SUMMER– 16 EXAMINATION

Subject Code: **0805** **Model Answer** Page No: 01/32

Important Instructions to examiners:

1. The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2. The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3. The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.
4. While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for any equivalent figure drawn.
5. Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate's answers and model answer.
6. In case of some questions credit may be given by judgment 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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1. Attempt any EIGHT of the following: 16

a) What are advantages of liquid dosage form? (0.5 X 4 =2 M)

Ans: i) Usually faster acting than the solid dosage forms

ii) Maybe easier to take than an oral solid dosage form for patients having difficulty in swallowing tablets or capsules.

iii) More flexibility in dosage than some other dosage forms.

iv) May be more practical to administer than solid dosage forms for specific patient cases.

v) Good patient compliance.

b) What are pharmacopoeias and why they are needed? (1 X 2 = 2M)

Ans: Pharmacopoeia: Pharmakon means "a drug" and poein means "to make". Pharmacopoeia is defined as a compressive book which is issued under the authority of government and contains a list of drug and formulae used for medicinal preparation with description and the tests for those substances and the standards to which they must confirm.

Need:

Pharmacopoeias are necessary because it gives **complete information about the drugs**, such as its molecular weight, formula, identification test, standards, assay, preparations etc.

c) Name various mechanisms of size reduction.(0.5 X 4 = 2M)

Ans: i. Cutting

ii. Compression

iii. Impact

iv. Attrition

v. Combined impact and attrition

d) Differentiate between hard gelatin capsule and soft gelatin capsule.

(0.5 X 4 = 2M)

Ans:

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

e) Define: (1 X 2 = 2M)

Ans: i) Capping: Capping is partial or complete removal of top or bottom portion of the tablet.

ii)Lamination: Tablet splits or cracks on the sides by air expansion.

f) What are objectives of mixing? (0.5 X 4 =2M)

Ans: i. To form uniform mixture.

ii. To promote chemical reaction.

iii. Dispersion of solid particles in liquid.

iv. Dispersion of two immiscible liquids.

g) Define. (1 X 2 =2M)

Ans: i) Arka: It is the liquid preparation obtained by distillation of certain liquid or crude drug soaked in water using distillation unit.

ii)Gutika: Medicament in the form of tablets or pills are known as vati or gutika.

h) Give any two application of fluidized bed dryer. (1 X 2 = 2M)

Ans: i. It gives high drying rate.

ii. Suitable for thermolabile material.

iii. Drying takes place of individual particles.

iv. Temperature can be controlled.

v. Prevent the risk of migration of soluble material.

vi. It can mostly used for drying of granules.

i) Give any four precautions to be taken during aseptic work. (0.5 X4=2M)

Ans: i. Self hygiene: avoid coughing, sneezing.

ii. Avoid contamination of products.

iii. Cover the whole body by Wear complete body suit up to foot.

iv. Wear hand gloves.

v. Allow minimum persons to work in aseptic area.

vi. Don't touch unnecessarily.

j) What are filter aid. What should be qualities of filter aid? (0.5 M for definition)

Ans: Filter Aid: These are the substance which reduces the resistance of filtrate to flow.

Ideal qualities of filter aid: (0.5 X 3 = 1.5M)

i. It should be remain suspended in the liquid.

ii. It should be free from impurities.

iii. It should be inert.

iv. It should have a particle size distribution suitable for retention of solid.

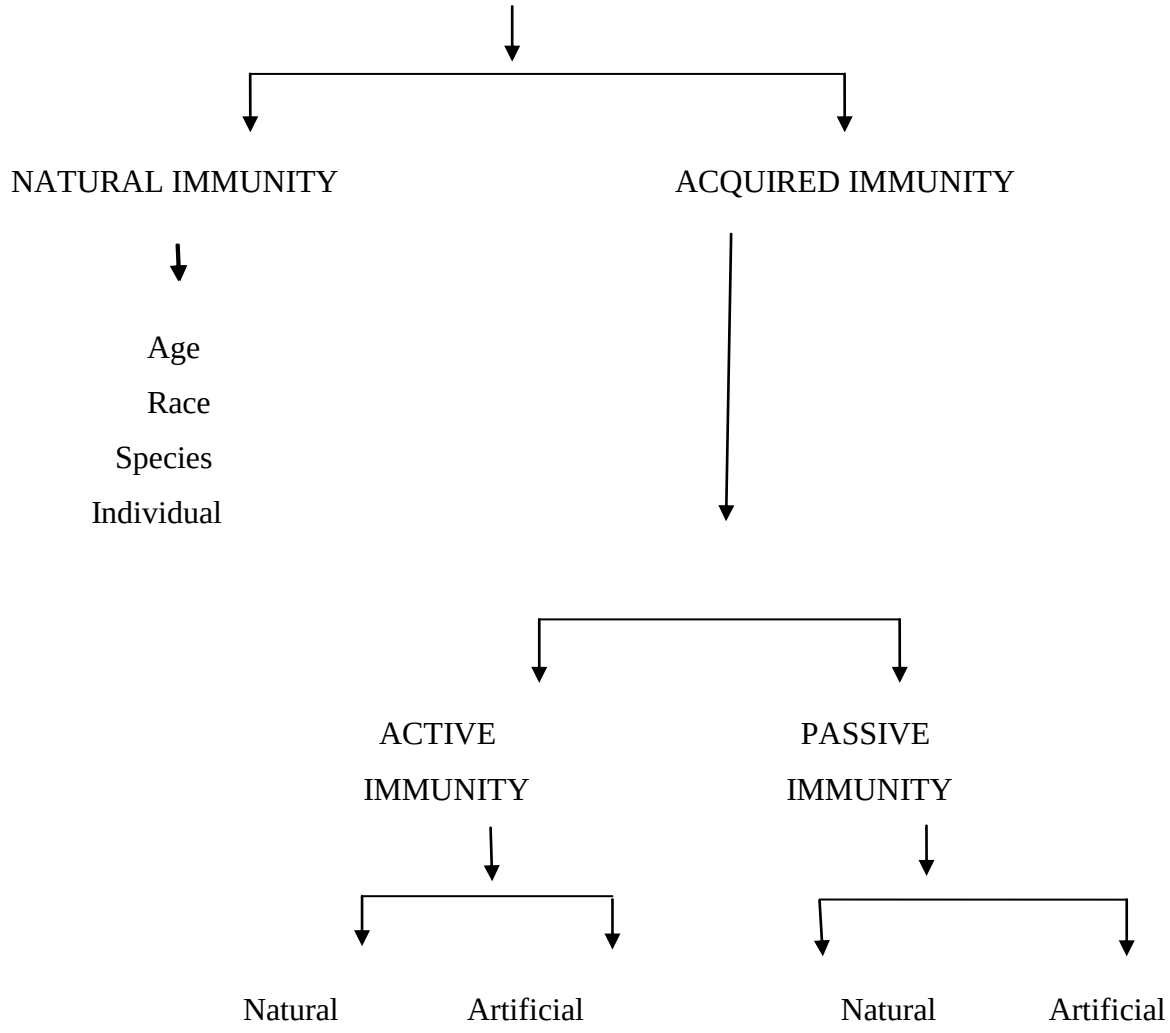
v. It should have structure that permits formation of porous cake.

k) Name various types of closures. (0.5 x 4 = 2M)

Ans: i. Plug type. ii. Crown type. iii. Push-fit cap. iv. Screw closure

l) Classify immunity. (2M)

Ans:



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Q. 2 Attempt any FOUR of the following: 12

a) Give construction and working of silverson mixer homogenizer.

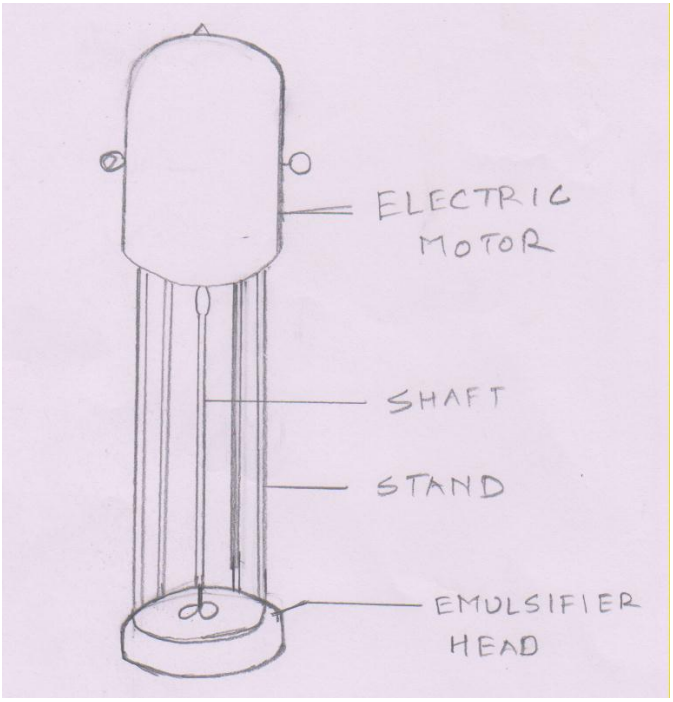
Ans: Construction (1M)

- 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.

Working: (1M)

- 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.

Diagram: (1M)



b) Discuss in brief the stepwise process of percolation used in preparation of tincture.

Ans: Stages involved in preparation of tincture by percolation: (each step 1M)

a. **Imbibition**:

- Drug is kept is moistened with sufficient quantity of menstruum.
- Allow to stand for 4 hr.

  Significance:
  - It allow the swelling of tissue of drug before packing.
  - It is imbibed for uniform packing in percolator.
  - It allows the entrapped air to escape.
  - Quantity of menstruum required can be reduced.

b. **Maceration**:

- The moistened drug is left in contact with menstruum for 24 hrs.
- During this period, menstruum dissolves the active constituents of the drug.

c. **Percolation**:

- It consists of downward displacement of the saturated solution formed in maceration and extraction.
- After collecting $3/4^{th}$ volume of product then marc is pressed.
- Mix the liquids.

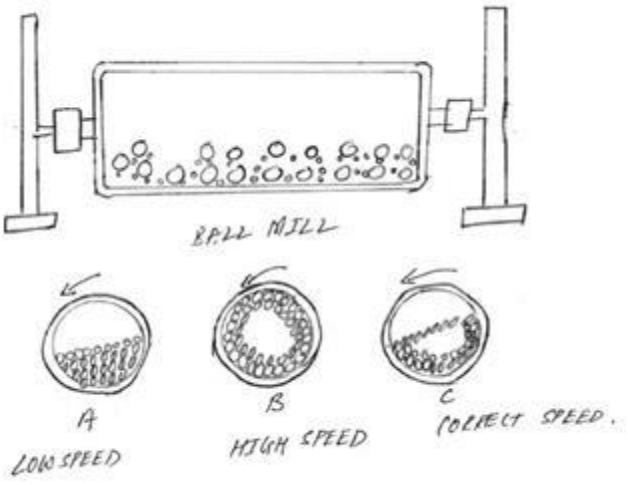
c) Give the principle, construction and working of ball mill.
(0.5 marks Principle, Construction 1 marks, working 1 marks, 0.5 marks diagram)

Ans: Principle: Impact and Attrition.

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)

Working:

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.



d) Describe various factors affecting size reduction.(0.5 X 6 = 3M)

Ans:

i. Hardness: Soft material easy 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 stickness.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 there size reduction in mill, dust is produced which may have effect on operator.

ix. Ration 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.

x. Bulk density: The output of the size reduction of the material in a machine depends upon the bulk density of the substance.

e) Explain principle of freeze drying. Give its advantages.

Ans: Principle: (1M)

i. The material is frozen in a suitable container connected to a high vacuum system, so that the vapour pressure of water is reduced to less than that of material being dried.

ii. Thus, it reduce the temperature and pressure to values bellow the triple point.

iii. Under these conditions, any heat transfer is used as latent heat and the ice sublimes directly to the vapour state.

iv. The water vapour is removed from the system by condensation in a condenser maintained at a temperature lower than a frozen material.

Advantages: (0.5 X 4 = 2 Marks)

i. The product obtained is light and porous having excellent solubility.
ii. The chances of hydrolysis are minimized as drying takes place at a very low temperature.
iii. Drying takes place under vacuum; hence oxidation is minimized as there is no contact with air.
iv. The heat-sensitive materials can be dried.
v. The loss of volatile material is minimum.
vi. The freeze-dried material can be stored at room temperature if it is properly sealed in an inert atmosphere.
vii. The sterility of the product can be maintained.

f) Describe the construction and working of evaporating pan with neat diagram.

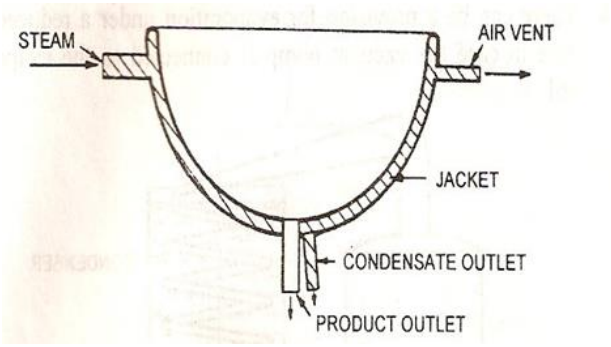
Ans: Construction: (1M)

i. It consists of a hemispherical pan made from copper or stainless steel and surrounded by a steam jacket.
ii. Hemispherical shape provides large surface area for evaporation.
iii. It consists of product outlet for fixed evaporating pan.
iv. In other type evaporator is mounted in such a way that they can be tilted.

Working: (1M)

i. Material to be evaporated is filled in pan.
ii. Pass the steam.
iii. Liquid will evaporate.
iv. After evaporation remove the product from product outlet.

Diagram: (1M)



Q.3. Solve any FOUR of the following. **12**

a. Describe in detail various oral cavity tablet.

Ans: Oral cavity tablet: (1 Mark for classification)

i. Buccal Tablet.
ii. Sublingual Tablet.
iii. Lozenge tablet and tracheas.
iv. Dental cones.

(0.5 mark for explanation of each type)

1] Buccal Tablet's –

a. These tablets are to be placed in buccal pouch or between the gum & lip or cheek.
b. Tablet dissolve & disintegrated slowly & absorb directly.

2] Sublingual Tablet –

a. These tablets are to be placed under the longue.
b. They dissolve & disintegrated quickly &
c. Absorb directly without passing into G.I.T.
d. Buccal and sublingual tablet should be formulated with bland excipients, which do not stimulate salivation.

3] Lozenge tablet & troches-

a. These tablets are designed to exert a local effect on mouth or throat.
b. These tablets are usually used in treatment of sore throat or control coughing.

c. The tablets are usually used to such drug as anaesthetic, antiseptic and antibacterial agent, demulcent, astringent and antitussive agent.

d. Lozenges were earlier called pastilles.

4] Dental cones –

a. These are relatively minor compressed tablet meant for placing them in the empty socket after tooth extraction.

b. Usually, these tablets contain an antibacterial, compound which is released slowly.

c. Prevent the growth of bacteria.

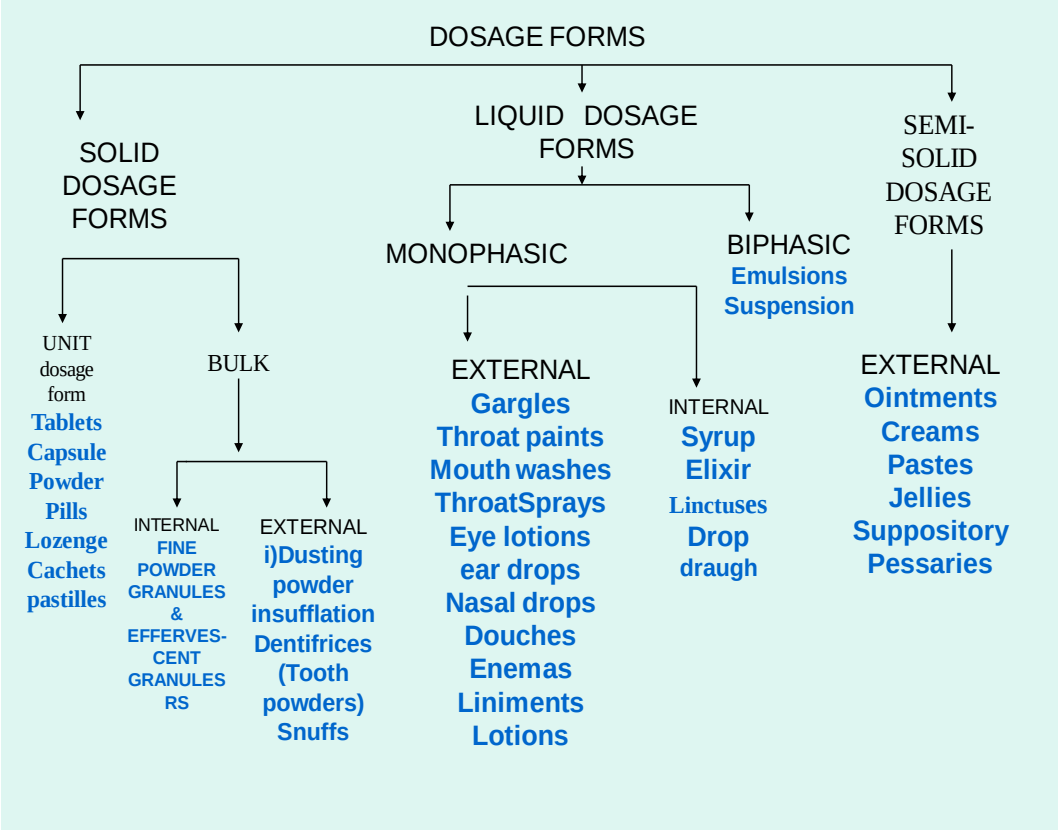
d. These tablets may contain an astringent or coagulant to reduce bleeding.

e. The base for these types is sodium bicarbonate, sodium Chloride or it may be amines acid.

f. These cones generally get dissolved in 20 to 40 min time.

b. Classify different dosage forms with example. (3 marks for complete classification)

Ans:



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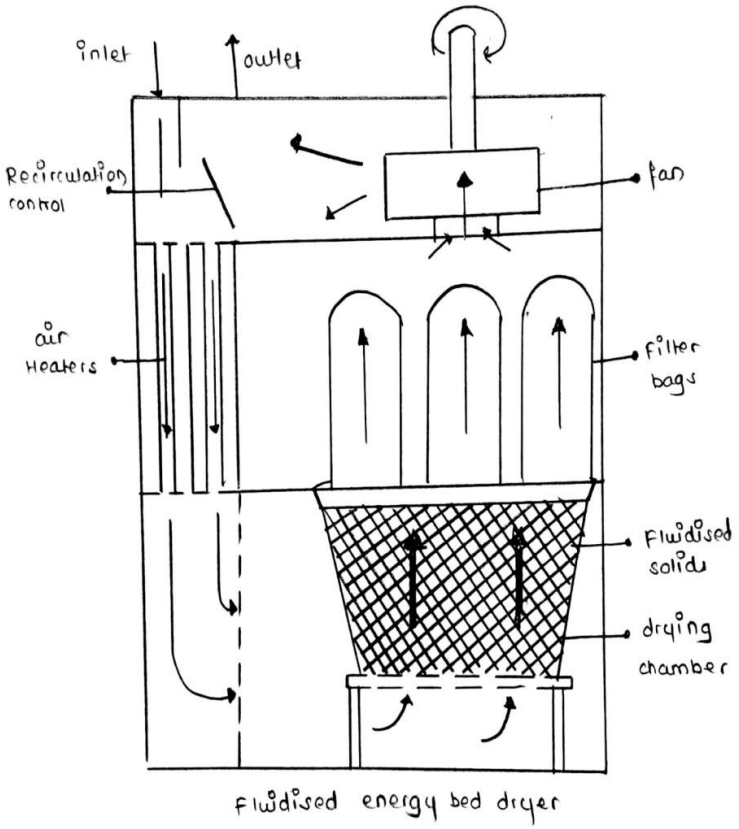
c. Draw a well labelled diagram of Fluidised bed dryer. (3 marks)

Ans:



Fluidised energy bed dryer

d. Discuss the silent features of third edition of pharmacopoeia. (0.5 marks for any 6 points)

Ans: Salient Features III Edition 1985:

i. New analytical techniques such as flame photometry, Flurometry, have been introduced as official method for certain chemical analysis.
ii. Dissolution test has introduced in the case of certain tablets.
iii. Disintegration Test has been amended by modifying the design of apparatus and method of testing.
iv. A microbial limit test has been prescribed for certain pharmaceutical aid & oral liquid preparation.
v. Pyrogen test has been revised to make the test less time consuming than the previous method.

vi. Gas liquid chromatography has been recognized as an alternative method for the determination of alcohol concentration in various preparations.

vii. Test for determination of viscosity has been modified by introduction to other method involves.

viii. The new appendix on water for pharmaceutical use" has been introduced to clearly indicate the different official standard in respect of purified water.

ix. Some of the drugs have been renamed in this edition.

x. Many drugs have been omitted from the third edition and many new drugs have been included in the third edition.

xi. It provides the official standard to the new drug which came into use after the publication of first addendum to third edition.

e. Explain the factors which affect rate of filtration by Darcy's law. (3marks)

Ans: According to Darcy's Law,

$$V = \frac{KA \Delta P}{\mu l}$$

Where

v = volume of filtrate

K= permeability coefficient & is dependent on filter medium & filter cake.

A = Area of filter bed.

ΔP=Pressure drop across filter medium & filter cake.

L = Thickness of filter cake

μ = Viscosity of filtrate

i. Pressure difference: 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.

ii. **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.

iii. **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.

iv. **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.

f. Define aerosol. Classify aerosol. Give formula of aerosol with example.

Ans: Definition: Aerosol (1 Mark)

Aerosols may be defined as disperse phase system in which very fine solid particles or liquid droplet get dispersed in the gases which act as continuous phase. These are also called pressurized dosage form.

Classification of aerosol (1 Mark)

a. **Space Sprays-**

These are finally divided spray having particle size up to 50μ e.g. Insecticides, disinfectant.

b. **Surface coat's –**

These are also spray but disperse particle are coarse with size up to 200μ

They produce a wet coat when sprayed on a surface e.g. Hair sprays, personal deodorant powder spray's

c. **Foam –**

These are produced by rapid expansion of propellant through an emulsion. Hence, the product comes out in the form of foam or front.

E.g. Shaving cream & Vaginal product

OR

Aerosol system may be of two types

1.**Two phase system** : Two phase system is employed in cases where the product is a solid insoluble in the propellant or it is solid or liquid which dissolved in it. In the first case solid is suspended in the propellant, so that aerosol system will have one liquid phase and gaseous phase is above it.

2.**Three phase system** : Three phase system is employed in cases where the product is immiscible with the propellant. The medicaments are dissolved in a liquid which does not mix with the liquefied propellant.

Formula of aerosol: (1 Mark)

Aerosol formulations basically consist of propellant & the medicament to be propelled.

- **Propellant-**

1) It develops a pressure in the container.
2) Compressed gases such as carbon dioxide or nitrogen & liquefied like methane or ethane used as propellant.
3) Compressed gases are not commonly used.
4) The medicament to be propelled may be solid or liquid.
5) It may be soluble in the propelled or insoluble.
6) The various additives such as solvent , antioxidant surface active agent, flavouring agent are also included in the formulation.
7) The propellant, medicament, additives are filled into an aerosol container.

Q.4. Solve any FOUR of the following. **12**

a. Discuss in brief gaseous sterilization using ethylene oxide.

Ans: Gaseous sterilization using Ethylene oxide: (0.5 Mark)

It is gas at room temperature, highly inflammable & forms explosive mixture with air. This disadvantage can be overcome by using mixture of 10% ethylene oxide & 90 % carbon dioxide which is inert or halogenated hydrocarbon.

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Mechanism of action: (0.5 Mark)

Ethylene oxide exerts its lethal effect on microorganisms by alkylation essential metabolites. The alkylation probably occurs by replacing an active hydrogen on sulphahydral, amino, carboxyl, hydroxy group in enzymes ,proteins & nucleic acids

Method: (1 Mark)

- The sterilization is done in pressure chamber which is designed in such a way to give controlled temp., humidity , gas conc. & exposure time.
- The material to be sterilized is first exposed to high humidity of about 98% leading to humidification of organism.
- Then it is exposed to sterilizing gas. (fuming ethylene oxide) under pressure till desired concentration is obtained.
- Exposure period may range from 6-24 hrs depending upon degree of contamination & penetrability of material .

Advantages: (0.5 Mark)

1) It is suitable for heat sensitive substances.
2) It is very reactive compound.
3) It has good penetration power.
4) The method is very reliable.
5) Method is useful for sterilization of mist sensitive substance and equipment because only low humidity is required.

Disadvantages: (0.5 Mark)

- It is slow & more expensive.
- Control of relative humidity & hydration of organism is critical.
- IT is toxic & inflammable gas.
- Sophisticated instruments are required & skilled persons are needed.

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b. Give merits and demerits of rubber as a material for closure.

Ans: Merits of rubber: (1.5 Marks)

1) Soft in nature.
2) It is quite elastic therefore self sealing property
3) It withstands in the temperature & pressure of an autoclave therefore can be sterilised.

Demerits of rubber: (1.5 Marks)

1) Rubber closure should not be very hard otherwise it will create difficulty in piercing by hypodermic needle.
2) It significantly absorbs bactericides and active ingredients
3) Some of additives Such as Activators, Vulcanising agents, pigments, may get extracted into the product
4) Process cost is very high.

c. Explain the theory of fractional distillation?

Ans: Theory of fractional distillation: (3 Marks)

i. When substance dissolved in liquid, the vapour pressure of liquid is lowered.
ii. When two miscible liquids are mixed together each will act as solute or solvent for the other so when a mixture of two such liquids is heated, the vapour pressure of each is lowered.
iii. The pressure exerted by each liquid in the mixture is known as partial pressure.
iv. The liquid boils when the sum of the partial pressure is equals to atmosphere Pressure.
v. The vapour arising from two miscible liquids at boiling point is richer in component exerting the greater partial pressure.

d. Discuss factors affecting evaporation. (0.5 marks for each point)

Ans: Factors affecting evaporation:

1) **Temperature:**

The rate of evaporation is directly proportional to temp of liquid.

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.

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.

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

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

6) **Surface area:**

The rate of evaporation is directly proportional to the surface area of the evaporator, in which the liquid is evaporated.

7) **Vapour pressure of the liquid to be evaporated:**

The rate of evaporation is directly proportional to the vapour pressure of the evaporating liquid.

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e. Differentiate between maceration process for organised drugs and maceration for unorganised drugs. (3 Marks for 5 points)

Ans:

	Organised Drugs		**Unorganised drugs.**
1.	Drug along with whole menstrum is used in maceration process	1.	Drug along with $4/5^{th}$ of menstrum is used in maceration process
2.	The period of maceration is 7 days	2.	The period of maceration is 2-7 days
3.	Strain off the liquid and press the marc	3.	Decant the liquid. Marc is not pressed.
4.	Filtrate is not adjusted to volume.	4.	Filtrate is adjusted to make up the final volume.
5.	Examples of tincture made by this process are: a. Tincture of Orange b. Tincture of Lemon c. Tincture of Capsicum	5.	Examples of tincture made by this process are: a. Tincture of Tolu b. Tincture of Myrrh c. Tincture of Benzoin

f. Why there is need for formulation of different dosage forms. (0.5 marks for each point)

Ans:

i. To protect drug substances from oxidation, hydrolysis, reduction etc.eg. coated tablets, sealed ampoules etc.

ii. To protect the drug from destructive effect of gastric juice. eg. - Enteric coated tablets.

iii. To provide a safe and convenient delivery of accurate dose. eg. - Tablet, Capsule.

iv. To conceal the bitter taste or obnoxious odour of a drug substance.eg. – Capsule, coated tablets, flavoured syrups.

v. To provide optimum drug action in inhalation therapy. eg. Aerosols and inhalers.

vi. To provide for the insertion of drug into body cavity. Eg. Suppositories & pessaries.

vii. To provide maximum drug action from topical administration sites. Eg. Creams, ointments, ophthalmic preparations, ENT preparations.

viii. To provide liquid dosage form of the drugs which are insoluble or unstable in different vehicles.eg. Suspension

ix. To provide liquid dosage form of the drugs which are soluble in a suitable vehicle.eg. Solutions

x. To provide drugs within body tissues. Eg. Injection xi. Sustained release action to control the release mechanism. Eg. Sustained release tablets, capsules and suspensions.

Q. 5 Attempt any FOUR of the following: 12

a) What is the difference between 'Purified water' and 'Water for injection'? How will you prepare ' Water for injection' in laboratory.

Ans: Difference: (1 mark any 2 points)

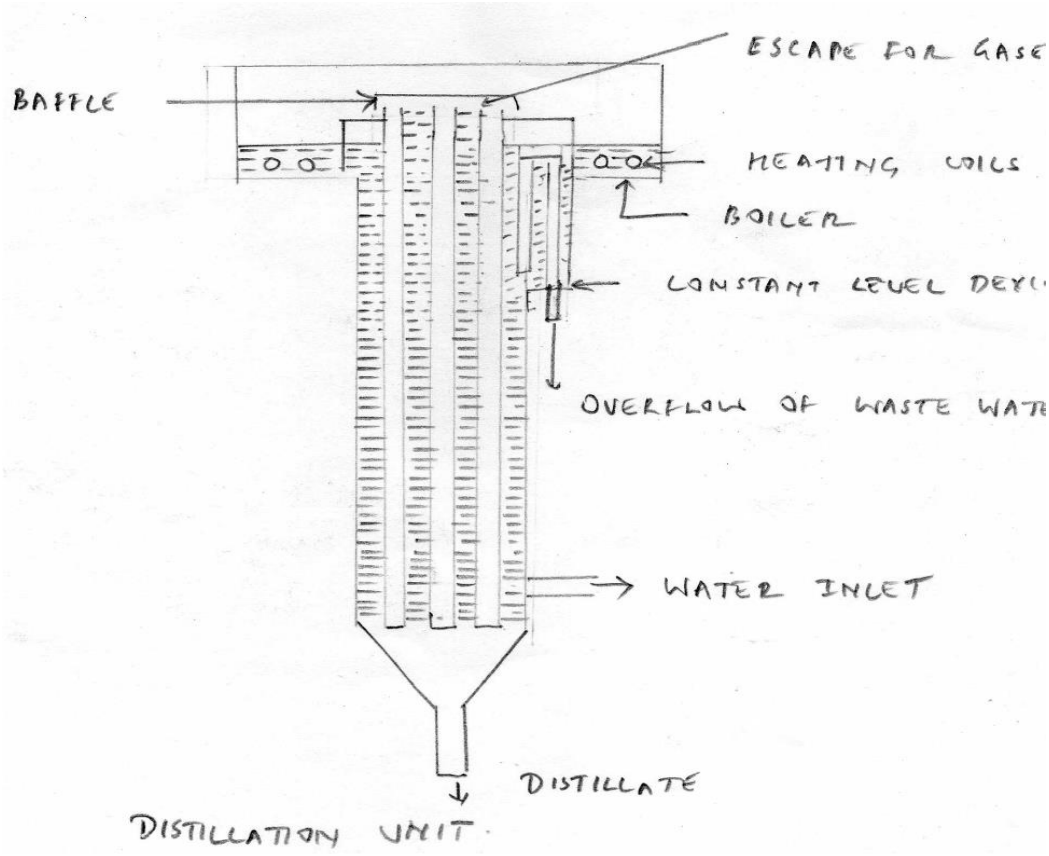
Purified Water	Water for injection
1) Water which is free from volatile and non-volatile impurities is called as purified water.	1) Water which is free from volatile and non-volatile impurities, micro-organisms and pyrogens is called as water for injection.
2) It may contain pyrogens.	2) It is free from pyrogens.
3)It can not be used in parenteral preparations.	3)It can be used in parenteral preparations.
4) pH is 4.5 to 7.0	4) pH is 5.0 to 7.0.
5) It is supplied in large volume.	5) It is supplied in small volume.
6) It is used for long duration.	6) It must be used within 24 hours for parenteral preparations.

Preparation of water for injection I.P.:(1mark preparation, 1 mark diagram)

Water for injection is prepared in a distillation unit. It consists of a boiler made of cast iron. It is connected to condenser tubes through the baffles. The condenser tubes and baffles are made of stainless steel. Baffles are provided over the top of the condenser tubes to avoid water drops getting mixed with the vapours. It is done to avoid carry-over of pyrogen and other water-soluble

materials in the droplets. The cooling water enters at the bottom of the condenser and is heated by the condensing vapours. The flow rate is adjusted in such a way that water gets heated at 90-95 ^{0} C before it enters the boiler. The top of the condenser jacket is open so that gases from the water can escape into the atmosphere. A constant level device is fitted in such a way that only the heated water free from gases enters the boiler.

Diagram:



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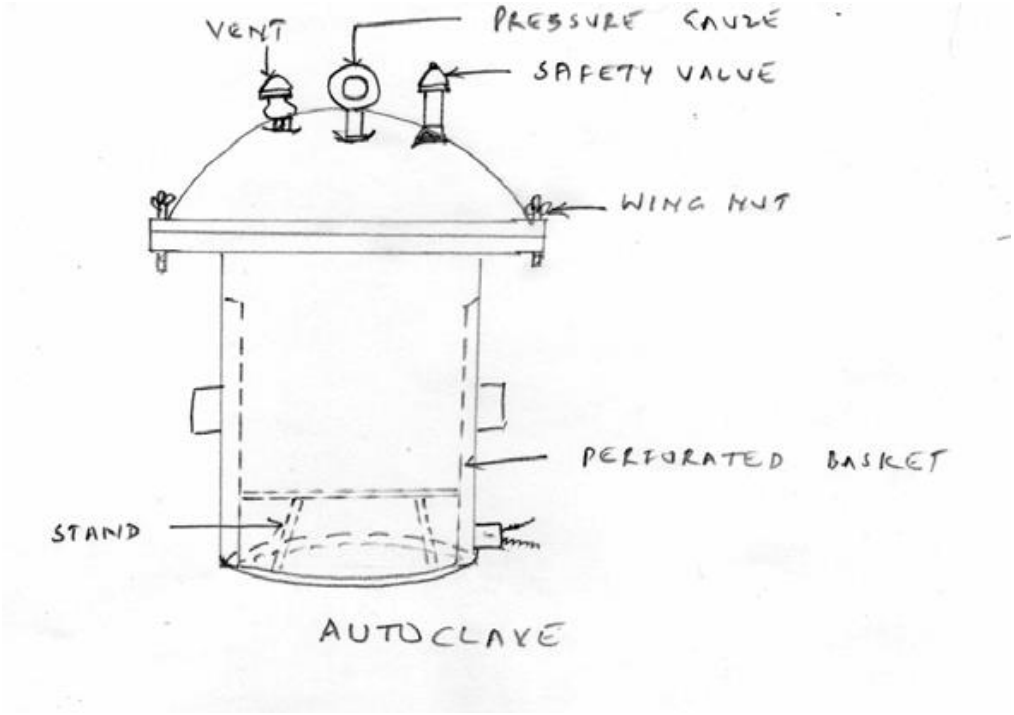
b) Describe construction and working of equipment used for moist heat sterilization.

Ans: Moist heat sterilizer or Autoclave:

Diagram: (1 mark)



Construction: (1 mark)

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.

Working: (1 mark)

A sufficient quantity of water is poured into the chamber after removing the perforated chamber. The level of the water is adjusted in such a way that it does not touch the bottom of the perforated chamber. The lid is then closed with wing nuts and bolts. The autoclave is switched on to heat the water. The vent is opened and safety valve is set at the required pressure.

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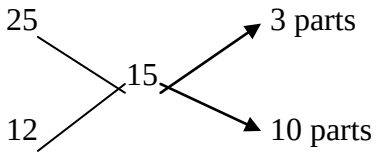
When steam starts coming out from the vent and it continues for 5 minutes, it is then closed. The steam pressure starts raising and it comes to the desired pressure i.e. 10 lbs/sq inch with corresponding temp 115 ^{0}C or 15 lbs/sq inch with corresponding temp 121 ^{0}C After the stated period, switch off the autoclave. Allow it to cool to about 40^{0}C before opening the vent. When whole of the steam is removed, the lid is opened and the sterilized material is taken out.

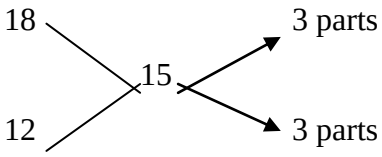
c) In what proportion 25% , 18%, 12% alcohol should be mixed to get 15% alcohol.

(3 marks)

Ans:



and



25 % = 3 parts

18 % = 3 parts and

12 % = 10 + 3 = 13 parts.

Therefore, 3 parts of 25 % , 3 parts of 18 % and (10 +3) 13 parts of 12 % alcohol should be mixed to get 15 % alcohol.

d) What are various ‘ Novel drug delivery systems’- explain implants.

Ans: Various drug delivery systems are: (1.5 marks for any three)

1. Implants
2. Liposome drug carriers
3. Nanoparticles
4. Prodrugs
5. Films and strips
6. Erythrocytes

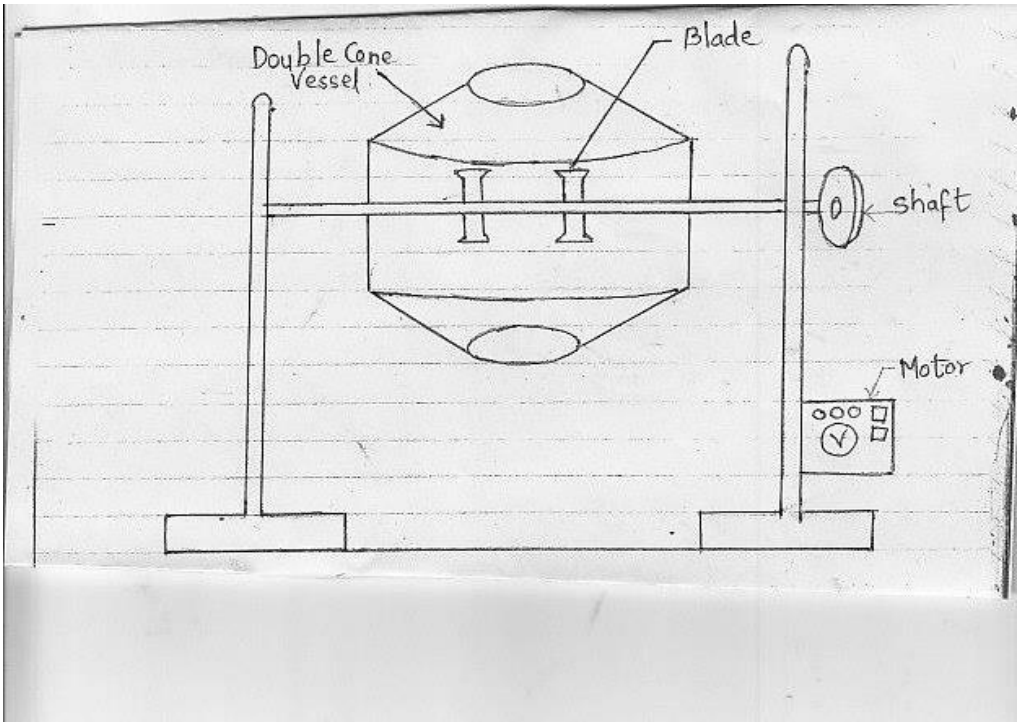
Implants: (1.5 marks for explanation)

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 on

the 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**.**

e) Describe construction and working of double cone blender.

Ans: Diagram: (1 mark)



Construction: (1 mark)

Double cone blender is made up of stainless steel and is available in different capacity ranging from 5 kg to 200 kg or even more. The efficiency of the blender depends mainly on the speed of rotation. The rate of rotation should be optimum which depends on the size and shape of tumbler as well as nature of material to be mixed. The common speed of rotation is of about 30-100 rpm.

Working: (1 mark)

The material to be blended is loaded in approximately 50-60% capacity of conical shaped vessel. As the blender rotates, the material undergoes tumbling motion and mixes the material thoroughly. Agitator blade can also be used in order to produce shearing action and design is useful for mixing powders of different densities in small quantities.

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f) Give the method of preparation of "Small pox vaccine" using egg.

Ans: Small pox vaccine is prepared by two methods 1) By using animals 2) By using Eggs

By using eggs: **(3 marks)**

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° C

↓

Add 50 % glycerin

↓

Material is ground to produce homogenized suspension.

↓

Transfer to suitable sterile container and freeze dried

SUMMER– 16 EXAMINATION

Subject Code: **0805** **Model Answer** Page No: 27/32

Q. 6 Attempt any FOUR of the following: 16

a) How will you prepare 4 ounces of solution so that 1 tablespoonful to 1 quart make 1 in 500 ml solution.

Ans: (1 quart= 40 fl oz)

1 in 500 = 100/500 = 0.2%

35 gr, in 8 fl oz , will make a 1% w/v solution

35 X 0.2 gr, in 8 fl oz, will make a 0.2 % w/v solution

$\frac{35 \times 0.2 \times 40}{8}$ gr, in 40 fl oz, will make a 0.2 % w/v solution

= 35 gr

So, 35 gr must be contained in every tablespoonful.

1 oz = 2 tablespoonfuls

4 oz = 8 tablespoonfuls

Therefore 35 x 8 gr = 280 gr must be contained in 4 oz (8 tablespoonful)

Or

Ans:

Data given;

1. Volume of concentrated used= ½ oz (1 tablespoonful).
2. Volume prepared = 1 quart (40 fl.oz)
3. Strength of dilute solution given= 1 in 500 = 0.2%

½ oz diluted to make 1 quart 1 in 500 solutions

Therefore,

Degree of dilution = volume prepared/volume of concentrated solution used

= 40 X 2 = 80 times.

Now,

Strength of concentrated solution = degree of dilution/ strength of dilute solution.

= 80/0.2 = 16%

Strength of concentrated solution = 16%

Now,

4 fl.oz 16% required,

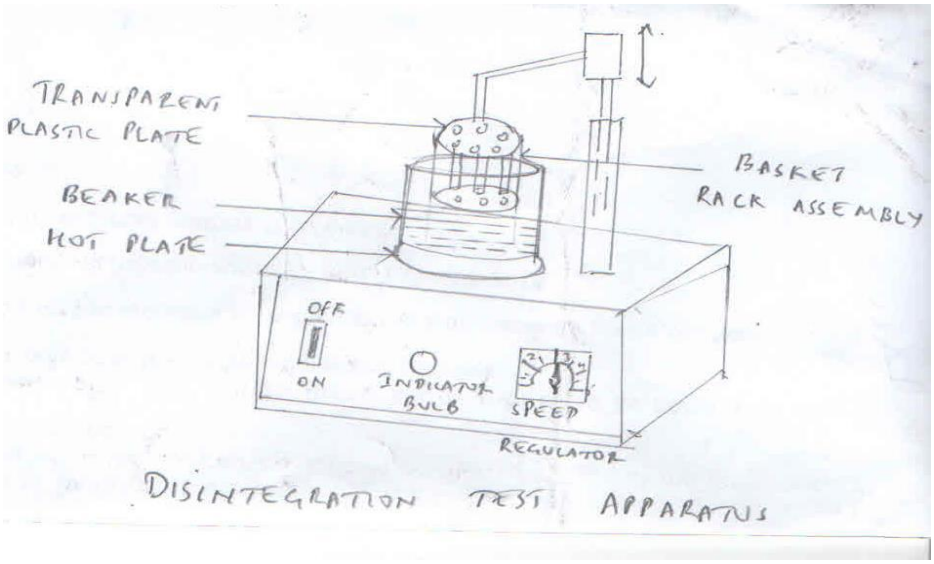
Therefore

Formula: Solid: 4.375 grain in 1 fluid ounce gives 1%w/v solution.

Now, 4.375 X 16 X 4 = 280 grain.

280 grain solid required to get 16% 4 fl.oz

b) Discuss in brief disintegration test for uncoated tablet. (Diagram: 2marks, Description: 2 marks)



Ans: Disintegration test: 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.

The apparatus consists of a rigid basket-rack assembly supporting 6 cylindrical glass tubes held vertically by two superimposed transparent plastic plates with six holes having the same diameter as the tubes. Woven wire gauze made from stainless steel is attached to the underside of

the lower plate. The assembly should be raised and lowered between 28 and 32 times per minute in the liquid at 37^0 C.

The tablets are kept immersed in the liquid within the tubes by means of cylindrical guided discs. 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.

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.

c) What are toxoids ? Discuss general methods for preparation of toxoids.

(1.5 marks for definition, 2.5 marks for general method of preparation)

Ans: Toxoids: The pathogenic bacteria during their growth in a suitable medium produce toxic substances known as "toxins". These toxins are disease producing and antigenic in nature. These toxins may be Exotoxins or Endotoxins.

These toxins are then treated with chemical such as formaldehyde to destroy their toxic properties. These are called as "Toxoids". They are employed for development of active immunity.

General method of preparation of toxoids:

A suitable strain of bacteria is grown on liquid medium. Incubation is carried out under optimum conditions until toxin productions has reached a satisfactory level. Filter the media and the filtrate containing toxins are converted by chemical treatment to toxoid in which toxicity has been reduced, but antigenic effect is maintained.

The conversion of toxin to toxoid is done by the treatment with formaldehyde solution at 37^0 C. The product obtained is known as formal toxoid (FT).

The formal toxoid obtained may be further purified by:

i. Precipitating with alum (APT)
ii. Flocculating it with the corresponding antitoxin (TAF)
iii. Adsorbing an aluminium hydroxide (PTAH) or hydrate aluminium phosphate (PTAP).

The official bacterial toxoids are Diphtheria vaccines, Tetanus toxoid (adsorbed) I.P., Staphylococcus toxoid I.P. etc

SUMMER– 16 EXAMINATION

d) Define: i) Sterilization

ii) Disinfection

Classify different methods of sterilization.

(1mark for each definition, 2 marks for classification)

Ans: i) Sterilization: Sterilization is a process of complete destruction of all micro-organisms & their spores present in a system.

ii) Disinfection: A process that removes the infection potential by destroying micro-organisms but not generally bacterial spores.

Methods of sterilization:

A) Physical Methods:
   1) Dry heat sterilization
   2) Moist heat sterilization
   3) Radiation sterilization
      a) Use of UV rays
      b) Ionising radiation

B) Chemical Methods:
   1) Sterilization by heating with bactericide
   2) Gaseous sterilization

C) Mechanical Methods: Sterilization involves the filtration of Parenteral preparations through the following bacteria proof filters:
   1) Ceramic filters
   2) Seitz filters
   3) Sintered glass filters
   4) Sintered metal filters
   5) Membrane filters

e) What are advantages of multiple maceration? Give formula for calculating volume required for double and triple maceration.

Ans: Advantages of multiple maceration: (0.5 X 4 = 2 marks)

1. Complete exhustation of crude drug achieved.
2. Less quantity of menstrum is required.
3. Concentrated extract/infusions can be prepared.
4. Loss of menstrum is less.
5. Reduce the cost of extraction.
6. Cheap process.

Formula for calculating volume required for double maceration (1mark)

1) Volume of menstrum required for first maceration =

$$\frac{\text{Total volume of menstrum} - \text{volume to be retained by drug}}{2} + \text{volume to be retained by drug}$$

2) Volume of menstrum required for second maceration =

Total volume of menstrum - Volume of menstrum used in first maceration

Formula for calculating volume required for triple maceration: (1 mark)

1) Volume of menstrum required for first maceration =

$$\frac{\text{Total volume of menstrum} - \text{volume to be retained by drug}}{3} + \text{volume to be retained by drug}$$

2) Volume of menstrum required for second and third maceration =

$$\frac{\text{Total volume of menstrum - Volume of menstrum used in first maceration}}{2}$$

f) Explain principle, construction and working of cyclone separator.

Ans: Principle: (1M)

In cyclone separator the centrifugal force is used to separate solids from fluids separation depends on particle size and density of particles.

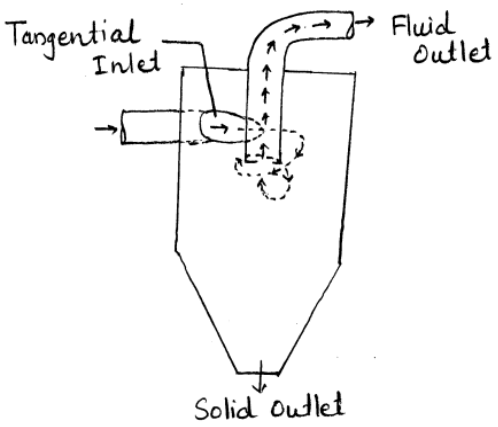
Construction: (1M)

- 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.

Working: (1M)

- 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.

Diagram (1M)



Cyclone Separator