**Subject Title: PHARMACEUTICS-I** Subject Code: 0805

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**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** | | **Answer any *Eight* of the followings:** | 16M |
| **1** | **a)** | **Give any four reasons for film coating**.<br>•To mask the disagreeable odour, colour or taste of the drug/tablet.<br>• To offer a physical and/or chemical protection to the drug.<br>• To protect drug from the deterioration effect of external environment.<br>• Increasing the mechanical strength of the dosage form.<br>• To improve the appearance of tablets | **2M (0.5x4)** |
| **1** | **b)** | **Explain any four factors affecting size reduction**<br>**Factor affecting size reduction are:**<br>**1.Hardness:** Soft material easy break than hard.<br>2.**Toughness:** Drug with fibrous nature or those having high moisture content are tough and hard to reduce in size.<br>3.**Stickiness:** Material adheres to the grinding surface or sieve surface of the mill. It is very difficult to powder a drug of having gummy or resinous material.<br>**4.Material structure:** Material with some special structure cause problem during size reduction e.g. Vegetable drug with cellular structure produce long fibrous particle on size reduction, similarly a mineral substance having lines of weakness, produce flake like particle on its size reduction.<br>5.**Moisture content:** The presence of moisture in the material influences a number of its properties such as hardness, toughness or stickiness. The material having 5% moisture in case of dry grinding and 50% in case of wet grinding is permissible.<br>**6.Temperature**: Waxy material such as stearic acid or drug containing oils or fat, become softened during the size reduction, due to heat. This can be avoided by cooling the mill.<br>**7.Purity**: In some mills during size reduction there is chances of addition of impurities. If | **2M (0.5x4)** |

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| | | high degree of purity is required avoid such mills or Mills should be cleaned thoroughly.<br>8.**Physiological effect:** Some drugs are very potent. During their size reduction in mill, dust is produced which may have effect on operator.<br>9.**Ratio of feed size to product size:** To get a fine powder in a mill, it is required that a fairly small feed size should be used. Hence to carry out size reduction in various stages e.g. preliminary crushing followed by coarse powder and then fine grinding.<br>10.**Bulk density:** The output of the size reduction of the material in a machine depends upon the bulk density of the substance. | |
| **1** | **c)** | **Define**<br>**(i) Drug**- A chemical agent intended for use in the diagnosis, mitigation, treatment, cure or prevention of disease in man or in other animals.<br>**(ii) Dosage forms**- Dosage form is a transformation of a pure chemical compound into a predetermined form by admixing drug components with non- drug components. | **2M**<br>**(1 X2 = 2M** |
| **1** | **d)** | **Give Significance of drying.**<br>1) In pharmaceutical industry it is used as a unit process in the **manufacture of granules** which can be dispensed in bulk or converted into tablets or capsules.<br>2) Drying can also be used to **reduce the bulk** and weight of the material, thereby lowering the cost of transportation and storage.<br>3) It helps in the **preservation** of crude drugs of plant from mould growth, which occurs due to presence of moisture.<br>4) It helps in the **size reduction** of crude drugs. The presence of moisture in the crude drug does not allow it to get powdered easily.<br>5) Drying is also used in the **processing of materials**eg. the preparation of dried aluminium hydroxide, the spray drying of lactose and in the preparation of solid extract.<br>6) **Improves solubility** of product, when powder is dried it gets solubilised fast.<br>7) Drying ensures **free flowing** of powders. | **2M**<br>**(0.5 X 4)** |

<table>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>1</td><td>e)</td><td>Write difference between Hard and Soft gelatin capsules
<table>
<tr><th>Sr. No.</th><th>Hard gelatin capsules</th><th>Soft gelatin capsules</th></tr>
<tr><td>1</td><td>The hard gelatin capsule shell consists of two parts: Body and cap</td><td>The soft gelatin capsule shell becomes a single unit.</td></tr>
<tr><td>2</td><td>They are cylindrical in shape</td><td>They are available in round, oval and tube-like shapes.</td></tr>
<tr><td>3</td><td>The contents usually consist of medicaments in the form of powder, beads or granules</td><td>The contents usually consist of liquids or semisolids.</td></tr>
<tr><td>4</td><td>These are prepared from gelatin, titanium dioxide, colouring agent and plasticizer</td><td>These are prepared from gelatin, more amount of plasticizer (sorbitol or glycerin) and preservative.</td></tr>
<tr><td>5</td><td>Filling and sealing takes place in different steps.</td><td>Filling and sealing are done in a combined operation of machines</td></tr>
<tr><td>6</td><td>Shell is perfectly dry</td><td>Shell is not perfectly dry</td></tr>
<tr><td>7</td><td>These capsules can be adulterated</td><td>These capsules cannot be adulterated</td></tr>
<tr><td>8</td><td>Eg: Amoxycillin Capsule</td><td>Eg: Pudin Hara Capsule</td></tr>
</table></td><td>2M (0.5×4)</td></tr>
<tr><td>1</td><td>f)</td><td>Find out the proportion of procaine HCL which will yield solution iso-osmotic with blood plasma (FP 1% procaine HCL = -0.122$^0$C )<br>Formula: %w/v of adjusting sub needed=0.52-a/b<br>Calculation : % w/v procaine HCLrequired = 0.52 – 000/ 0.122<br>= 4.26% w/v</td><td>2M</td></tr>
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| **1** | **g)** | **Explain tyndallisation process**<br>**Tyndallization**, also called **fractional sterilization** and **discontinuous heating**, is a form of sterilization.This method is relatively simple but somewhat time-consuming.<br>**Process:** This is a fractional sterilization method. This method is used for sterilization of medicaments unstable at $115^0$C but able to withstand low temperature heating. This method consist of heating the material at $80^0$C for 1 hour on three successive days presuming that on the first day all vegetative bacterial cells will be destroyed and the spores may germinate in the days to follow and will be killed subsequently. | **2M** |
| **1** | **h)** | **List the steps involved in slugging process**<br>i) Sieving<br>ii) Weighing<br>iii) Blending<br>iv) Slugging<br>v) Screening<br>vi) Blending<br>**vii)** Compression<br>Or.<br>**Drug + Excipients → Blending → Slugging(formation of big size tablet) → Screening → Blending → Compression.** | **2M**<br>**(0.5×4)** |
| **1** | **i)** | **Write advantages of water as solvent for extraction**<br>• It is cheap & easily available.<br>• Non –toxic<br>• Non inflammable.<br>• It has wide solvent action | **2M**<br>**(0.5×4)** |
| **1** | **j)** | **Write the precautions to be taken while placing the material in hot air oven**<br>1. It should be filled to its capacity only should not be overloaded.<br>2. Glass apparatus and equipment should be wrapped individually.<br>3. Articles should be placed in such a way that they should not interfere with air flow<br>4. Articles should not be placed at the floor of the oven.<br>5. Once in operation oven should not be open | **2M**<br>**(0.5×4)** |

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| | | 6. Proper biological indicators should be used<br>7. Thermolabile substance should not be sterilized in hot air oven | |
| **2** | | **Attempt any FOUR of the followings** | **12M** |
| **2** | **a)** | **Define emulsion and list the different emulsifying agents**<br>**Definition:**<br>Emulsions are biphasic liquid preparation consisting of two immiscible liquid phasesone of which is dispersed as minute globules into other phase that is continuous phase and made miscible by addition of emulsifying agents.<br>**Examples:**<br>Gum acacia, tragacanth, agar, starch, pectin, iris moss, wool fat, egg yolk, gelatin. Methyl cellulose, Na CMC, SLS, Cetrimide, benzalkonium chloride, Glycerylester-glyceryl monoesters, Milk of magnesia, Mg oxide, Mg trioxide, Carbowax, cholesterol and lecithin. | **3M**<br>**1M for def.**<br>**(0.5 X 4=2 M for ex.)** |
| **2** | **b)** | **Write the salient features of <u>fourth</u> edition of I.P.**<br>1. It contains 1149 monographs and 123 appendices and available in two volumes.<br>2. Introduction of computer generated formula<br>3. Some titles have been changed to include more commonly accepted names in India e.g.HyoscineHydrobromide for Scopolamine hydrobromide.<br>4. I.R and U.V absorption spectrophotometric tests for identification of drug substance have been introduced.<br>5. HPLC has been widely used as method of analysis in many formulations.<br>6. Test for bacterial endotoxins as a more suitable substitute for test for pyrogens.<br>7. Number of general monographs e.g. eye drops ,eye ointments pessaries have been included.<br>8. A quantitative method for determining particulate matter in injectable preparation has been replaced by qualitative test.<br>9. Biological assays provided for vaccines, hormones, blood products.<br>10. ORS-Citrate formula recommended by WHO introduced. | **3M**<br>**0.5 X 6 = 3M)** |

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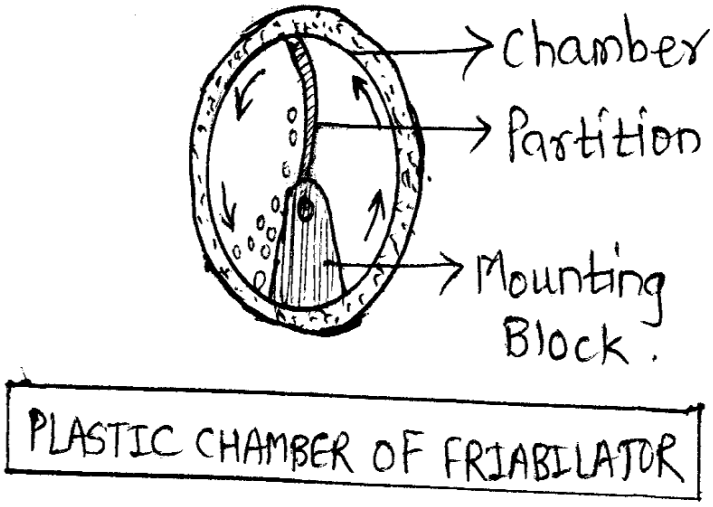
| **2** | **c)** | **Write any three qualities of packaging material and any three disadvantages of glass as a material for packaging.**<br>**Qualities of packaging material**<br>i. Neutral<br>ii. No interaction.<br>iii. Stability against environmental factor.<br>iv. Withstand wear and tear during handling.<br>v. Withstand changes in pressure and temperature.<br>vi. Labelled easily<br>vii. Non-toxic.<br>viii. Closure easily removable/replaceable<br>**Disadvantages of glass**<br>1) Glass is fragile,<br>2) Glass is heavy, that can increase transportation charges,<br>3) Glass containers may release alkali to aqueous preparations,<br>4) Flaking and weathering of glass are two serious issues related to glass. | **3M**<br>**(0.5 X 3)**<br>**1.5M**<br><br>**(0.5 X 3)**<br>**1.5M** |
| **2** | **d)** | **Explain following evaluation test for tablet (any one)**<br>**(i) Friability**<br>Friability test is performed to evaluate ability of the tablet to with stand wear and tear in Packing, handling, and transporting. The apparatus used to perform this test is known as "Friabilator".<br>**The apparatus**: consists of a plastic chamber, which is divided into two parts and itrevolves at a speed of 25 rpm. Twenty tablets are weighed and placed in a plasticchamber. The chamber is rotated for 4 minutes or 100 revolutions. During eachrevolution the tablet falls from a distance of 6 inch. The tablets are removed from thechamber after 100 revolutions and weighed. Loss in weight indicates the friability.<br>**Result:** The tablets are considered to be of good quality if the loss in weight is less than 0.8%. | **3M**<br>**(1 method +1 result +1 diagram= 3M)** |



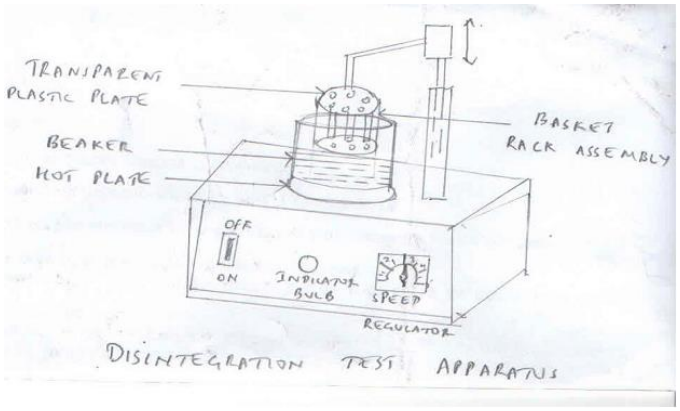

PLASTIC CHAMBER OF FRIABILATOR

(ii) **Disintegration**

Disintegration of a tablet means to break a tablet into smaller particles after swallowing. The time required to disintegrate the tablet is called disintegration time.

**Method:** The apparatus consists of a rigid basket-rack assembly supporting 6 cylindrical glass tubes placed with one tablet in each tubes. The assembly should be raised and lowered between 28 and 32 times per minute in the liquid medium at $37^0$ C. The assembly is suspended in the liquid medium in a 1000 ml beaker. The apparatus is operated generally for 15 minutes and observed for disintegration of tablets.

**Result:** The tablets pass the test if all the tablets disintegrate. In case one or two tablets fail to disintegrate, repeat the test on 12 additional tablets. The tablets pass the test if not less than 16 of the total 18 tablets tested have disintegrated.




DISINTEGRATION TEST APPARATUS

| Sr. No. | Type of Tablet | Time Limit |
|---|---|---|
| 1. | Oral Uncoated Tablets | 15 minutes |
| 2. | Film Coated Tablets | 30 minutes |
| 3. | Sugar Coated Tablets | 60 minutes |
| 4. | Soluble Tablets | 3 minutes |
| 5. | Effervescent Tablets | 5 minutes |
| 6. | Enteric Coated Tablets<br>In acidic medium pH 1.2<br>In phosphate buffer pH 6.8 | Should not disintegrate for 120 minutes. Must disintegrate within 60 minutes |

**2 e) Describe aerosol container with labelled diagram** — **3M (0.5 X 4 = 2M for parts and 1 M for dig.)**

**PARTS OF AEROSOL PACKAGING:**

1. Container: In pharmaceutical aerosol packaging, the containers are made from metal (tin-plated steel, aluminium and stainless steel), glass and plastic. These containers can withstand high pressures.
2. Valve: The valve should be such that it can be opened and closed. It delivers the content in the desired form. Three types of valves are continuous spray valve, metered valve and foam valve.
3. Actuator: It is fitted on the valve stem. It helps in easy opening and closing of the valve whenever it is required.
4. Dip tube: These are made from polyethylene or polypropylene. It is used to convey the liquid from the bottom of the container to the valve at the top and also

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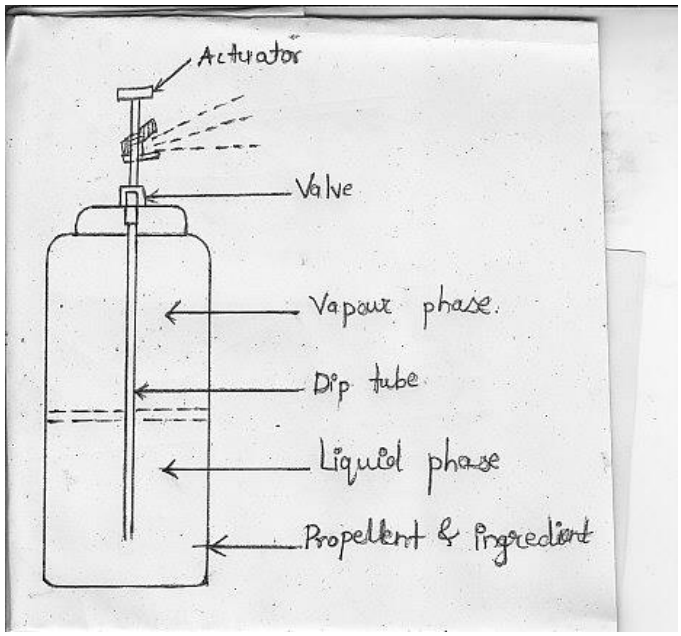
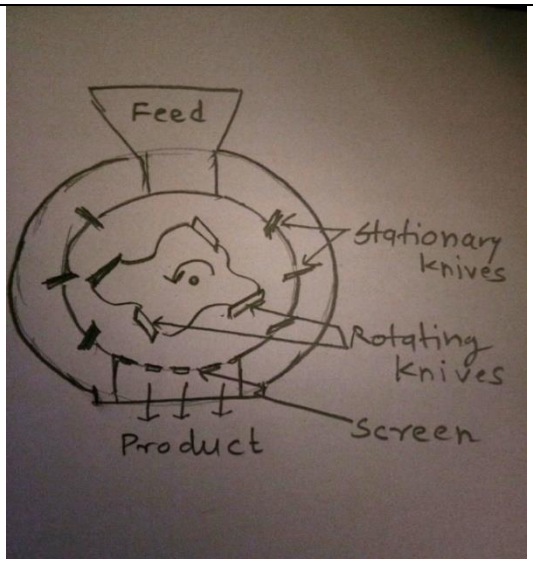
| | | prevents the propellant to come out without dispensing content of package.<br>**Aerosol container:**<br>  <br> | |
| **2** | **f)** | **Explain construction and working of Cutter mill or Hammer mill**<br>**Cutter mill**<br>**CONSTRUCTION:**<br>It consists of a hopper at top and metal casing enclosing two sets of knives i.e. stationary knives attached to stator and rotating are attached to rotor. The lower part of the casing consists of a screen , through which material can pass and collected in a suitable receiver, when the desired degree of size reduction is reached<br>**WORKING:**<br>The material is put in to the hopper. The material is powdered to the desired size, due to fast moving knives ( cutting phenomenon) and is collected under the screen This mill has the advantage of continuous operation because of change of jamming is less as the cutters are not fixed. | **3M**<br>**(1+1+1)** |




**Hammer mill**

**CONSTRUCTION:**

It consists of a stout metal casing enclosing to which four or more swinging hammer are attached. The lower part of the casing consists of a screen , through which material can pass and collected in a suitable receiver , when the desired degree of size reduction is reached

**WORKING:**

The material is put in to the hopper which is connected with the drum. The material is powdered to the desired size, due to fast rotation of hammer and is collected under the screen. This mill has the advantage of continuous operation because of change of jamming is less as the hammers are not fixed. The mill can produce coarse to moderately fine powder

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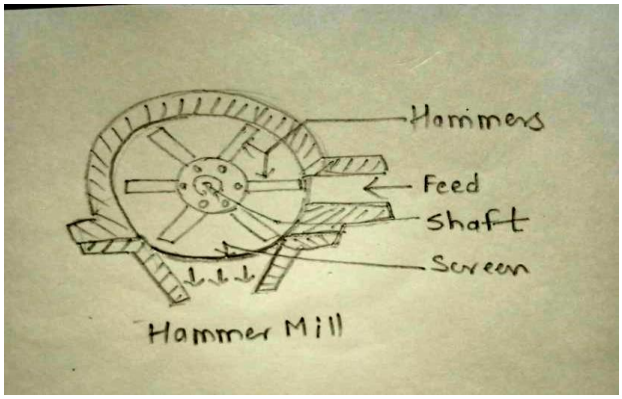
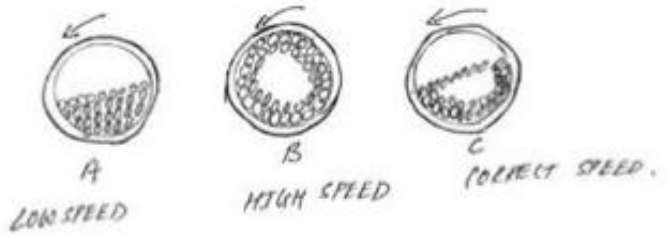
| | | **DIAGRAM:**<br>  | |
| **3** | | **Attempt any FOUR of the followings** | **12M** |
| **3** | **a)** | **Explain the working of ball mill with a well labeled diagram and give any two advantages**<br>**Working**: **(1.5M)**<br>The drug to be ground is put into the cylinder of the mill and is rotated. The speed of the rotation is very different. At low speed, the mass of balls will slide or roll over each other and only a negligible amount of size reduction will occur. At a high speed, the balls will be thrown out to the walls by centrifugal force and no grinding will occur. But at about 2/3rd of the speed, the centrifugal force just occurs, the balls are carried almost to the top of the mill and cascading occurs. By this way, the maximum size reduction is effected by the impact of particles between the balls and by attrition between the balls. After a suitable time, the material is taken out and passed through a sieve to get powder of the required size.<br>**Diagram :0.5M**<br>  | **3M**<br>**Working 1.5M,diagram 0.5M and advantage 1M** |

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| | | **Advantages:(1M=0.5x2)**<br>i)It can produce very fine powder<br>ii)It is capable of grinding wide variety of materials of differing character & of different degree of hardness.<br>iii)It can be used in a completely enclosed form , which makes it especially suitable for use with toxic materials.<br>iv)Can be sterilized & usedfor parenteral& ophthalmic preparations.<br>v)Can be used for batch as well as continuous grinding<br>vi)can be used for dry as well as wet grinding. | |
| **3** | **b)** | **Explain construction and working of cyclone separator with a well labelled diagram.**<br><br>**Construction: (1M)**<br>• It consists of cylindrical vessel with a conical base.<br>• In upper part of vessel is fitted with a tangential inlet and fluid outlet.<br>• At the base it is fitted with solid outlet.<br><br>**Working: (1M)**<br>• In cyclone separator the centrifugal force is used to separate solids from fluids separation depends on particle size and density of particles<br>• The suspension of solid in gas is introduced tangentially at a very high velocity.<br>• The rotary movement takes place within the vessels.<br>• The fluid is removed from the outlet at the top.<br>• The rotatory flow within the cyclone separator causes the particle to be acted on by centrifugal force.<br>• The solids are thrown out to the wall and fall to the conical base for discharge. | **3M,**<br><br>**(1 Construction,1M working and 1 for diagram)** |

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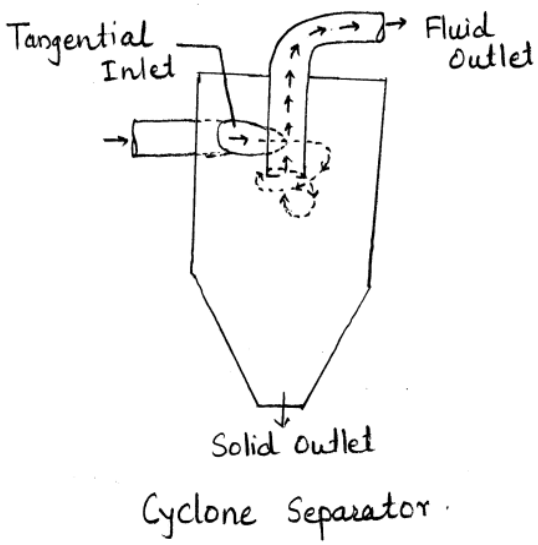
| | | **Diagram (1M)**<br>  <br><br>Cyclone Separator | |
| **3** | **c)** | **Describe the stages of percolations**<br>**a. Imbibition**:<br>• Drug is kept is moistened with sufficient quantity of menstruum.<br>• Allow to stand for 4 hr.<br>**Significance**:<br>i. It allow the swelling of tissue of drug before packing.<br>ii. It is imbibed for uniform packing in percolator.<br>iii. It allows the entrapped air to escape.<br>iv. Quantity of menstrum required can be reduced.<br>**b.Maceration**:<br>• The moistened drug is left in contact with menstruum for 24 hrs.<br>• During this period, menstruum dissolves the active constituents of the drug.<br>**c.Percolation**:<br>• It consists of downward displacement of the saturated menstrum formed in maceration and extraction.<br>• After collecting 3/4$^{th}$ volume of product then marc is pressed.<br>• Mix the liquids. | **3M**<br>**For each stage 1M** |

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| **3** | **d)** | **Explain various grades of powders**<br>**According to IP 2010 official grades of powders are as follows:**<br>**(consider if 5 grades are correctly mentioned according to old volumes)**<br>**i. Coarse powder:** A powder of which all particles pass through sieve no 10 with nominal aperture size 1.7mm and not more than 40% pass through sieve no 44 with nominal aperture size 355um.<br>**ii. Moderately Coarse powder:** A powder of which all particles pass through sieve no 22 with nominal aperture size 710um and not more than 40% pass through sieve no 60 with nominal aperture size 250um.<br>**iii. Moderately fine powder:** A powder of which all particles pass through sieve no 44 with nominal aperture size 355um and not more than 40% pass through sieve no 85 with nominal aperture size 180um.<br>**iv. Fine powder:** A powder of which all particles pass through sieve no 85 with nominal aperture size 180 um.<br>**v.Very fine powder:** A powder of which all particles pass through sieve no 120 with nominal aperture size 125 um.<br>Vi. **Microfine powder:** A powder of which not less than 90%by weight of particles pass through a sieve with nominal mesh aperture size of 45 um<br>vii. **Superfine powder:** A powder of which not less than 90%by weight of particles are less than 10 µm in size. | **3M**<br>**(0.5 X 6 = 3M)** |
| **3** | **e)** | **Write the applications of simple distillation in pharmacy.**<br>i.It is used for the preparation of distilled water and water for injection.<br>ii. Preparation of many volatile oils and aromatic water.<br>iii. Purification of organic solvent.<br>iv. Preparation official compound like spirit of nitrous ether.<br>v. Preparation official compound like spirit of aromatic spirit of ammonia.<br>vi. To separate volatile and non-volatile solvents | **03M.**<br>**0.5 X 6** |

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| **3** | **f)** | **State the following:**<br>**i)Arista:** These are weak alcoholic preparations prepared by making a decoction of the drugs and then allowing them to undergo fermentation by the help of raw sugar or honey. The fermentation is done for a period of 7-10 days in hot weather and for 15-30 days in cold weather<br>**ii) Churna:** These are powdered mixtures prepared by mixing dry mineral, animal or vegetables substances in a pestle mortar. The powdered mixture is then passed through cloth, linen or fine sieve. In case jiggery is to be mixed with powder, it should be equal to the quantity of churna and in case of sugar, it should be double the quantity of churna. Churnas are usually taken with milk, hot water and cow's urine. Churnas are usually given in bulk. Its action is quick but its effect is only temporary.<br>**iii)Taila:**<br>These are medicated oils which are prepared by boiling drugs in water, milk or other liquid substances mixed with oil until water content is evaporated .The oil thus prepared are generally meant for local application in some cases ,the oils are used internally. | **3M**<br>**1M for each definition** |
| **4** | | **Attempt any FOUR of the followings** | **12M** |
| **4** | **a)** | **Describe the factors which affect rate of the evaporation of liquid**<br>**Factors affecting evaporation:**<br>**1)Temperature:**<br>The rate of evaporation is directly proportional to temp of liquid.<br>**2)Temperature and time of evaporation:**<br>It has been observed that exposure to relatively a high temp for short period of time may be less harmful to the active principles of a drug than a lower temp with exposure for a longer period.<br>**3)Temp and moisture content:**<br>Some drug constituent decomposes more readily in the presence of moisture if heated at high temp. This is due to the hydrolysis of the active constituent<br>To avoid decomposition to the active principle of such material the evaporation is done at low temp and then final drying is done at high temp. When only little moisture remains in it. | **03M.**<br>**0.5 X 6** |

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| | | **4)Types of product required:**<br>On evaporation of the liquid the conc. Liquid, semisolid and solid are formed. The selection of the method and the equipment required for the evaporation depends upon the type of the product required<br>**5)Effect of concentration:**<br>During evaporation the upper layer of the liquid under evaporation has a tendency to form a film and formation of precipitate in the product which results in lowering down of the rate of evaporation. Therefore, efficient steering is required in order to prevent degradation of the product at the bottom due to excessive heat and it will also prevent deposition of solid<br>**6)Surface area:**<br>The rate of evaporation is directly proportional to the surface area of the evaporator, in which the liquid is evaporated.<br>**7)Vapour pressure of the liquid to be evaporated:**<br>The rate of evaporation is directly proportional to the vapour pressure of the evaporating liquid. | |
| **4** | **b)** | **Describe construction of autoclave with diagram.**<br>**Construction: ( 2 mark)**<br>It consists of a string metallic chamber usually made of stainless steel. It has a cover fitted with a steam vent, pressure gauze and a safety valve. Rubber gasket is fitted on the inner side of the lid in order to make autoclave airtight. The cover is closed with wing nuts and bolts. The electrically heated element is fitted at the bottom to heat the water to convert into steam. The perforated inner chamber is place on the stand. The material to be sterilized is loosely packed into it. | **3M**<br>**1M Diagram and 2M construction** |

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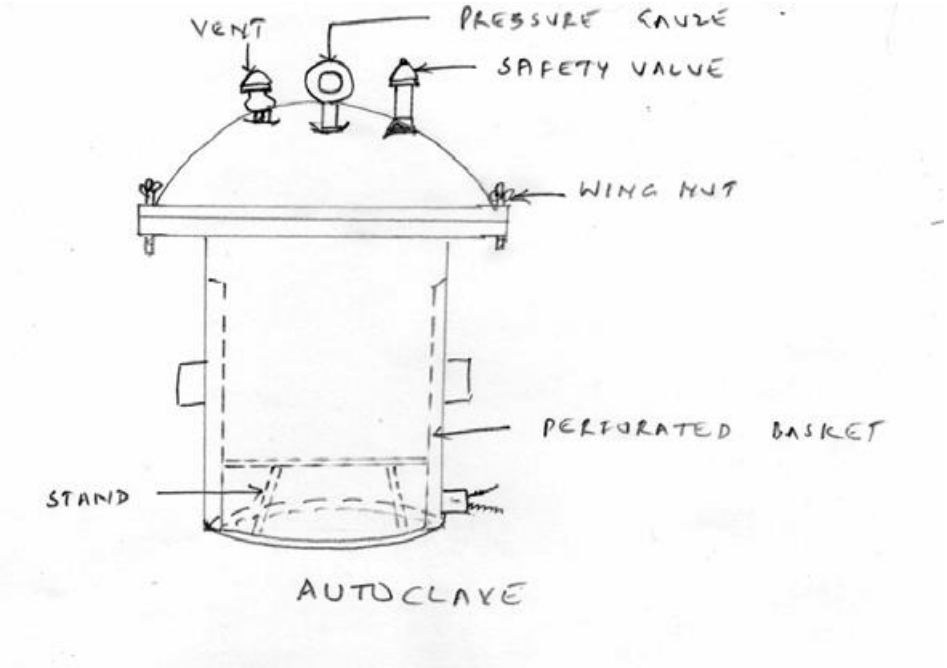
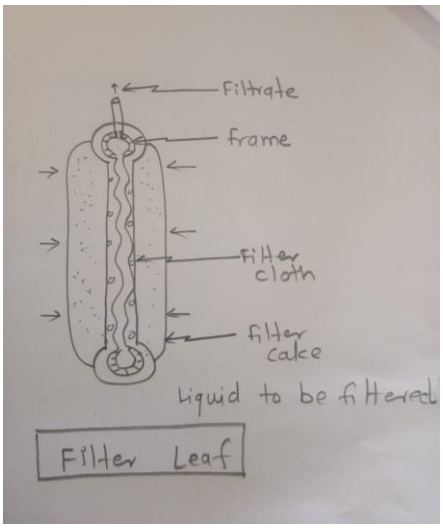
| | | **Diagram: ( 1 mark)**<br>  | |
| **4** | **c)** | **Explain working,construction of filter leaf with neat diagram.**<br>**Construction of filter leaf (1M)**<br>It consists of metal frame enclosing a wire screen or a grooved plate.<br>The screen is covered by filter cloth which is fitted in frame, to grip the cloth.<br>The frame may be square, rectangle or circular in shape & outlet is connected to vacuum.<br>**Diagram: (1M)**<br>  | **3M.**<br>**(1+1+1)** |

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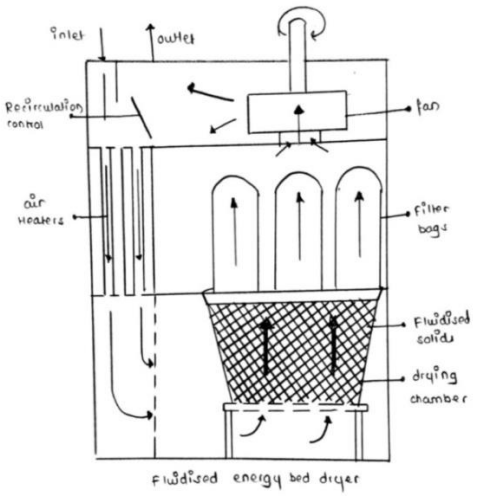
| | | **Working of Filter leaf:**<br>• The filter leaf is placed in a vessel containing slurry.<br>• When vacuum is applied, the liquid flows inside the filter through filter cloth, leaving behind the cake on the surface of cloth.<br>• The cake can be washed by immersing in a vessel containing water or reverse flow of air | |
| **4** | **d)** | **Describe working of FBD with well labelled diagram.**<br>**Working of FBD(2M)**<br>Two types of FBD are used in pharmaceutical industry. There are:<br>1. Vertical FBD<br>2. Horizontal FBD<br>The fluidising air stream is induced by a fan which is mounted in the upper part of dryer. The air is heated to the required temperature in air heaters and passed through the wet material contained in a drying chamber fitted with a wire mesh support at bottom. The air flow rate is adjusted by means of recirculation control and fabric filter bags are provided to prevent the passage of fine particles. This type of FBD is a batch type dryer and the drying chamber is removed from the unit for charging ad dumping. The FBD available in different capacities ranging from 5 kg to 200 kg with an average drying time of about 20-40 min.<br>**Diagram:(1M)**<br>  <br><br>Fluidised energy bed dryer | **3M**<br>**2M Working and 1M for diagram** |

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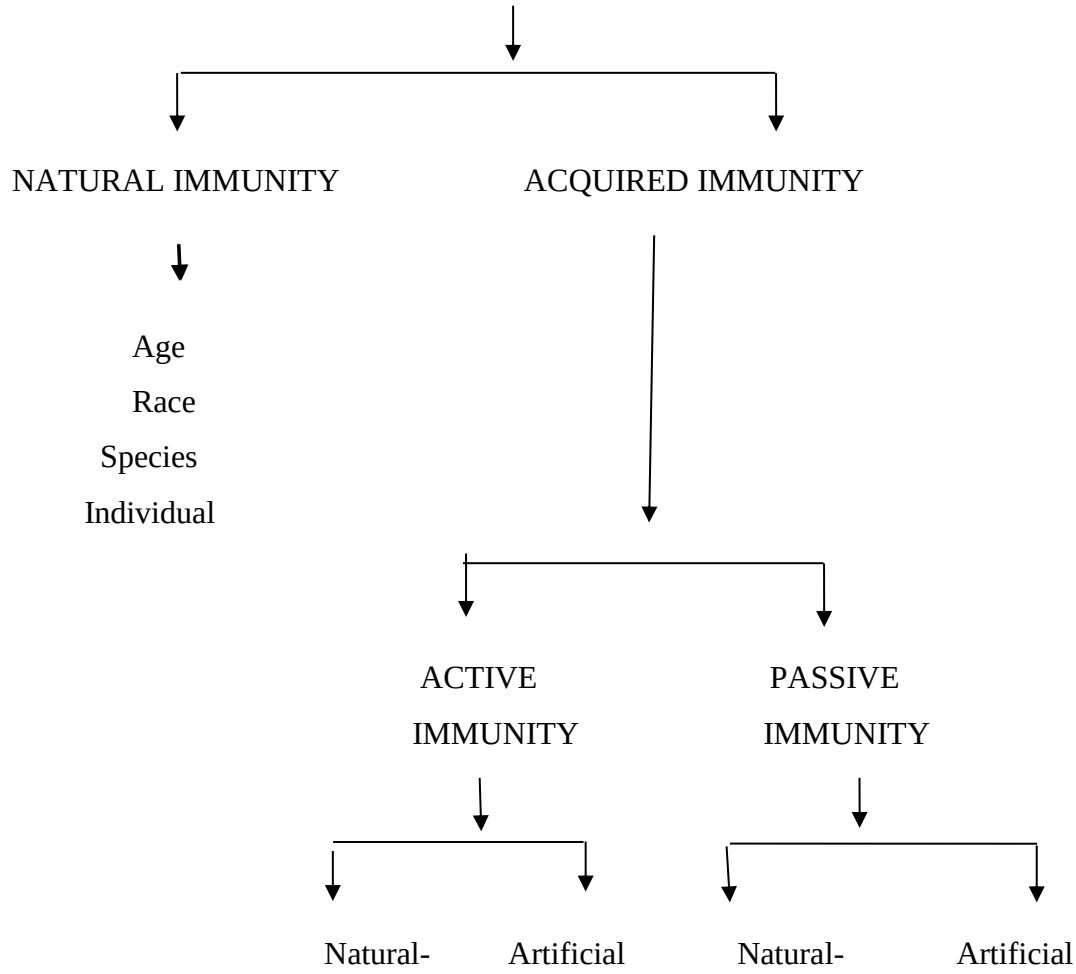
| **4** | **e)** | **Explain types of Immunity.** | **3M.** |

**TYPES OF IMMUNITY**




**Natural immunity**

- **Age** : Majority of children in the age group between 2-5 years are susceptible to diphtheria disease, whereas adults are immune to it.
- **Race** : While the negroes have a high resistance to yellow fever, the white races are very susceptible to it.
- **Species**: Men are susceptible to typhoid fever, whereas mice are immune to it.
- **Individuals**: Some persons have more resistance against cold and skin diseases than others.

**Acquired Immunity**

| | | | |
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| | | **(i)Naturally acquired active immunity**<br>• Body takes active part in formation of antibodies<br>• The infection stimulates the body to produce antibodies, which remain in the body to immune the person.<br>• Immunity may last for a life time *e.g.* small-pox, polio *etc.*,<br>• May be for a short duration e.g. pneumonia, influenza<br>**(ii)Artificial acquired active immunity**<br>• When **the antigenic substances** such as vaccines are introduced into the body, it stimulates the body, to produce antibodies.<br>• It is produced by **injecting** attenuated living micro-organisms, dead bacteria and bacterial derivatives. The process is also called immunization**.**<br>**Passive immunity**<br>• The body does **not play an active role** in, having immunity against a disease.<br>• It **receives readymade antibodies** to produce immunity.<br>**(i)Naturally acquired passive immunity**<br>• Children aged less than a month, are generally immune to certain infectious diseases. This is because they have received the antibodies from the mother.<br>• The antibodies of diphtheria, measles and chicken-pox are transmitted in this way.<br>**(ii) Artificial acquired passive immunity:**<br>• The immunity is produced by injecting ready-made antibodies containing preparation (antiserum, sera) into the body<br>• It lasts for a short time only. | |
| **4** | **f)** | **Describe the process of manufacturing of hard gelatine capsules.**<br>**Process of manufacturing of hard gelatine capsules. (2M)**<br>i)Capsules are filled in the loading tray& placed over the filling bed.<br>ii) Cam handle is operated to separate the capsule caps from their bodies.<br>iii) The powder tray is placed on the filling tray to prevent the material from being lost,<br>iv) The powder to be filled in the capsules is placed in powder trays and spread with the | **3M.**<br>**2M for process and 1M for** |

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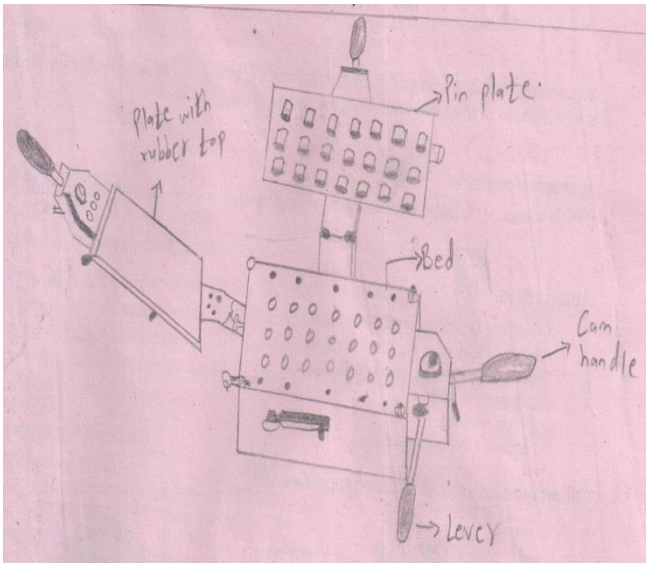
| | | help of a powder spreader, to fill the bodies of the capsules uniformly.<br>v) The pin plate is lowered so as to press the powder into the bodies<br>vi) After pressing, the pin plate is raised and the excess powder is filled into the bodies of the capsules.<br>vii) The cap-holding tray is again placed in position. The sealing plate with rubber top is lowered and the lever is operated forcing the bodies into the caps,<br>vii)The well-filled capsules are then cleaned by wiping with clean cloth. This gives good shine to the capsules.<br>**Diagram (1 M)**<br>  <br> | **diagram** |
| **5** | | **Attempt any FOUR of the followings** | **12M** |
| **5** | **a)** | **Describe the method of preparation of BCG vaccine with dose, storage and uses.**<br>**Method of preparation of BCG vaccine**:<br>It is freeze- dried preparation containing live culture of the bacillus Calmette and Guerin strain of Mycobacterium tuberculosis.<br>**Preparation**: The bacilli are grown on a suitable culture media until 1 mg when plated out on a suitable solid culture media shows not less than 20 million colonies. The growth period should not be more than 14 days in any case. After a suitable growth, they are separated by filtration in the form of a cake. The cake is homogenized in a grinding flask | **3M (1.5 + 0.5+0.5+0 .5)** |

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| | | and suspended in a suitable sterile liquid medium designed to preserve the antigenicity and viability of the vaccine. The suspension is transferred into the final sterile containers and freeze-dried. Then containers are sealed so as to prevent contamination or deterioration of the vaccine. The vaccine contains no antimicrobial agent.<br>**Dose**: Prophylactic, 0.1 ml as a single dose by intra-cutaneous injection.<br>**Storage**: Store in hermetically sealed light resistant glass containers at a temperature between $2^0$ C and $8^0$ C. The reconstituted vaccine should be used immediately after its preparation.<br>**Uses**: Immunising agent which provides protection against tuberculosis. | |
| **5** | **b)** | **Give the significance of sterilization using bactericidal solution, explain the method and name the bactericidal agents.**<br>**Significance:**<br>The lethal effect of bactericide increases with the rise of temperature.<br>This method is used for sterilizing aqueous preparation, which is unstable at the higher temperature, hence moist heat sterilization is not applicable method for sterilization.<br>It is official in British Pharmacopoeia and Indian Pharmacopoeia.<br>**Method**<br>In this process the medicament is dissolved or suspended in a suitable solution of following bactericidal, as given in table, then preparation is sealed in final container and heated at 98°-100°C for 30 minutes in boiling water.<br>IP 1985 permitted the use of following bactericides- | **3M (1+1+1)** |

| **Name of Bactericides** | **Concentration of Bactericide % w/v** |
|---|---|
| **For Injection:**1) Chlorocresol | 0.2 |
| 2) Phenyl mercuric acetate<br>or Phenyl mercuric nitrate | 0.002 |
| **For Eye drops:** 1) Chlorohexidine acetate | 0.01 |
| 2) Benzalkonium chloride | 0.01 |
| 3) Thiomersal | 0.01 |

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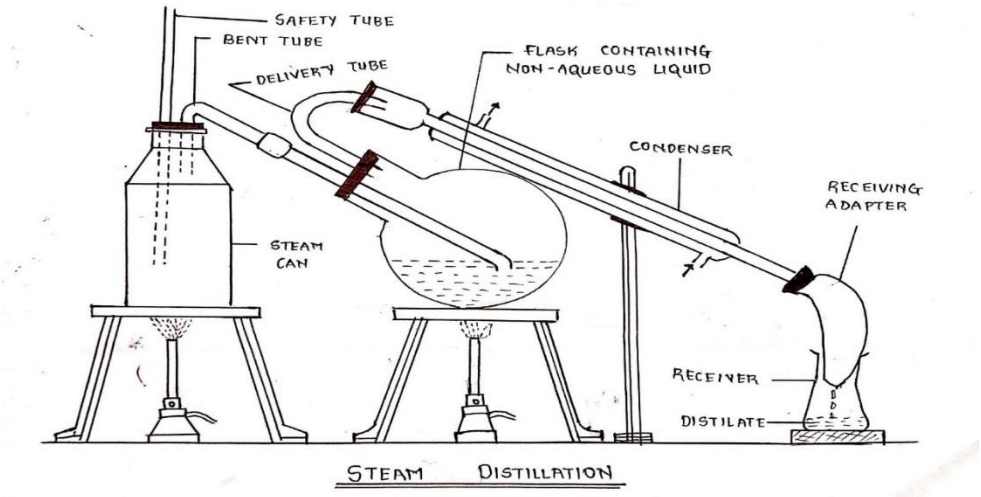
| **5** | **c)** | **Describe the method of distillation for immiscible solution.**<br>**Method of separation of two immiscible liquids**.<br>• The apparatus consists of steam generator,still,condenser,and receiver. In steam distillation process, a current of steam is passed through a immiscible liquids in a still at boiling point of water.<br>• The mixed vapour from still (steam vapour& immiscible liquid) vapour are condensed & mixed distillate is collected. The distillate consists of water & immiscible liquid in suitable proportion<br>• The distillate can be collected in Florentine receiver for separation of oil & water.<br><br>**Diagram:**<br>  <br><br>STEAM DISTILLATION | **3M**<br>**(1.5 +1.5 =3M)** |
| **5** | **d)** | **Explain the construction and working of triple roller mill.**<br>**Construction:**<br>• It consists of 3 rollers.<br>• Rollers are made up of hard abrasion resistant material.<br>• Rollers are arranged very close to each other's.<br>• Rollers are rotated at different speed & in opposite directions.<br>• Material gets crushed when it comes in between rollers. | **3M**<br>**(1+1+1)** |

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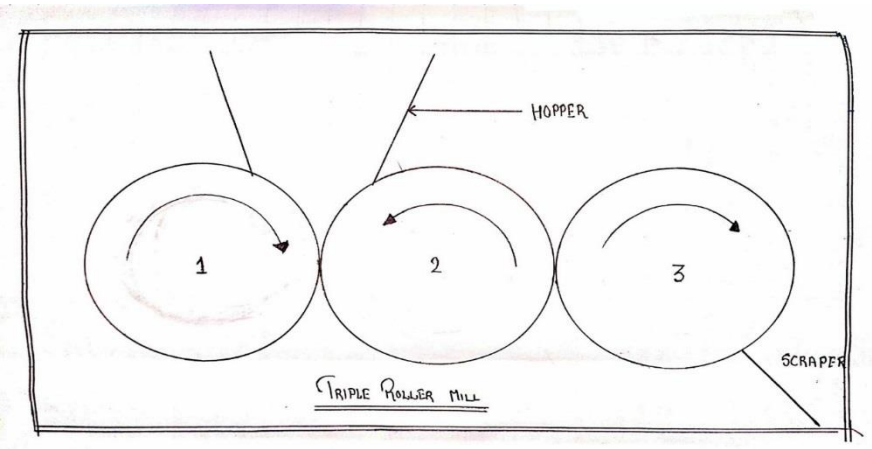
| | | **Working:**<br>• Material want to be mixed put in to hopper.<br>• From hopper material come between roller no.1 and roller no.2 and is reduced in size.<br>• The gap between roller no.2 and roller no.3 is less than that between roller no.1 and roller no.2<br>• Due to which material is crushed and gets mixed.<br>• A Scraper is provided to remove the material from roller no.3<br><br>**Diagram**:<br>  <br> | |
| **5** | **e)** | **Write the stages involved in sterilization of surgical dressing.**<br>**Stages of sterilisation are:**<br>1) Pack or wrap the unsterilized surgical dressing into a suitable device/perforated container or any packaging material i.e parchment paper.<br>2) Load this container into sterilizer. Loading ang packaging should be done properly to ensure the uniform steam penetration and movement.<br>3) Close the sterilizer and expose the surgical dressing at 121°C for 30-45 min.<br>4) Switch off the sterilizer and condense the steam in it, allow to cool and unload the sterilizer.<br>5) Containers are labelled with date of sterilization to prevent overload storage. | **3M** |

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| **5** | **f)** | **How will you prepare 5 fl. 02 solutions and using that prepare a 5 litre 1 in 2000 solutions?**<br>**Note: Let the student assume any data for strength of concentrated solution and solve the problem, appropriate marks should be allotted**<br>Data Given:<br>Strength of concentrated solution = 5% (assumption)<br>Strength of Dilute solution = 1/2000 = 0.05%<br>Volume of dilute solution required = 5 litre = 5000 ml<br>**Part A: Preparation of 5% , 5 Fl.Oz solution**<br>Amount required for preparing 1% w/v solution in imperial = 4.375 grain<br>Therefore, for preparing 5% w/v solution<br>= 4.375 X 5 X 5<br>= 109.37 grain.<br>**Part B: Preparation of dilute solution.**<br>Degree of dilution = Strength of concentrated/ Strength of Dilute solution<br>= 5/0.05<br>= 100 times.<br>Volume of concentrated solution required = volume of dilute solution to be prepared/ Degree of dilution<br>= 5000/100<br>= 50 ml.<br>Therefore, 50 ml of 5% concentrated solution is used to prepare 5 litre 1 in 2000 solution. | **3M** |
| **6** | | **Attempt any FOUR of the followings** | **16M** |
| **6** | **a)** | **Explain any four manufacturing defects in tablet manufacturing.**<br>**i) Capping:** There is partial or complete removal of top or bottom portion of the tablet. The reasons are: Excessive fines, defective punches and dies, high speed of the machine, too dry granules, or high degree of compaction.<br>**ii) Picking and sticking:** In picking, the material is removed or picked up by the upper punch from the upper surface of the tablet. In sticking, the material sticks to the wall of the die. These defects appear due to worn out dies and punches, small quantity of | **4M**<br>**(1 X 4 = 4M)** |

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| | | lubricants, presence of moisture in granules, excess powder in granules, scratches on the surface of face of punch or defects in the formulation.<br>**iii) Mottling:** Mottling means an unequal distribution of colour on the surface of coloured tablets. This defect occurs due to following reasons: migration of dye in the granules during drying, use of different colour of medicament and excipients.<br>**iv) Weight variation:** During compression of granules in a tablet machine, the tablets do not have a uniform weight. The reasons are: Granules not uniform in size, Excess powder in granules, no proper mixing of lubricants, no uniform flow of granules from hopper to die, variation in speed of machine.<br>**v) Hardness variation:** Causes same as weight variation. Hardness depends upon weight of material and space between upper and lower punches during compression. If any of these varies the hardness will vary.<br>**vi) Double impression:** This defect occurs when the lower punch has a monogram or some other engraving on it. During compression, the tablet receives an imprint on the punch. Due to some defect in the machine, the lower punch moves slightly upward before ejection of a tablet and gives a second though light imprint on the tablet. | |
| **6** | **b)** | **What is aseptic technique? List the various sources of contamination and explain the sterility test.**<br>**Aseptic technique**: **(0.5 M)**<br>The method which is used to prevent the access of microorganism during the preparation of parenteral product and their testing are called "Aseptic Technique".<br>**Sources of contamination: (any 4 = 2M)**<br>1) Atmosphere, which is contaminated with dust, droplet and droplet nuclei becomes the breeding ground of microorganism.<br>2) The hands are a major means of transmitting infection.<br>3) Coughing, sneezing and spitting can cause contamination considerable distance.<br>4) The clothes which absorb dust particles are also a source of contamination. A handkerchief is the richest source of contamination.<br>5) The hair.<br>6) Unsterile equipment. | **4M (0.5 +2+1.5 = 4M)** |

7) Working surface.

**Test for Sterility: (1.5M)**

**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. These test should be carried out in strictly aseptic condition.

**Method of testing :** Test of sterility may be carried out by

1) Membrane filtration method

2) Direct inoculation method

**1) Direct inoculation method:** 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) are 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.

**2) Membrane filtration method :** 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.

**Results :**If no growth of micro-organism is found in any of the tubes, the sample is declared to have pass the test and same test is repeated for two times.

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| **6** | **c)** | **Find the volume of 20%, 15%, 10% and 8% alcohol should be mixed to get 12% alcohol 300 ml**<br>20 % 12-8 = 4 parts of 20 %<br>15 % 12-10 = 2 parts of 15 %<br>12 %<br>10 % 12-15 = 3 parts of 10 %<br>8 % 12-20 = 8 parts of 08 %<br><br>Total parts = 4 + 2 + 3 + 8 = 17 parts<br><br>For 300 ml of 20 % alcohol = $\frac{300 \times 4}{17}$ = 70.58 ml<br>For 300 ml of 15 % alcohol = $\frac{300 \times 2}{17}$ = 35.29 ml<br>For 300 ml of 10 % alcohol = $\frac{300 \times 3}{17}$ = 52.94 ml<br>For 300 ml of 8 % alcohol = $\frac{300 \times 8}{17}$ = 141.17ml | **4M** |
| **6** | **d)** | **Define mixing, explain types and mechanism of mixing.**<br>**Definition of Mixing: (1M)**<br>Mixingis the method in which two or more than two substances are combined together. | **4M (1+1.5+1.5)** |

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| | | **Types of mixtures- (any three 1.5M)**<br>**1) Positive Mixture**-When two/more miscible liquids are mixed or soluble solid is dissolved in water, the mixtures are called as positive mixture .e.g. Solution. It is irreversible.<br>**2) Negative Mixture**-Two immiscible liquids are mixed or insoluble solids are mixed with water it forms negative mixture. E.g. emulsion, suspension, mixtures. It is reversible.<br>**3) Neutral Mixture**-The substances do not have tendency to mix but once mix, don't separate after mixing. E.g. ointment, paste, cream.<br><br>**Mechanisms Of Mixing:(any three 1.5M)**<br>**1. Connective Mixing**: There is bulk movement of groups of particle from one part of powder bed to another. It occupy by inversion of the powder bed by means of blades or paddles.<br>**2. Shear Mixing:** When shear force occur it reduces the scale of segregation by thinning of dissimilar layers of a solid particles.<br>**3. Diffusion Mixing:** It occur when random motion of particles within a powder bed causes them to change position relative to one another. It produced by any agitation of powder. | |
| **6** | **e)** | **Discuss novel drug delivery system.**<br>New drug delivery system delivers or aimed at maximizing the drug effectiveness or minimizing the side effects.<br>Some of the Novel dosage forms are:<br>1) Implants<br>2) Controlled drug delivery system<br>3) Sustained release system<br>4) Liposomes<br>5) Erythrocytes<br>6) Nanoparticles | **4M (any four 1 marks each)** |

7) Prodrugs

8) Film and strips.

**1) Implants:**

The hypodermic tablets are placed under the skin by a minor surgery in order to release drugs over a prolonged periods of time. Now the magnetically controlled implants have been developed which can be opened or closed in order to release or stop the drug. The implants which are in capsule form, consist of a body and a cap. It can be opened by placing a magnet onthe skin and moving it in the desired direction. These implants are placed in the upper thigh at a depth of 5 mm. These implants are useful in hormone therapy

**2) Controlled Drug Delivery System:**

Controlled Drug Delivery Systems are devices which are formed by embedding the drug within polymeric matrix so that it get released slowly to the body over a very long period of time .The polymeric matrices used to hold drug reversibly are polyethylene silicon elastomer and cellulose ester.

These controlled drug delivery modules are punctured before administration with laser beam to make a small orifice of a few microns in diameter for the release of drug.

**3) Sustained Release system:**

Sustained released dosage forms are the new drug delivery system. They provide a therapeutic blood level of the drug which is attained rapidly and is maintained within narrow limits over extended period of a time, usually for 10 to 12 hrs. afer administration of single dose. Sustained release of dosage are achieved because they are enteric coated which get released in specific part of body.

**4) Liposomes:**

They are phospholipids which can be transported with hydrophilic and hydrophobic drugs.

Applications:

1) Liposomal drugs are used in diseases caused by intracellular parasites.

e. g. Malaria, Tuberculosis

2) Liposomes can be used to transport functional DNA/RNA molecules into cells.

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| | | **5) Erythrocytes:**<br>As the life span of Erythrocytes is 120 days drugs are encapsulated in Erythrocytes. The drug release for a prolonged period of time.<br>Applications:<br>1) Resealed erythrocytes of asparaginase have shown good results in asparaginase dependant leukaemia.<br>2) Resealed erythrocytes of methotrexate and adrianycin have been tried in cancer therapy.<br>**6) Nanoparticles:**<br>The particle size ranges from 200-500 nm. The system consists of drug and carrier to deposit the drug at the target site. The carrier used are serum albumin, bovine serum, albumin, gelatin, casein, s ethyl cellulose.<br>**7) Prodrugs:**<br>The compounds that shows desirable pharmacological activity after its metabolism are called as prodrugs. Prodrugs are used to increase solubility, stability and bioavailability of drug, masking the unpleasant taste and odour of the parent drug and reducing the toxicity.<br>**8) Film and strips:**<br>These are meant for topical application for slow release of drug over predetermined period of time. The film and strips which are becoming popular these days are<br>I. Zero order release film.<br>II. Buccal Stip.<br>III. Spray bandages. | |
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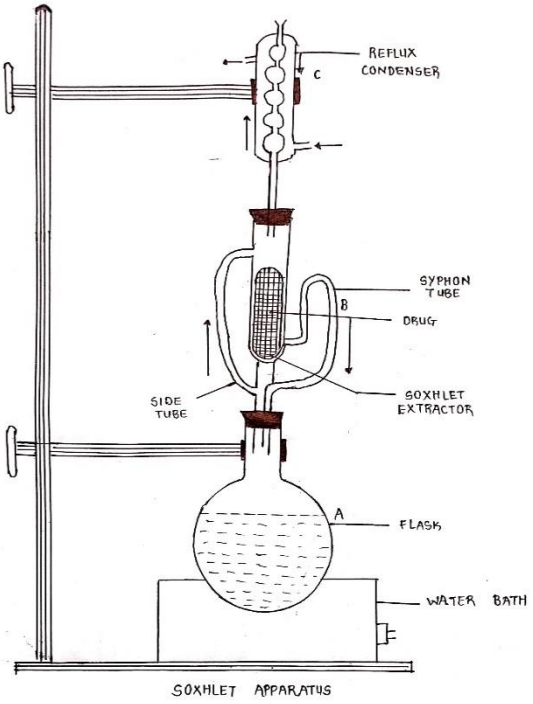
| **6** | **f)** | **Explain the method of hot percolation process with well labelled diagram and write its limitations.**<br>**Diagram: (1.5M)**<br>  <br><br>SOXHLET APPARATUS<br>**Procedure : (1.5M)**<br>1) The menstrum is placed in a round bottom flask.<br>2) The drug to be extracted is packed in a filter paper and placed in the body of Soxhlet extractor.<br>3) Solvent is boiled on heating a flask.<br>4) The vapour enter into the condenser through the side tube. The vapour get condensed into hot liquid, which falls on the column of drug.<br>5) The extractor gets filled with the solvent. Hot solvent extracts the active constituents of the drug.<br>6) The solvent having active constituents syphon over and run into the flask through the syphon tube.<br>7) The alternate process of filling and emptying the body of extractor goes on | **4M (1.5 +1.5 + 1)** |

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| | | continuously.<br>8) The soluble active constituents of the drug remain in the flask, while the solvent evaporates respectively.<br>9) This process continues till drug exhausted.<br>10) Normally the process is repeated about 15 times to exhaust the drug properly.<br>**Limitation : (0.5 X 2=1)**<br>1. Physical character of the drug: If the drug would block the soxhlet apparatus then this process cannot be used for extraction. Eg opium. Gum, resin, orange peel, etc.<br>2. Solvent: Only pure solvents or constant boiling mixtures can be used.<br>3. Chemical constituents of the drug: The process is unsuitable for drugs having thermolabile active constituents such as enzymes, alkaloids, anthraquinone derivatives, esters, etc. | |