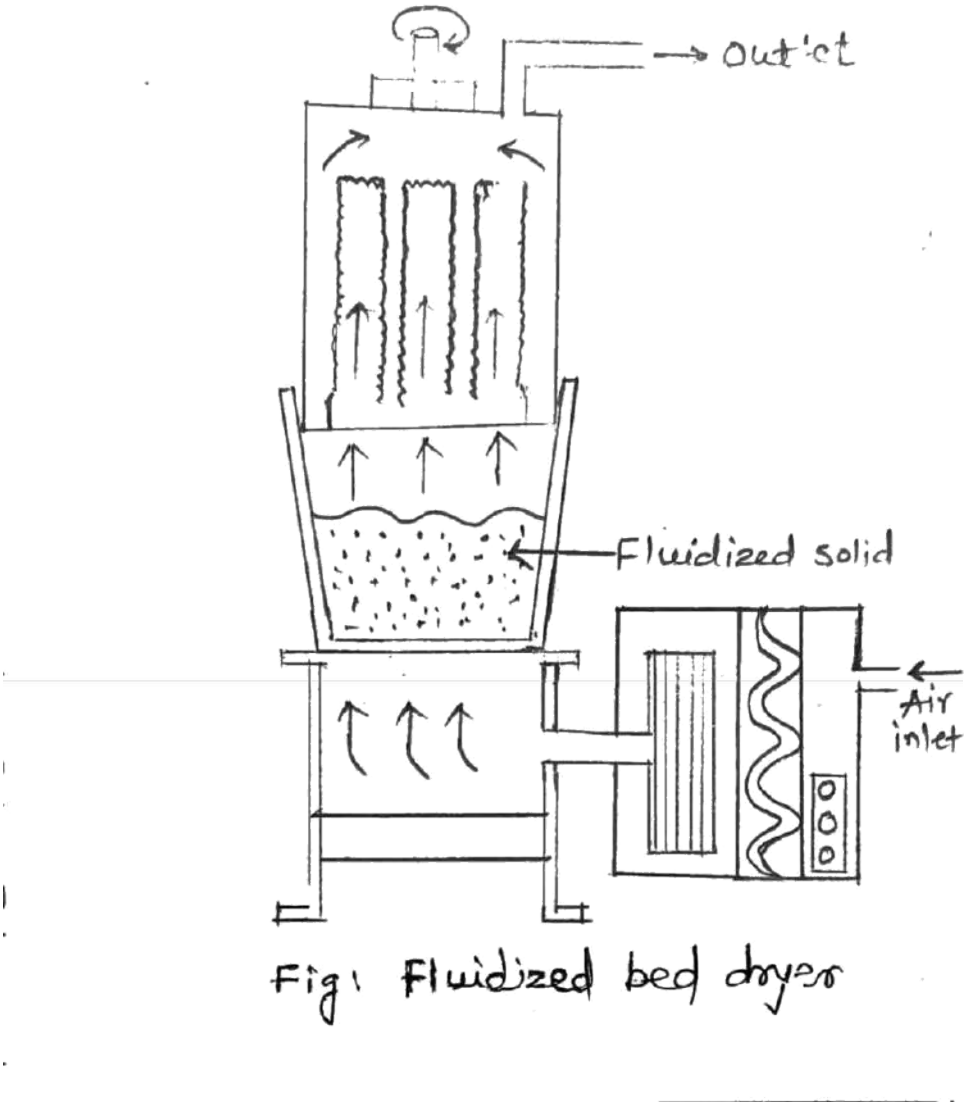
**4. Site-targeted DDS**

Depending upon the release of the drug at the active site they are divided into three parts:

a. First order targeting: The DDS, release the drugs at the targeted site such as organ, tissue, cavity, etc.
b. Second order targeting: The DDS, release the drugs at the specific cell such as tumors cells not to the normal cells.

<table>
<tr><th>Q. No.</th><th>Sub No.</th><th>Answers</th><th>Marking Scheme</th></tr>
<tr><td></td><td></td><td>c. Third order targeting: The DDS, release the drugs at the intracellular site of targeted site.</td><td></td></tr>
<tr><td></td><td>e</td><td>Differentiate between powders and granules.<br>Marking Scheme: ½ marks for each point difference. Consider any six points. (3 points of either side)<br>Answer:
<table>
<tr><th>Sr. No.</th><th>Powders</th><th>Granules</th></tr>
<tr><td>1</td><td>Any distinct/discrete particles having size less than 1000µm is known as powder.</td><td>Aggregations of small particle of powder varies in size between 0.2 and 0.4 mm known as granules.</td></tr>
<tr><td>2</td><td>Having higher cohesive strength due to fine particle.</td><td>Having lower cohesive strength due to coarse particle.</td></tr>
<tr><td>3</td><td>Flow property is very low compare to granules and not suitable for tablet compression</td><td>High flow property compare to Powder can produce uniform tablet weight.</td></tr>
<tr><td>4</td><td>During compression this can be separated if it contains different ingredients.</td><td>Less chance of separation during compression though it contains different ingredients.</td></tr>
<tr><td>5</td><td>Due to high cohesive strength, it forms high density layer at the upper portion create weight variation during compression.</td><td>Due to low cohesive strength, it forms uniform layer in every portion produce Less weight variation during compression.</td></tr>
<tr><td>6</td><td>Air may be entrapped during compression of tablets increase capping tendency.</td><td>Less chance of air entrapping during compression so significantly reduces capping tendency.</td></tr>
<tr><td>7</td><td>It may be blown from the die and cause frequently sticking problem during tablet compression.</td><td>It can't blow out from the die so less chance to cause sticking problem during compression.</td></tr>
<tr><td>8</td><td>The Flow-Function [FF] value is lower limit, so it shows low flow property on hopper.</td><td>The Flow-Function [FF] value is higher limit, so it shows high flow property on hopper ensure smooth operation.</td></tr>
<tr><td>9</td><td>It requires steeper hopper angle to ensure flow property.</td><td>Not require to steeper hopper angle, work well in any suitable hopper.</td></tr>
<tr><td>10</td><td>Not suitable for compression tablet, Encapsulation process, may be used for dry solid preparation which further tend to form solution and suspension upon addition of solvent.</td><td>Very much suitable to compress tablet ad Encapsulation process, produce uniform tablet and Capsule.</td></tr>
</table></td><td>3M<br>0.5 m for each point.</td></tr>
</table>

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| 2 | f | **Define current good manufacturing practices. State importance and objectives of cGMP.**<br>**Marking Scheme: Definition: 1M; Importance: at least two importance (0.5M each)**<br>**Objective: at least two objective (0.5M each)**<br>**Answer:**<br>**Definition:**<br>cGMP is current Good Manufacturing Practice (cGMP) regulations given by the FDA under the authority of Food, Drug and Cosmetics Act.<br>The cGMP regulations for drugs contain minimal essentials for the facilities, processes, methods, procedures and controls followed in manufacturing, processing and packing of a drug product. The regulations of cGMP assure the delivery of drug product for safe and efficient use by confirming the claimed quantity of ingredients.<br>**Importance:**<br>1. Avoids the unintentional addition of poisonous or toxic substances present in the drugs or excipients which are in poor quality.<br>2. If the claimed quantity of the drug specified in the label is not present, there will not be intended therapeutic effect.<br>3. Avoids risks in the pharmaceutical production like cross contamination, false labelling, etc.<br>**Objective of cGMP:**<br>1. Ensure that products are consistently manufactured and controlled to the specified quality.<br>2. Concerned with all aspects of production and quality control<br>3. In the manufacture of cosmetic products of specified quality<br>4. Ensure that the consumer receives products of specified quality.<br>5. CGMP regulations assures the identity, strength, quality, and purity of drug product | **3M**<br>**1M**<br>**1M (0.5M for each point)**<br>**1M (0.5M for each point)** |
| 2 | g | **Draw a neat diagram of Fluidized bed dryer and label the following components.**<br>**i) Inlet**<br>**ii) Outlet**<br>**iii) iii) Fluidized solid**<br>**Marking Scheme: 1 ½ M for neat diagram; ½ M for label of each component**<br>**Answer:** | **3M** |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| | |  **Fig : Fluidized bed dryer** | **1.5M for diagram**<br>**0.5 M for each label** |
| **2** | **h** | **State and explain any three types of ointment bases.**<br>**Marking Scheme: Each type of ointment base: 1M; Any three types – 3M.**<br>**Answer:**<br>"Ointments are semisolid oily preparation containing active medicaments dissolved, emulsified or suspended in a suitable base intended for application to the skin."<br>The ointment bases are classified into four categories; hydrocarbon or oleaginous bases, absorption bases, water-washable or removable bases, and water-soluble bases.<br>1. Hydrocarbon or Oleaginous bases<br>2. Absorption bases<br>3. Emulsion or water washable or water removable bases<br>4. Water soluble bases | **3M**<br>**1M for each type with explaination. Consider any three types** |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|

**1. Hydrocarbon or Oleaginous bases**

✓ The oleaginous bases include hydrocarbons which are derived from petroleum and hence termed as hydrocarbon bases.

✓ These bases are oily or greasy in nature.

✓ They are anhydrous and not soluble in water.

✓ They are used to hydrate the skin or as an occlusive dressing.

✓ Generally, they are not preferred since they stain the clothes.

✓ Examples of hydrocarbon bases are petrolatum, liquid petrolatum, synthetic esters such as glycerol monostearate, isopropyl palmitate.

**2. Absorption bases:**

✓ Absorption bases are the combination of both hydrocarbon base and water in oil (w/o) emulsion. Hence, they can absorb water. They are used as an emollient but not as an occlusive dressing.

✓ They are meant to decrease the scaling and drying of skin.

✓ Absorption bases contain oil in its external phase and hence difficult to remove with water.

✓ The drugs can be added on any phase depending on the nature of the drug.

✓ The absorption bases are further classified into anhydrous bases and water in oil (w/o) emulsion bases.

✓ The anhydrous hydrocarbon bases allow incorporating the aqueous solutions to form w/o emulsion.

✓ In case if the bases are w/o emulsion, they easily allow the addition of aqueous solutions. E.g. Lanolin, hydrophilic petrolatum.

**3. Emulsion or water washable or water removable bases:**

✓ Since these bases have aqueous external phase, they are water-washable or water-removable. Hence, they are generally used as an ointment base in many ointment preparations.

✓ This emulsion base consists of three constituents namely an internal oil phase (hydrocarbon base), an emulsifying agent and an external aqueous phase.

✓ Depending on the nature of the drug/s, it can be incorporated to any one of the phase to form emulsion.

✓ Examples of water removable bases are hydrophilic ointment, white soft paraffin, and liquid paraffin.

**4. Water soluble bases:**

✓ Water soluble bases are water-washable.

✓ They do not contain lipids or oils and hence not occlusive.

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| | | ✓ They dehydrate skin and affect the percutaneous absorption since water soluble bases absorb water from skin.<br>✓ Examples of water-soluble bases are carbowax, polyethylene glycol. | |
| 2 | i | **Enlist the evaluation tests for parenterals. Discuss the sterility test in details.**<br>**Marking Scheme:**<br>**List of evaluation tests for parenterals – 1M; Explanation of sterility test – 2M.**<br>**Answer:**<br>**Evaluation tests for parenterals:**<br>1. Sterility test<br>○ Membrane filter method<br>○ Direct inoculation method<br>2. Pyrogen test<br>○ LAL Test<br>○ In vivo Rabbit test<br>3. Clarity test/Foreign particulate matter test<br>4. Leakage test<br>5. Isotonicity<br>6. Content uniformity & Weight<br>7. pH<br>8. Viscosity<br>9. Extractable Volume<br>**Test for Sterility:**<br>**Principle:** These tests are based on the principle that if bacteria or fungi are placed in medium provided favourable conditions like nutritive material, moisture, temperature, the organism will grow, and their presence can be indicated by the turbidity in clear solution. This test should be carried out in strictly aseptic conditions.<br>**Method of testing: Test of sterility may be carried out by**<br>1. Membrane filtration method<br>2. Direct inoculation method<br>**1. Direct inoculation method:**<br>The substance to be tested is aseptically drawn from the container by a suitable device and transferred to the final culture medium in the test tube. The inoculated medium (test tubes) is incubated at 20-25°C for fungi and 30-37°C for bacteria for the period of seven days. Observe the growth of micro-organism in the medium. | **3M**<br>**1M**<br>**0.5M**<br>**0.5M**<br>**1M for any one method.** |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| | | **2. Membrane filtration method:**<br>This method is preferred in the following cases- An oil or oily preparations, ointment, a non-bacteriostatic solid, soluble powder or a liquid that possesses bacteriostatic and fungistatic properties, liquid products where volume in a container is 100 ml or more. Carry out filtration of sample under test through membrane filter having pore size of 0.45 µ and diameter of about 47 mm. After the filtration, the membrane is removed aseptically from the metallic holder and divided into two halves. The first half is transferred into 100 ml of culture media meant for fungi and incubated at 20 to 25°C for not less than 7 days. The other half is transferred into 100 ml of fluid thioglycolate medium meant for bacteria and incubated at 30 to 35°C for not less than 7 days. Observe the growth of the media.<br>**Results:**<br>If no growth of micro-organism is found in any of the tubes, the sample is declared to have pass the test and the same test is repeated for two times. | |
| 2 | j | **Differentiate between Quality assurance and Quality control.**<br>**Marking Scheme: ½ marks for each point difference. Consider any six points. (3 points of either side)**<br>**Answer:** | **3M**<br>**0.5M for each point.** |

| Sr. No. | Quality assurance (QA) | Quality control (QC) |
|---|---|---|
| 1 | This department ensures the overall quality of the product and the respective activities which impact on the quality of the product like GMP, documentation, etc. | This department is specifically responsible for sampling, analysis of raw materials, in- process during production, finished products and maintaining the respective documents including stability studies. |
| 2 | It plays a major role in quality management system on providing confidence to fulfill the requirements of quality. | It plays a significant role in quality management system by concentrating to fulfill the requirements of quality. |
| 3 | The activities performed in this department helps for the prevention of defects by providing advanced testing and development processes. | The activities performed in this department helps to detect the both in-process and finished product. |
| 4 | It is a managerial tool | It is a corrective tool. |
| 5 | It is a proactive process in the quality of the product. | It is a reactive process in quality of the product. |
| 6 | It follows the guidelines of the concerned regulations. | It follows the Standard Operating Procedures (SOP) laid down by quality assurance department. |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| 2 | k | **Write the advantages and disadvantages of Liposomes.**<br>**Marking Scheme: 1.5M for any three advantage; 1.5M for any three disadvantages**<br>**Answer:**<br>**Advantages:**<br>a) Liposomes increase the potency, bioavailability and therapeutic index as well as therapeutic safety of drug (e.g. actinomycin-D).<br>b) Liposomes are able to transport hydrophobic as well as hydrophilic drugs.<br>c) Liposomes are site specific drug delivery systems. Change in site specific drug delivery can be achieved by modifying the surface of liposome.<br>d) They can entrap macromolecules like interleukin 2, interferon-g etc.<br>e) PEG-coated liposomes are able to deliver drug for longer periods of time.<br>f) Liposomes are seen to improve stability by the process of encapsulation.<br>g) Liposomes are non-destructive, flexible, biocompatible, bio-degradable<br>**Disadvantages:**<br>a) Low solubility in aqueous solutions.<br>b) Short half-life in the body environment.<br>c) High production cost.<br>d) Leakage and fusion of the loaded drugs<br>e) Allergic reactions to some liposomal compounds<br>f) Sometimes phospholipid undergoes oxidation and hydrolysis-like reactions. | **3M**<br>**1.5M (0.5m for each point)**<br>**1.5M (0.5m for each point)** |
| 3 | | **Attempt ALL questions** | **20 M** |
| | | ***Important Instructions: In case, multiple answer options are observed for the same sub question of question No. 3, the option (Answer) appearing first in the answer book shall be treated as answer and assessed accordingly.*** | |
| 3 | a | **Define Sublimation.**<br>**Marking Scheme: 1M for correct definition.**<br>**Answer:**<br>Sublimation is the process where a solid changes from solid to a vapor without passing through the liquid state. OR<br>Sublimation is the transition of a substance from sloid phase to the gas phase without passing through an intermediate liquid phase. | **1M** |
| 3 | b | **Name the First pharmaceutical industry started in India.**<br>**Marking Scheme: 1M**<br>**Answer:** Bengal Chemicals and Pharmaceuticals Ltd. | **1M** |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| 3 | c | **Give two examples of natural gel forming substances.**<br>**Marking Scheme: 1M (Any Two Examples)**<br>**Answer:** Gelatine, Alginate, Carboxy Methyl Cellulose, Chitosan, Alginic acid. | 1M |
| 3 | d | **What is the pH value of Tears?**<br>**Marking Scheme: 1M**<br>**Answer:** The normal pH range was **6.5 to 7.6** | 1M |
| 3 | e | **Which step involves moistening of drug during percolation process?**<br>**Marking Scheme: 1M**<br>**Answer:** Imbibition | 1M |
| 3 | f | **_____ container protects the product from dust, moisture and air.**<br>**Marking Scheme: 1M consider any one of following**<br>**Answer:** Air-tight containers or Hermetic containers. | 1M |
| 3 | g | **Give two examples of artificial sweetening agents.**<br>**Marking Scheme: 1M (Any two examples)**<br>**Answer:**<br>Saccharin, Aspartame, Acesulfame potassium (acesulfame-K, or Ace-K), Sucralose, Neotame. | 1M |
| 3 | h | **Give the disintegration time of sugar-coated tablets.**<br>**Marking Scheme: 1M**<br>**Answer:** 60 Minutes | 1M |
| 3 | i | **Define Nasal drop.**<br>**Marking Scheme: 1M**<br>**Answer:**<br>Nasal drops are solutions, emulsions or suspensions intended for instillation into the nasal cavities with a dropper. | 1M |
| 3 | j | **The preparations containing antibiotics are called as……**<br>**Marking Scheme: 1M**<br>**Answer:** Antibacterials or Antimicrobials. | 1M |
| 3 | k | **The dissolution test has been introduced in……edition of I.P.**<br>**Marking Scheme: 1M**<br>**Answer:** Third Edition of I.P 1985 | 1M |
| 3 | l | **Define pharmacy.**<br>**Marking Scheme: 1M** | 1M |

| Q. No. | Sub No. | Answers | Marking Scheme |
|---|---|---|---|
| | | **Answer:**<br>Pharmacy is the art, science of compounding, packaging, labelling and dispensing medicinal drugs. | |
| 3 | m | **The extraction of vegetable drugs with cold or boiling water for a short period of time is____**<br>**Marking Scheme: 1M**<br>**Answer:** Infusion | 1M |
| 3 | n | **A major component of glass is___**<br>**Marking Scheme: 1M**<br>**Answer:** iii) Silica | 1M |
| 3 | o | **An example of inorganic or mineral colour is___**<br>**Marking Scheme: 1M**<br>**Answer:** i) Titanium dioxide | 1M |
| 3 | p | **Define sieve number.**<br>**Marking Scheme: 1M**<br>**Answer:**<br>The sieve number denotes the number of meshes present in the sieve within a one-inch length of the sieve mesh. | 1M |
| 3 | q | **What will be the allowed variation if the average weight of tablet is 300mg.**<br>**Marking Scheme:1M, consider any one correct option from following.**<br>**Answer:** ii) ± 5.0% (as per IP) **or**<br>iv) ±7.5% (as per USP) | 1M |
| 3 | r | **Elixirs are_____**<br>**Marking Scheme: 1M**<br>**Answer**: i) hydroalcoholic liquids | 1M |
| 3 | s | **Which of the following is the example of artificial preservative.**<br>**Marking Scheme: 1M**<br>**Answer:** iv) Sodium benzoate | 1M |
| 3 | t | **Calamine lotion is used as a_____**<br>**Marking Scheme: 1M, consider any one correct use.**<br>**Answer:**<br>Protective or Astringent or used to relieve the itching, pain, and discomfort of minor skin irritations. | 1M |