



WINTER– 18 EXAMINATION

Subject Title: PHARMACEUTIC-1

Subject Code:

0805

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.



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Q. No.	Sub Q. N.	Answer	Marking Scheme
1		Answer any TEN of the followings:	20M
1	a)	Define following terms: (i) Syrups: are concentrated aqueous solution of sucrose (66.7% W/W) or other sugars .They are viscous in consistency & sweet in taste. (ii) Cream: Creams usually signifies a solid or semisolid emulsions or non-aqueous products of oils, fats & waxes used for emollient & protective effect.	2M (1M each)
1	b)	Enlist the ideal qualities of container. 1. Neutral 2. No interaction. 3. Stability against environmental factor. 4. Withstand wear and tear during handling. 5. Easy to remove dose. 6. Withstand changes in pressure and temperature. 7. Labelled easily 8. Non-toxic. 9. Closure easily removable/replaceable.	2M (0.5x4)
1	c)	Explain any four factors affecting size reduction. Factors affecting Size Reduction: i. Hardness: Soft material easy to break than hard. ii. Toughness: Drug with fibrous nature or those having high moisture content are tough and hard to reduce in size. iii. 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. iv. 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. v. Moisture content: The presence of moisture in the material influence 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. vi. 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. vii. Purity: In some mills during size reduction there is chances of addition of impurities. If high degree of purity is required avoid such mills or Mills should be cleaned thoroughly. viii. Physiological effect: Some drugs are very potent. During their size reduction in mill, dust is produced which may have effect on operator. ix. 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	2M (0.5x4)



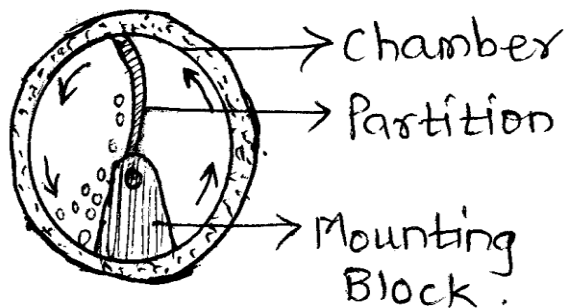
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		various stages e.g. preliminary crushing followed by coarse powder and then fine grinding. x. Bulk density: The output of the size reduction of the material in a machine depends upon the bulk density of the substance.	
1	d)	<u>Describe</u> simple maceration process. Simple maceration is a maceration process for tinctures made from organised drugs. In this process, the drug is placed with the whole of the menstruum in a closed vessel for seven days. During this period, shaking is done occasionally. After seven days, the liquid is strained and marc is pressed. The expressed liquid is mixed with strained liquid. It is then filtered to make a clear liquid. The final volume is not adjusted. The tinctures made by simple maceration process are Tincture of Orange, Tincture of Lemon, Tincture of Squill, etc.	2M
1	e)	<u>List</u> the precautions to be taken while using hot air oven. 1. Glass apparatus and equipment should be wrapped individually. 2. Articles should be placed in such away that they should not interfere with air flow 3. Once in operation oven should not be open 4. Proper biological indicators should be used 5. Thermolabile substance should never be sterilized in hot air oven. 6. It should never be over loaded.	2M (0.5×4)
1	f)	<u>Explain</u> friability test for evaluation of tablets. 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". The apparatus consists of a plastic chamber, which is divided into two parts and it revolves at a speed of 25 rpm. Twenty tablets are weighed and placed in a plastic chamber. The chamber is rotated for 4 minutes or 100 revolutions. During each revolution the tablet falls from a distance of 6 inch. The tablets are removed from the chamber after 100 revolutions and weighed. Loss in weight indicates the friability. The tablets are considered to be of good quality if the loss in weight is less than 0.8%.	2M



PLASTIC CHAMBER OF FRIABILATOR

1	g)	<p>Differentiate between Endotoxins and exotoxins.</p> <table border="1"> <thead> <tr> <th data-bbox="250 842 800 905">Exotoxin</th> <th data-bbox="800 842 1360 905">Endotoxin</th> </tr> </thead> <tbody> <tr> <td data-bbox="250 905 800 1115">1) These are toxins which can diffuse freely through the bacterial cell wall into the blood or the medium in which the microorganisms are growing</td> <td data-bbox="800 905 1360 1115">1) These toxins cannot diffuse through the bacterial cell wall, but remains in the cell of bacteria</td> </tr> <tr> <td data-bbox="250 1115 800 1220">2) These toxins are carried to all parts of the body</td> <td data-bbox="800 1115 1360 1220">2) Endotoxins are liberated only when the bacteria are disintegrated.</td> </tr> <tr> <td data-bbox="250 1220 800 1356">3) In its response the human body produces antibodies to neutralize its effect which is called as antitoxin</td> <td data-bbox="800 1220 1360 1356">3) The antibodies are named according to their mode of action</td> </tr> <tr> <td data-bbox="250 1356 800 1419">4) Diphtheria Antitoxin</td> <td data-bbox="800 1356 1360 1419">4) Diphtheria Toxoid</td> </tr> </tbody> </table>	Exotoxin	Endotoxin	1) These are toxins which can diffuse freely through the bacterial cell wall into the blood or the medium in which the microorganisms are growing	1) These toxins cannot diffuse through the bacterial cell wall, but remains in the cell of bacteria	2) These toxins are carried to all parts of the body	2) Endotoxins are liberated only when the bacteria are disintegrated.	3) In its response the human body produces antibodies to neutralize its effect which is called as antitoxin	3) The antibodies are named according to their mode of action	4) Diphtheria Antitoxin	4) Diphtheria Toxoid	2M (0.5x4)
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1	h)	<p>Name various Novel drug Delivery systems.</p> <ol style="list-style-type: none"> 1. Implants 2. Liposome drug carriers 3. Nanoparticles 4. Prodrugs 5. Films and strips 6. Resealed Erythrocytes etc. 	2M (0.5x4)										
1	i)	<p>Enlist the ideal qualities of Filter aids.</p> <p>Ideal qualities of filter aid: It should remain suspended in the liquid.</p> <ol style="list-style-type: none"> 1. It should be free from impurities. 2. It should be inert. 3. It should have a particle size distribution suitable for retention of solid. 4. It should have structure that permits formation of porous cake. 	2M (0.5x4)										



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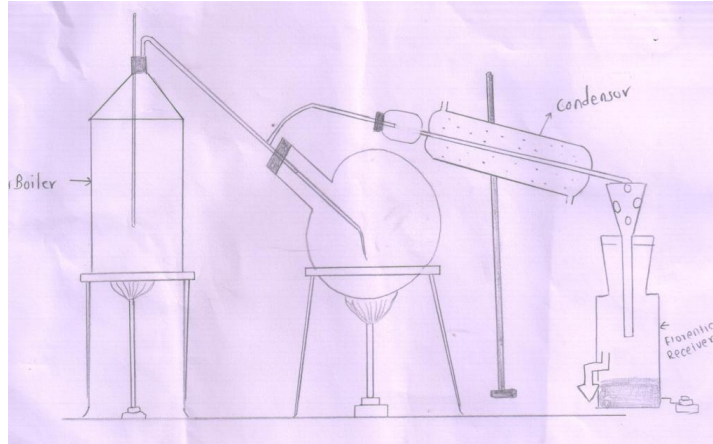
1	j)	<p>Write the <u>disadvantages</u> of formaldehyde gas when used for sterilization.</p> <ol style="list-style-type: none"> i. Weak penetration power. ii. Difficult to maintain high conc. iii. Require high humidity for effectiveness. iv. Readily inactivated. v. Irritant to respiratory tract. vi. Difficult to remove adsorbed gas. 	2M (0.5×4)																											
1	k)	<p><u>Differentiate</u> between hard and soft gelatin capsules.</p> <table border="1" data-bbox="354 642 1295 1388"> <thead> <tr> <th data-bbox="354 642 477 680">Sr.No</th> <th data-bbox="477 642 911 680">Hard gelatin capsules</th> <th data-bbox="911 642 1295 680">Soft gelatin capsules</th> </tr> </thead> <tbody> <tr> <td data-bbox="354 680 477 789">1.</td> <td data-bbox="477 680 911 789">The hard gelatin capsule shell consists of two parts: Body and cap</td> <td data-bbox="911 680 1295 789">The soft gelatin capsule shell becomes a single unit.</td> </tr> <tr> <td data-bbox="354 789 477 865">2.</td> <td data-bbox="477 789 911 865">They are cylindrical in shape.</td> <td data-bbox="911 789 1295 865">They are available in round, oval and tube-like shapes.</td> </tr> <tr> <td data-bbox="354 865 477 974">3.</td> <td data-bbox="477 865 911 974">The contents usually consist of medicaments in the form of powder, beads or granules.</td> <td data-bbox="911 865 1295 974">The contents usually consist of liquids or semisolids.</td> </tr> <tr> <td data-bbox="354 974 477 1125">4.</td> <td data-bbox="477 974 911 1125">These are prepared from gelatin, titanium dioxide, colouring agent and plasticizer.</td> <td data-bbox="911 974 1295 1125">These are prepared from gelatin, more amount of plasticizer (sorbitol or glycerin) and preservative.</td> </tr> <tr> <td data-bbox="354 1125 477 1234">5.</td> <td data-bbox="477 1125 911 1234">Filling and sealing takes place in different steps.</td> <td data-bbox="911 1125 1295 1234">Filling and sealing are done in a combined operation of machines</td> </tr> <tr> <td data-bbox="354 1234 477 1272">6.</td> <td data-bbox="477 1234 911 1272">Shell is perfectly dry.</td> <td data-bbox="911 1234 1295 1272">Shell is not perfectly dry</td> </tr> <tr> <td data-bbox="354 1272 477 1348">7.</td> <td data-bbox="477 1272 911 1348">These capsules can be adulterated</td> <td data-bbox="911 1272 1295 1348">These capsules cannot be adulterated</td> </tr> <tr> <td data-bbox="354 1348 477 1388">8.</td> <td data-bbox="477 1348 911 1388">Eg. Becosules capsules</td> <td data-bbox="911 1348 1295 1388">Eg. Pudín Hara</td> </tr> </tbody> </table>	Sr.No	Hard gelatin capsules	Soft gelatin capsules	1.	The hard gelatin capsule shell consists of two parts: Body and cap	The soft gelatin capsule shell becomes a single unit.	2.	They are cylindrical in shape.	They are available in round, oval and tube-like shapes.	3.	The contents usually consist of medicaments in the form of powder, beads or granules.	The contents usually consist of liquids or semisolids.	4.	These are prepared from gelatin, titanium dioxide, colouring agent and plasticizer.	These are prepared from gelatin, more amount of plasticizer (sorbitol or glycerin) and preservative.	5.	Filling and sealing takes place in different steps.	Filling and sealing are done in a combined operation of machines	6.	Shell is perfectly dry.	Shell is not perfectly dry	7.	These capsules can be adulterated	These capsules cannot be adulterated	8.	Eg. Becosules capsules	Eg. Pudín Hara	2M (0.5 ×4)
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1	l)	<p><u>Describe</u> the type of mixing.</p> <p>Positive Mixing: In Positive mixing ,two or more than two miscible liquids are mixed or soluble solids are dissolved in water, This mixture does not represent any problem in mixing. Mixture formed is irreversible.</p> <p>Negative Mixing: In negative mixing,two immiscible liquids are mixed or insoluble solids are mixed with water it forms negative mixtures. For preparing such type of mixing a higher degree of mixing of materials is required. The mixture formed is reversible mixture.</p> <p>Neutral Mixing: In Neutral mixing, substances do not have the tendency to mix with each other immediately, but once mixed they do not separate after mixing. These mixtures are static in their behaviour</p>	2M																											

2		<p>Attempt any FOUR of the followings</p>	12M
2	a)	<p>Define and classify dosage form.</p> <p>Defination: Is a combination of the drug and different kinds of non drug components called additives.</p> <div data-bbox="321 569 1328 1209" data-label="Diagram"> <pre> graph TD DF[DOSAGE FORMS] --> SD[SOLID DOSAGE FORMS] DF --> LD[LIQUID DOSAGE FORMS] DF --> SS[SEMI-SOLID DOSAGE FORMS] SD --> U[UNIT dosage form] SD --> B[BULK] U --> U_list["Tablets Capsule Powder Pills Lozenge Cachets pastilles"] B --> I["INTERNAL FINE POWDER GRANULES & EFFERVES- CENT GRANULES RS"] B --> E["EXTERNAL i)Dusting powder insufflation Dentifrices (Tooth powders) Snuffs"] LD --> M[MONOPHASIC] LD --> BIP[BIPHASIC Emulsions Suspension] M --> EX["EXTERNAL Gargles Throat paints Mouth washes ThroatSprays Eye lotions ear drops Nasal drops Douches Enemas Liniments Lotions"] M --> IN["INTERNAL Syrup Elixir Linctuses Drop draugh"] SS --> SE["EXTERNAL Ointments Creams Pastes Jellies Suppository Pessaries"] </pre> </div>	<p>3M Defi. 1M</p> <p>2M</p>
2	b)	<p>Explain construction and working of ball mill.</p> <p>Construction: It consists of a hollow cylinder which is mounted on a metallic frame in such a way that it can be rotated on its longitudinal axis. The cylinder contains balls that occupy 30-50% of the mill volume. The ball size depends on the size of the feed and the diameter of the mill. The cylinder and balls are made of metal (also of rubber or porcelain)</p> <div data-bbox="500 1476 1023 1879" data-label="Diagram"> <p>The diagram shows a horizontal cylindrical ball mill mounted on a frame. Below it are three circular cross-sections labeled A, B, and C. Section A is labeled 'LOW SPEED' and shows balls at the bottom of the cylinder. Section B is labeled 'HIGH SPEED' and shows balls being lifted against the inner wall. Section C is labeled 'CORRECT SPEED' and shows balls cascading down from the wall.</p> </div>	<p>3M (1M)</p> <p>Dig. (1M)</p>



		<p>Working of Ball Mill: 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 $2/3^{\text{rd}}$ 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.</p>	(1M)
2	c)	<p>Define extraction and explain reserve percolation process.</p> <p>Definition: Extraction may be defined as the treatment of the plant or animal tissues with solvent, whereby active constituents are dissolved, and most of the inert matter remains undissolved.</p> <p>Reserve percolation:</p> <ul style="list-style-type: none">• In this process a part of percolate, generally $3/4^{\text{th}}$ volume of the finished preparation is reserved.(contains high solute concentration)• Then the percolation process is continued till the drug is completely exhausted.• The percolate is subjected to evaporation or distillation to convert in to soft extract.• Distillation will help to recover the costly solvent.• Hence the major portion of active constituents of the drugs are saved from deterioration• This soft extract is dissolved in reserve portion of percolate and sufficient menstruum is added to make up the volume.	3M 1M 2M
2	d)	<p>Give any <u>two</u> applications of simple distillation.Describe method of separation of two immiscible liquids.</p> <p>Applications of simple distillation(0.5 ×2)</p> <ol style="list-style-type: none">1) Preparation of distilled water and water for injection.2)Recovery of alcohol in preparation of dry extracts3)Many volatile oils and aromatic waters are prepared by simple distillation.4)Many official preparations are prepared by distillation, eg spirits of nitrous ether and Aromatic spirit of ammonia.5)Concentration of liquid and to separate non-volatile solid from volatile liquids such as alcohol and ether. <p>Method of separation of two immiscible liquids.</p> <ul style="list-style-type: none">• In case of immiscible liquids , each liquid exerts its own vapour pressure & neither liquid has any appreciable effect on the vapour pressure of the other.A mixture of immiscible liquids begins to boil, when sum of their vapour pressure is equal to atmospheric Pressure.• Thus in case of water & liquid which boils at much higher temp. than	3M (1M) 2M

water, the mixture boils below the boiling point of pure water



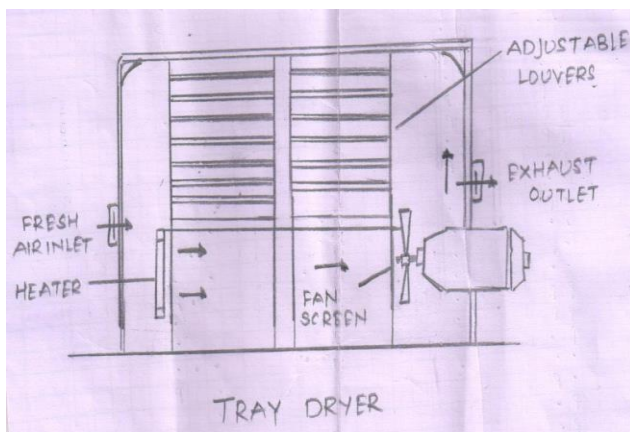
Separation of immiscible liquid is carried out by steam distillation.

- The apparatus consists of steam generator , still , condenser , receiver. In steam distillation process, a current of steam is passed through a immiscible liquids in a still at boiling point of water.
- 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
- The distillate can be collected in Florentine receiver for separation of oil & water.

2

e)

Explain construction and application of tray dryer.
Construction of tray dryer.



- The simplest form of dryer , the source of heat (electric heater or steam coil) is at floor level & relies on natural convection.
- Therefore no efficient heat transfer.
- Modern dryer consists of well insulated cabinet with strategically placed fans and heating coils.

3M
(1+1+1)



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		<ul style="list-style-type: none"> The air circulates through the dryer at 200- 2000 feet/mins In small ovens , there may be provision for a single passage of heated air , while in large units, the thermal efficiency is improved by recirculation of air which is reheated after its passage over each shelf. The forced air circulation increases heat transfer & reduces local vapour concentration. <p>Application of tray dryer. Used1) For drying of crude drugs 2)For chemicals 3)For powders 4)For Granules used in tablet manufacturing</p>	
2	f)	<p>In what volumes 30%.25%,18% alcohol should be mixed to get 500ml 20% alcohol.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>30 → 20 → 2 parts 18 → 20 → 10 parts</p> </div> <div style="text-align: center;"> <p>and</p> <p>25 → 20 → 2 parts 18 → 20 → 5 parts</p> </div> </div> <p>30 % = 2 parts 25% = 2 parts and 8 % = 10 + 5 = 15 parts.</p> <p>Volume of 30%: 19 parts; 02 parts 500 ml; ? $500 \times \frac{2}{19} = 52.63 \text{ ml}$</p> <p>Volume of 25%: 19 parts; 02 parts 500 ml ; ? $500 \times \frac{2}{19} = 52.63 \text{ ml}$</p> <p>Volume of 18%: 19 parts; 15 parts 500 ml ; ? $500 \times \frac{15}{19} = 394.73 \text{ ml}$</p> <p>Therefore, 52.63 ml of 30%, 52.63 ml of 25 % and 394.73 ml of 18 % alcohol should be mixed to get 20 % alcohol.</p>	3M
3		Attempt any FOUR of the followings	12M

3	a)	<p>Define and Classify immunity. Definition: The power of body to resist the effects of invasion of micro-organisms is called immunity. Classification:</p> <div style="text-align: center;"> <pre> graph TD Immunity --> NaturalImmunity[Natural Immunity] Immunity --> AcquiredImmunity[acquired Immunity] NaturalImmunity --> Age[1)age] NaturalImmunity --> Race[2)Race] NaturalImmunity --> Species[3)Species] NaturalImmunity --> Individual[4)Individual] AcquiredImmunity --> Active AcquiredImmunity --> Passive Active --> ActiveNatural[Natural] Active --> ActiveArtificial[Artificial] Passive --> PassiveNatural[Natural] Passive --> PassiveArtificial[Artificial] </pre> </div>	<p>3M 1M</p> <p style="text-align: center;">2M</p>
3	b)	<p>Define container and closure. Draw a well labelled diagram of Aerosol container. Definition: Container is a device that holds the drug and it may or may not be in direct contact with the pharmaceutical preparations. Closure is the device by means of which container can be opened and closed.</p> <p>Diagram of aerosol container:</p> <div style="text-align: center;"> </div>	<p>(1M for each def., 1 M diagram)</p>
3	c)	<p>Write construction and disadvantages of short tube evaporator.</p>	<p>3M (1+1+1)</p>

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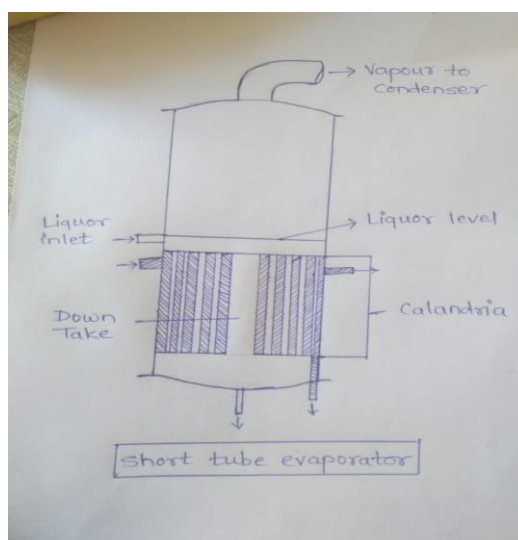
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Construction: (1M)

- It consists of number of tubes which are from 1 to 2 meters in length and from 40-80 mm in diameter.
- About 1000 tubes are fitted in a vessel upto 2.5 meter or more in diameter.
- This part is called as “calandria”.
- The tubes are filled with liquid and surrounded by steam.
- The level of liquid is maintained slightly above the top of the tube so that the space which is left in the evaporator can be used for the purpose of separation of from boiling liquid.

Diagram: (1M)



Disadvantages: (0.5 X 2 = 1M)

1. It is quite complicated and expensive in construction.
2. Difficult to clean.
3. Maintenance is costly.

3

d) **Explain any four factors affecting filtration. Draw a well labelled diagram of leaf filter.**

3M

Factors which affect the rate of filtration are: (0.5x 4)

1. Pressure: The rate of filtration of liquid is directly proportional to the pressure difference between the filter medium and filter cake. Thus, the rate of filtration can be increased by applying pressure on the liquid being filtered or by decreasing the pressure beneath the filter.

(2+1)

2. Viscosity: The rate of filtration is inversely proportional to the viscosity of the liquid undergoing filtration. Liquids which are very viscous get filtered slowly. Reduction of viscosity of a liquid by raising the temperature is frequently done in order to accelerate filtration.

3. Surface area of filter media: The rate of filtration is directly proportional to the surface area of filter media. Filter press works on this principle.

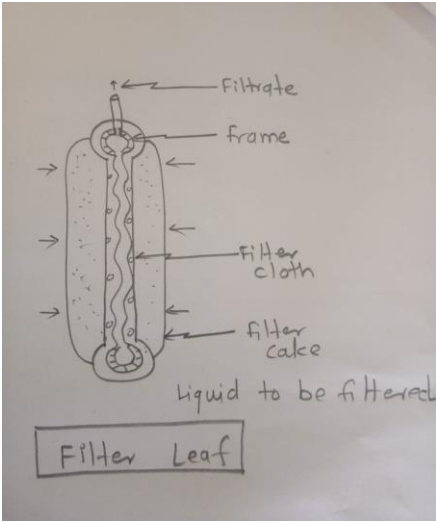
4. Temperature of liquid to be filtered: Viscosity is reduced by a rise in temperature and filtration of viscous oils, syrups, etc. is often accelerated by filtering them while they

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	<p>are still hot.</p> <p>5. Particle size: The rate of filtration is directly proportional to the particle size of the solid to be removed. It is easier to filter a liquid having coarse particles than that having finely divided particles.</p> <p>6. Pore size of filter media: The rate of filtration is directly proportional to the pore size of filter media.</p> <p>7. Thickness of cake: The rate of filtration is inversely proportional to the thickness of the filter cake formed during filtration. As the filtration process proceeds, thickness of cake increases which decreases the rate of filtration.</p> <p>Diagram of leaf filter :</p> 	
<p>3</p>	<p>e) Define the official grades of powders according to I. P.</p> <p>According to IP 2010 official grades of powders are as follows: (consider if 5 grades are correctly mentioned according to old volumes)</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>iv. Fine powder: A powder of which all particles pass through sieve no 85 with</p>	<p>3M</p>

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		<p>nominal aperture size 180 μm.</p> <p>v. Very fine powder: A powder of which all particles pass through sieve no 120 with nominal aperture size 125 μm.</p> <p>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 μm</p> <p>vii. Superfine powder: A powder of which not less than 90% by weight of particles are less than 10 μm in size</p>	
3	f)	<p>Define Menstrum and Marc. Write the advantages of alcohol as menstrum.</p> <p>Menstrum :- Solvent used to extract the drug.</p> <p>Marc:- The drug residue which remains behind after extraction.</p> <p>Advantages of alcohol as menstrum (0.5 X 2) = 1M</p> <ol style="list-style-type: none"> The mould and bacteria cannot grow in an alcoholic solution (20% or more). It is neutral and hence extraction products obtained are compatible with other products. It is non-toxic in the concentration mostly present in the preparations. A small amount of heat is required to concentrate the alcoholic preparations. It dissolves selective active ingredients of drugs. 	<p>3M</p> <p>(1+1+1)</p>
4		<p>Attempt any FOUR of the followings</p>	12M
4	a)	<p>With a well labeled diagram explain the <u>construction</u> of Autoclave.</p> <div style="text-align: center;"> </div> <p>Construction: It consists of a strong metallic chamber usually made of stainless steel.</p>	<p>3M</p> <p>(2+1)</p>



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		<p>It has a cover fitted with a steam vent, pressure gauge 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 placed on the stand. The material to be sterilized is loosely packed into it.</p>									
4	b)	<p>Give any three importance of dosage forms. Differentiate between Mouthwash and Gargle. Importance of dosage forms :</p> <ol style="list-style-type: none"> To protect drug substances from oxidation, hydrolysis, reduction etc.eg. coated tablets, sealed ampoules etc. To protect the drug from destructive effect of gastric juice. eg. - Enteric coated tablets. To provide a safe and convenient delivery of accurate dose. eg. - Tablet, Capsule. To conceal the bitter taste or obnoxious odour of a drug substance.eg. - Capsule, coated tablets, flavoured syrups. To provide optimum drug action in inhalation therapy.eg. Aerosols and inhalers. To provide for the insertion of drug into body cavity. Eg. Suppositories & pessaries. To provide maximum drug action from topical administration sites. Eg. Creams, ointments, ophthalmic preparations, ENT preparations. To provide liquid dosage form of the drugs which are insoluble or unstable in different vehicles.eg. Suspension To provide liquid dosage form of the drugs which are soluble in a suitable vehicle.eg. Solutions To provide drugs within body tissues. Eg. Injection xi. Sustained release action to control the release mechanism. Eg. Sustained release tablets, capsules and suspensions. <table border="1"> <thead> <tr> <th>Mouthwash</th> <th>Gargle</th> </tr> </thead> <tbody> <tr> <td>1. Mouth washes are aqueous solutions with pleasant taste and smell for refreshing effect.</td> <td>1. Gargles are aqueous solutions to prevent & treat throat infections</td> </tr> <tr> <td>2. Used to cleanse & deodorize buccal cavity</td> <td>2.Used to relieve soreness in mild throat infections.</td> </tr> <tr> <td>3.These are used for rinsing mouth cavity</td> <td>3.The gargle brings drug into intimate contact with mucous membrane of throat</td> </tr> </tbody> </table>	Mouthwash	Gargle	1. Mouth washes are aqueous solutions with pleasant taste and smell for refreshing effect.	1. Gargles are aqueous solutions to prevent & treat throat infections	2. Used to cleanse & deodorize buccal cavity	2.Used to relieve soreness in mild throat infections.	3.These are used for rinsing mouth cavity	3.The gargle brings drug into intimate contact with mucous membrane of throat	<p>3M</p> <p>1.5 M (0.5x 3)</p>
Mouthwash	Gargle										
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		4. More used for cosmetic purpose	4. used for medicated purpose.		1.5 M (0.5x 3)
		5.It contains antibacterial agent,Coloring&flavoring agent.	5.It contains antibacterial agent -Phenol, thymol and Astringent-Potassium chlorate etc.		
		6 Examples: Compound sodium chloride mouth wash, Listrin.	6. Examples: Phenol gargle, potassium chlorate gargle, Betadine.		
4	c)	<p>Write any six salient features of <u>IVth edition</u> of I. P.</p> <ol style="list-style-type: none"> 1. It contains 1149 monographs and 123 appendices and available in two volumes. 2. Introduction of computer generated formula 3. Some titles have been changed to include more commonly accepted names in India e.g.HyoscineHydrobromide for Scopolamine hydrobromide. 4. I.R and U.V absorption spectrophotometric tests for identification of drug substance have been introduced. 5. HPLC has been widely used as method of analysis in many formulations. 6. Test for bacterial endotoxins as a more suitable substitute for test for pyrogens. 7. Number of general monographs e.g. eye drops ,eye ointments pessaries have been included. 8. A quantitative method for determining particulate matter in injectable preparation has been replaced by qualitative test. 9. Biological assays provided for vaccines, hormones, blood products. 10. Monograph for (ORS) Bicarbonate dropped due to stability problem 			0.5 X 6 = 3M.
4	d)	<p>Find the amount of sodium chloride required to make 0.5% Ephedrine HCL isotonic with blood plasma. (Given: F.P. 1%, w/v solution of ephedrine HCL= -0.165⁰ C</p> <p>As the concentration of ephedrine hydrochloride in the preparation is 0.5% w/v, the depression in freezing point of ephedrine hydrochloride = 0.165 X 0.5 = 0.0825⁰C</p> <p>Percentage w/v of sodium chloride required = <u>0.52 – 0.0825</u></p>			3M



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		0.576 $= 0.759 \% \text{ w/v}$ <p>Amount of sodium chloride required to make 100 ml of solution of Ephedrine HCL isotonic with blood plasma is 0.759 g</p>	
4	e)	<p>Write the <u>advantages</u> of microencapsulation and list different <u>methods</u> of microencapsulation.</p> <p>Advantages of microencapsulation: (0.5 X 3)</p> <ol style="list-style-type: none">1. To mask the bitter taste of drugs like Paracetamol, Nitrofurantoin etc.2. To reduce gastric and other gastro intestinal (G.I) tract irritations, For eg., sustained release.3. A liquid can be converted to a solid for easy handling and storage,4. Hygroscopic properties of core materials may be reduced by microencapsulation.5. Protection against external environment.6. Microencapsulation has been employed to provide protection to the core materials7. Separation of incompatible substance has been achieved by encapsulation. <p>Different methods of microencapsulation: (0.5 X 3)</p> <ol style="list-style-type: none">1) Pan Coating2) Fluidized bed Coating3) Coacervation4) Electrostatic Deposition5) Vacuum deposition6) Polymerization7) Multiorific Centrifugal Process.	3M (1.5+ 1.5)
4	f)	<p>Explain <u>theory and construction</u> of FBD.</p> <p>Theory of FBD: The equipment works on a principle of fluidization of the feed materials. In fluidization process, hot air is introduced at high pressure through a perforated bed of moist solid particulate. The wet solids are lifted from the bottom and suspended in a stream of air (fluidized state). Heat transfer is accomplished by direct contact between the wet solid and hot gases. The vaporised liquid is carried away by the drying gasses.</p> <p>construction of FBD: In FBD, good contact between hot air and particles to be dried is obtained which cause rapid drying. Two types of FBD are used in pharmaceutical industry. They are:</p> <ol style="list-style-type: none">1. Vertical FBD2. Horizontal FBD <p>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</p>	3M (1+1+1)

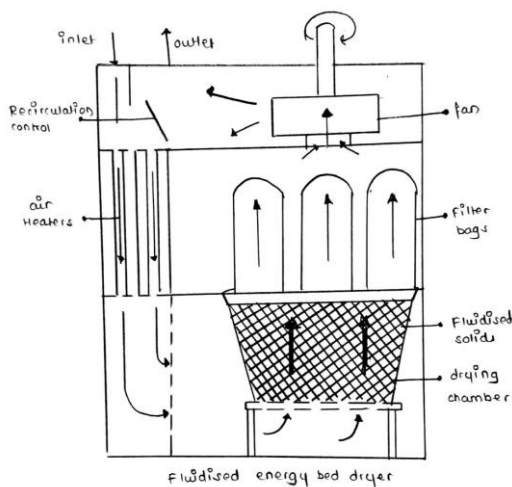
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flow rate is adjusted by means of recirculation control and fabric filter bags are provided to prevent the passage of fine particles.
This type of FBD is a batch type dryer and the drying chamber is removed from the unit for charging and dumping.
The FBD available in different capacities ranging from 5 kg to 200 kg with an average drying time of about 20-40 min.



5	Attempt any FOUR of the followings	12M
Q.5	a. Explain any <u>one</u> method for preparation of small pox vaccine.	3M
	<p>Ans: Small pox vaccine is prepared by two methods : By using animals and by using Eggs</p> <p style="text-align: center;">1) By using animals:</p> <ul style="list-style-type: none"> • Animal: calves or Sheep. • Selection of animal: healthy, non-diseased, animal kept for 10 to 14 days under observation. • Scarification: Abdominal part & flanks parts shaved and disinfected. • Inoculation: light incision made in the cleared skin without drawing blood with scarifies. Then area is rubbed with some seeds vaccine of known potency. • Incubation: 7-9 days, pustule formed at lining. • Collection of virus: Animal operated and killed, the material in pustules is withdrawn in aseptic condition. • Purification: pustules + glycerin mixed and stored at -10^0C to remove impurities. • Filling sealing and storage: filled in final container under aseptic condition and freeze drying. 	(Any one 3M)



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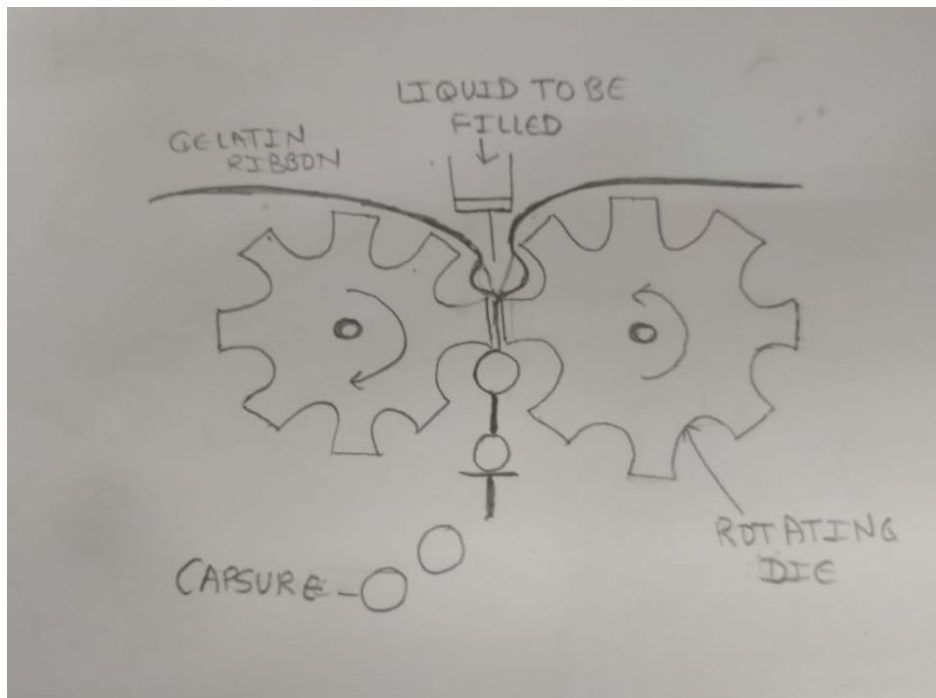
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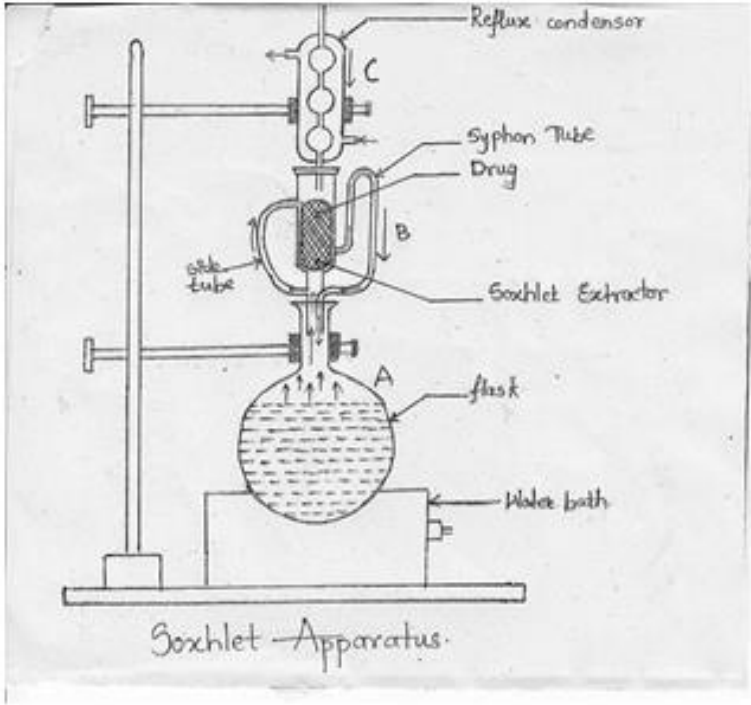
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	<p>2) By using Eggs: Hen egg is used (Which is incubated after 12 days) ↓ Small cut on the shell (exposed chorio-allantoic membrane) ↓ In this membrane, viruses are inoculated (by seed of known potency) ↓ Cut was sealed by flap or paraffin wax ↓ Again incubate for 72 hours ↓ Using aseptic condition, shell is removed and chorio-allantoic membrane is separated ↓ Contents are added in normal saline solution at 0° ↓ Add 50 % glycerin ↓ Material is ground to produce homogenized suspension. ↓ Transfer to suitable sterile container and freeze dried</p>	
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Q.5 **b.** **Describe method for preparation of soft gelatin capsule using rotary machine.** **3M**
Method of Preparation: (2M)
Liquid gelatin produce two ribbon
↓
These come between rotating dies which rotates in opposite direction.
↓
Form half shell of capsule
At this stage measured quantity of drug is filled in shell
↓
With further movement of dies other half is formed
↓
Sealing is done by hot rotating dies
↓
The capsule formed are washed and dried.

Diagram: (1M)



Q.5	c.	<p>Draw a labelled diagram of apparatus used for continuous hot extraction process. Mention limitations of the process.</p> <p>Diagram: (2M)</p>  <p>Limitations: process cannot be used in following conditions. (0.5 X 2 = 1)</p> <ul style="list-style-type: none"> • Physical character of the drug: Drugs which may block the apparatus such as opium, gums, resins, etc cannot be used. • Solvent: Only pure solvents or constant boiling mixtures can be used for this process. • Chemical constituents: Unsuitable for thermolabile drugs, such as enzymes, alkaloids, etc 	<p>3M</p> <p>(2+1)</p>
Q.5	d.	<p>Explain the <u>construction and working</u> of filter press.</p> <p>Construction: (1M)</p>	<p>3M</p> <p>(1+1+1)</p>



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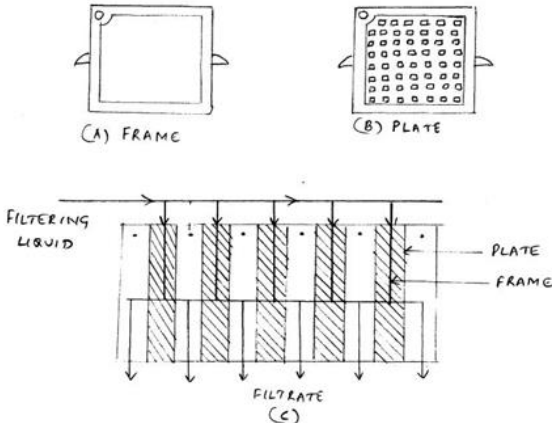
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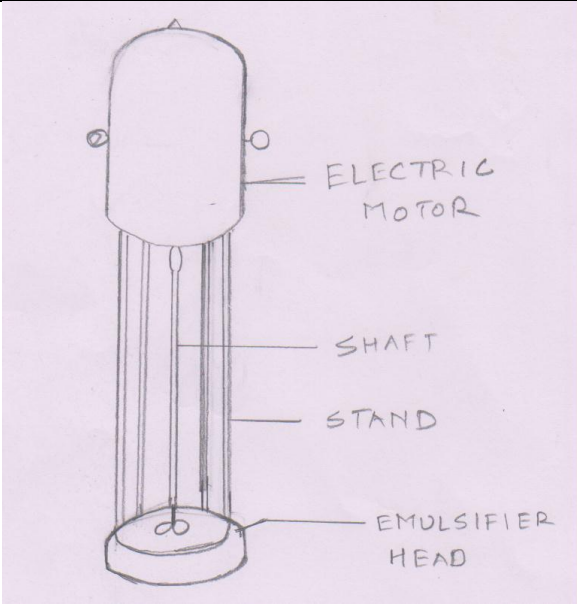
- It consists of alternative plate and frame mounted on two parallel support bars.
- The pressure can be applied through screw thread so that the plate and frame are rigidly fixed between two end plates.
- The frame is open and is used as an inlet for material to be filtered.
- Plates has grooved surface which give support to the filter cloth.
- The plate and frame are made of non-corrosive material.
- Filter cloth is placed at each side of the plate.
- Each plates acts as single filtration unit and outlet is connected to common outlet for plate.

Working: (1M)

- The slurry is pumped in under positive pressure up to 20 bar and fill each frame.
- The filtrate passes through the cloths on opposite sides of the frame and runs down between the studs on the plate surface.
- There is an outlet cock in the bottom right hand corner of the frame allowing the filtrate to discharge in to channel.
- The solid in the slurry build up to form cake in each frame which will eventually meet in the centre of the frame.
- When the process is stopped, the frame is emptied and cycle is restarted.
- Thickness of cake can be varied by using frame of different thickness.

Diagram: (1M)

		 <p>(A) FRAME</p> <p>(B) PLATE</p> <p>FILTERING LIQUID</p> <p>PLATE</p> <p>FRAME</p> <p>FILTRATE (<)</p>	
<p>Q.5</p>	<p>e.</p>	<p>Explain the <u>construction and working</u> of silverson mixer homogenizer.</p> <p>Ans: Construction (1M)</p> <ul style="list-style-type: none"> • It consists of emulsified head which is covered with fine meshed stainless steel sieve. • The emulsifier head consist of a number of blades which rotates at a very high speed, to produce powerful shearing action. • The blades are rotated by using an electric motor fitted at the top. <p>Working: (1M)</p> <ul style="list-style-type: none"> • The emulsified head is placed in the vessel containing immiscible liquid, in such a way that it should get dipped into it. • When the motor is started, the liquid is sucked through the fine holes and the oil is reduced into fine globules due to the rotation of blades. • So a fine emulsion is produced which is then expelled out. <p>Diagram: (1M)</p>	<p>3M</p> <p>(1+1+1)</p>

			
<p>Q.5</p>	<p>f.</p>	<p>Explain the following manufacturing defects of tablets:</p> <p>1. Capping and lamination: (1.5M)</p> <p>Capping: is partial or complete removal of top or bottom portion of tablet.</p> <p>Lamination: is whenever tablet is breaking or separating anywhere rather than top.</p> <p>Reasons:</p> <ul style="list-style-type: none"> • Excessive fine. • Defective punch and die. • High speed of machine. • Granules too dried • Entrapment of air. • Less use of binder etc. <p>Remedies:</p> <ul style="list-style-type: none"> • Setting the die and punch properly. • Reduce % of fine. • Punches should be polished. • Maintain the desire moisture in granules. • Maintain the speed at optimum. • Regulate the pressure of punches. 	<p>3M</p> <p>(1.5 +1.5)</p>



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		<p>2. Picking and Sticking: (1.5M)</p> <ul style="list-style-type: none">• The material is removed or picked up by upper punch from the upper surface of the tablet.• In the sticking he material sticks to the wall of the die cavity.• Reasons:<ol style="list-style-type: none">i. Use of worn out die and punch.ii. Use of small quantity of lubricants.iii. Presence of excess moisture in the granules.iv. Scratches on the surface of the face of the punches.v. Defect in formulation.• Defect can be removed:<ol style="list-style-type: none">i. Using new set of die.ii. Adding proper quantity of lubricants in granules.iii. Dry granules.	
Q.6		Answer any FOUR of the following:	12M
Q.6	a.	<p>Explain the <u>construction and working</u> of cyclone separator.</p> <p>Construction: (1M)</p> <ul style="list-style-type: none">• It consists of cylindrical vessel with a conical base.• In upper part of vessel is fitted with a tangential inlet and fluid outlet.• At the base it is fitted with solid outlet. <p>Working: (1M)</p> <ul style="list-style-type: none">• The suspension of solid in gas is introduced tangentially at a very high velocity.• The rotary movement takes place within the vessels.• The fluid is removed from the outlet at the top.• The rotatory flow within the cyclone separator causes the particle to be acted on by centrifugal force.• The solids are thrown out to the wall and fall to the conical base for discharge. <p>Diagram (1M)</p>	3M (1+1+1)

<p>Q.6</p>	<p>b.</p>	<p>Give <u>principle, method and application</u> of sterilization using UV radiation.</p> <p>Principle: (1M)</p> <ul style="list-style-type: none"> • Direct sunlight can destroy the microorganism on account of its ultra-violet rays of longer wave length. • UV light of shorter wavelength kills or inactivates microorganisms by destroying nucleic acids and disrupting their DNA, leaving them unable to perform vital cellular functions. • UV light of 265 nm wave length is lethal to microorganism. <p>Method: (1M)</p> <ul style="list-style-type: none"> • UV rays for sterilization are produced by passing a low current at high voltage through mercury vapour in an evacuated glass tube. <p>Application: (0.5 X 2 =1M)</p> <ul style="list-style-type: none"> • Sterilization of air. • Sterilization of aseptic area. • Sterilization of thermolabile material. • Sterilization of surface of working table. 	<p>3M (1+1+1)</p>
<p>Q.6</p>	<p>c.</p>	<p>Define evaporation and explain any <u>four</u> factors affecting evaporation.</p> <p>Definition: (1 M)</p> <ul style="list-style-type: none"> • Evaporation is the free escape of vapour from the surface of a liquid below its boiling point. <p>Factors affecting evaporation: (0.5 X 4 =2M)</p>	<p>3M (1 + 2)</p>



		<p>1) Temperature: The rate of evaporation is directly proportional to temp of liquid.</p> <p>2) Temperature and time of evaporation: 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.</p> <p>3) Temp and moisture content: 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 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.</p> <p>4) Types of product required: 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</p> <p>5) Effect of concentration: During evaporation the upper layer of the liquid under evaporation has a tendency to form a film and formation of ppt 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</p> <p>6) Surface area: The rate of evaporation is directly proportional to the surface area of the evaporator, in which the liquid is evaporated.</p> <p>7) Vapour pressure of the liquid to be evaporated: The rate of evaporation is directly proportional to the vapour pressure of the evaporating liquid.</p>	
Q.6	d.	List the various equipment's used for liquid mixing and explain how vortex formation can be avoided in liquid mixing.	3M

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		<p>Equipment used for mixing of liquid: (0.5 X 2 =1M)</p> <ol style="list-style-type: none"> 1. Propeller mixture. 2. Turbine Mixture. 3. Paddle mixture. <p>Vortex formation can be avoided in liquid mixing by making the following changes in the position of the propeller shaft. (0.5 X 4 = 2M)</p> <ol style="list-style-type: none"> 1. Offset from center. 2. Mounted at angle. 3. Enter the side of vessels. 4. Using push pull propeller. 5. Using baffles. <div style="text-align: center;"> <p>Propeller mixer showing different positions of propeller shaft</p> </div>	<p>(1+2)</p>
<p>Q.6</p>	<p>e.</p>	<p>Define tables. Enlist various excipients used in tablet manufacturing with one example each.</p> <p>Definition: (1M)</p> <p>Tablet is a solid unit dosage form containing medicament/s usually circular in shape and may be flat or biconvex.</p> <p>OR Tablet is a solid unit dosage form prepared by compression.</p> <p>List of excipients : (0.5 X 2 = 2)</p>	<p>3M</p> <p>(1+2)</p>



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		<p>i. Diluents: e.g. lactose, sorbitol, starch etc.</p> <p>ii. Granulating agents: e.g. water, alcohol, starch mucilage, acacia mucilage, tragacanth mucilage, gelatin solution, isopropyl alcohol, etc</p> <p>iii. Binding agents: e.g. gum acacia powder, gum tragacanth, gelatin, sucrose, methyl cellulose, etc.</p> <p>iv. Disintegrating agents: e.g. starch, sodium bicarbonate, citric acid and tartaric acid.</p> <p>v. Glidants & lubricants: e.g. talc and magnesium stearate.</p> <p>vi. Colours, flavours and sweetening agents:</p>	
Q.6	f.	<p>Give advantages and disadvantages of glass as a material used for pharmaceutical container and state its types.</p> <p>Advantages: (0.5 X 2 =1M)</p> <ul style="list-style-type: none">❖ Economical.❖ Available in variety of sizes and shapes.❖ Chemically inert, impermeable, strong and rigid.❖ Does not deteriorate with age.❖ Easy to label.❖ Excellent barrier against light. <p>Disadvantages: (0.5 X 2 =1M)</p> <ul style="list-style-type: none">❖ Fragile, easy to break.❖ Heavy, Bulky to carry.❖ Leaching and absorption of alkalis.❖ Flake formation <p>Types of Glass: (0.5 X 2 =1M)</p> <ol style="list-style-type: none">1. Neutral Glass (Type-I)2. Surface treated soda-lime glass (Type-II)3. Regular soda-lime glass or Alkali glass (Type-III).4. General Purpose soda-lime glass (Type-IV).	<p>3M</p> <p>(1+1+1)</p>