WINTER– 19 EXAMINATION

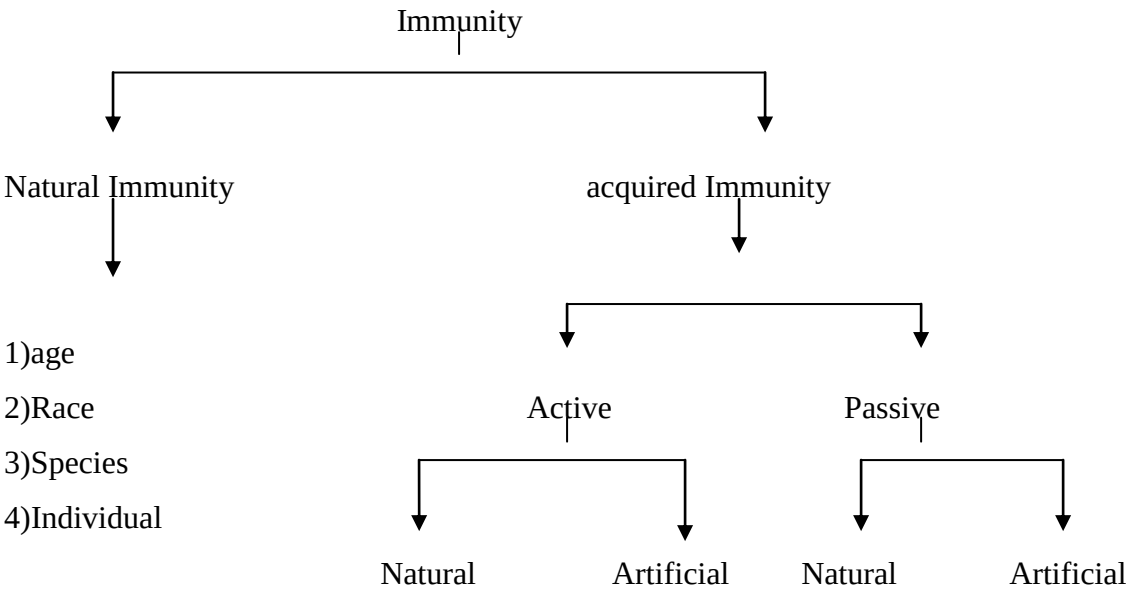
Subject Title: PHARMACEUTIC-I Subject Code: 0805

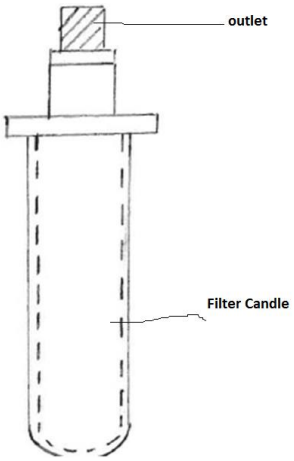
Important Instructions to examiners:

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.

WINTER– 19 EXAMINATION

Subject Title: PHARMACEUTIC-I Subject Code: 0805

Q. No.	Sub Q. N.	Answer	Marking Scheme
1		**Answer any EIGHT of the followings:**	**16M**
1	**a)**	**Define:** **(1) Sieve number:** It is the number of mesh in 2.54cm transverse direction parallel to wire. **(2) Pharmaceutical Aid:** Pharmaceutical aids are the substances which have no or little pharmacological effect but they are essentially used in the preparation of pharmaceutical dosage form.	**(1+1=2M)**
1	**b)**	**Define and classify Immunity.** **Definition:** The power of body to resist the effects of invasion of micro-organisms is called immunity. **Classification:**  	**(0.5 +1.5=2M)**
1	**c)**	**Give disadvantages of glass.** **Disadvantages:** ❖ Fragile, easy to break. ❖ Heavy, Bulky to carry. ❖ Leaching and absorption of alkalis. ❖ Flake formation	**(0.5 X 4 =2M)**
1	**d)**	**Mention precautions to be taken while using of eye drop.** ☐ Do not touch the tip of the dropper.	**(0.5 X 4 = 2M)**

		☐ Never rinse the dropper. ☐ Never use eye drop that have changed colour. ☐ After instillation of drop, do not close eyes tightly or blink more than usual. ☐ Discard the content after one month of use.	
1	**e)**	**Give reason why glycerine is added in throat paint.** **Glycerine** is commonly added in throat paint as a base because being viscous; it adheres to mucous membrane for a long period. It also provides a sweet taste to preparation.	**(2M)**
1	**f)**	**Mention different mechanisms for size reduction.** i. Cutting ii. Compression iii. Impact iv. Attrition v. Combined impact and attrition	**(0.5 X 4= 2M)**
1	**g)**	**Draw well labelled diagram of filter candle.**  	**2M**
1	**h)**	**What is galanicals?** A standard medicinal preparation (as an **extract** or tincture) containing usually one or more active constituents of a plant and made by infusion decoction, maceration or percolation process that leaves the inert and other undesirable constituents of the plant undissolved.	**(2M)**
1	**i)**	**Name any two polymers used for film and enteric coating.** **Film Coating.** 1. Hydroxypropyl methyl cellulose. 2. Hydroxyethyl methyl cellulose. 3. Carbowax.	**(1+1=2M)**

		4. PEG-400 5. Ethyl cellulose **Enteric coating:** 1. Cellulose acetate phthalate. 2. Cellulose acetate trimellitate. 3. Cellulose acetate succinate. 4. HPMC acetate succinate. 5. HPMC phthalate. 6. Polymethacrylate. 7. PVAP	
1	**j)**	**State difference between syrup and elixirs** **Syrup** | **Elixir** Syrup is sweet, viscous, concentrated or nearly saturated aqueous solution of sucrose containing 66.7%w/w of sugar | Elixirs are clear, sweetened and flavored hydroalcoholic liquid preparation intended for oral use. Syrup does not contain alcohol. | Elixirs contain both water and alcohol. Syrup contains 66.7%w/w of sucrose. | Elixir does not contain 66.7%w/w of sucrose. Syrup not necessarily a clear preparation | Elixirs are clear preparation Syrups are more viscous than elixir | Elixirs are less viscous than elixir	**(0.5 X 4 = 2M)**
1	**k)**	**List different excipients used in processing of capsule.** i. **Diluents:** To increase bulk, e.g. lactose, sorbitol, starch etc. ii. **Absorbents:** Eutectic or hygroscopic drug need absorbent, e.g. oxides and carbonates of magnesium and calcium. iii. **Glidants:**	**(0.5 X 4 = 2M)**

		To ensure a regular flow of powder, e.g. talc and magnesium stearate. iv. **Antidusting agents:** During filling of capsule in automatic filling machine a lot of dust comes out to avoid this antidusting agent added e.g. inert oils.	
1	**l)**	**Give Metric equivalents for :** (i) **One pint =** 576ml ≈ 600ml (ii) **One fluid drachm =** 4 ml. (iii) **One teaspoonful =** 4 ml (iv) **15 grain =** 972 mg ≈ 1gram.	**(0.5 X 4 =2M)**
2		**Attempt any FOUR of the followings**	**12M**
2	**a)**	**Define sterilization. Classify different methods used for sterilization.** **Sterilization:** It is the process of complete destruction of microorganisms present in the system **Different methods of Sterilization :** **I. Physical methods** 1. Dry heat sterilization 2. Moist heat sterilization 3. Radiation sterilization i) Use of U.V rays ii) Ionizing radiation **II. Chemical methods** 1. Sterilization by heating with bactericide 2. Gaseous sterilization **III. Mechanical methods** 1. Ceramic filters 2. Seitz filters 3. Sintered glass filters 4. Sintered metal filters 5. Membrane filters	**(1+2=3M)**
2	**b)**	**Give principle, working and use of fluidized bed drier.** **Principle:** • If a gas is allowed to flow upward through a bed of solid particle at a velocity greater than the settling velocity of the particle, particle partially suspended in the	**(1+1+1=3 M)**

		gas stream. • The resultant mixture behaves like a liquid and the solid are said to be fluidized. • Each individual particle is surrounded by drying gas with the result that drying take place in much shorter period. • It also provides uniform condition of temperature, composition and size distribution. **Working:** • In fluidized bed dryer air is introduced by fan situated in the upper part of dryer. • Air is heated by heater to required temp and air flow is adjusted by recirculation control and air is filtered by filter bags to prevent the passage of fine particles to dryers, then air is passed to the bottom to flow through the bed of material to be dried. • They are available in different capacity ranging from 5 kg to 200 kg and drying time is 20 to 40 mins. **Use: (0.5X2=1M)** • Used in granulation process for tablet preparation • It is used in coating. • Used for drying of filter cake.	
2	**c)**	**Define capsule. Differentiate between hard and soft gelatine capsules.** **Capsule:(1M)** Capsules are a solid unit dosage form in which the drug substances are enclosed in a water soluble shell or an envelope.	**(1M +2M = 3M)**

Differentiate: (0.5 X 4=2M)

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. Pudin Hara

2 d) Mention advantages and disadvantages of plastic containers. (1.5 +1.5 = 3M)

Advantages: (Any 3, 1.5 mark)

1. Light in weight and can be handled easily.
2. Poor conductor of heat.
3. Sufficient mechanical strength.
4. Transported easily.
5. Unbreakable.
6. Available in various shapes and sizes.
7. Good protection power.
8. No formation of flakes.

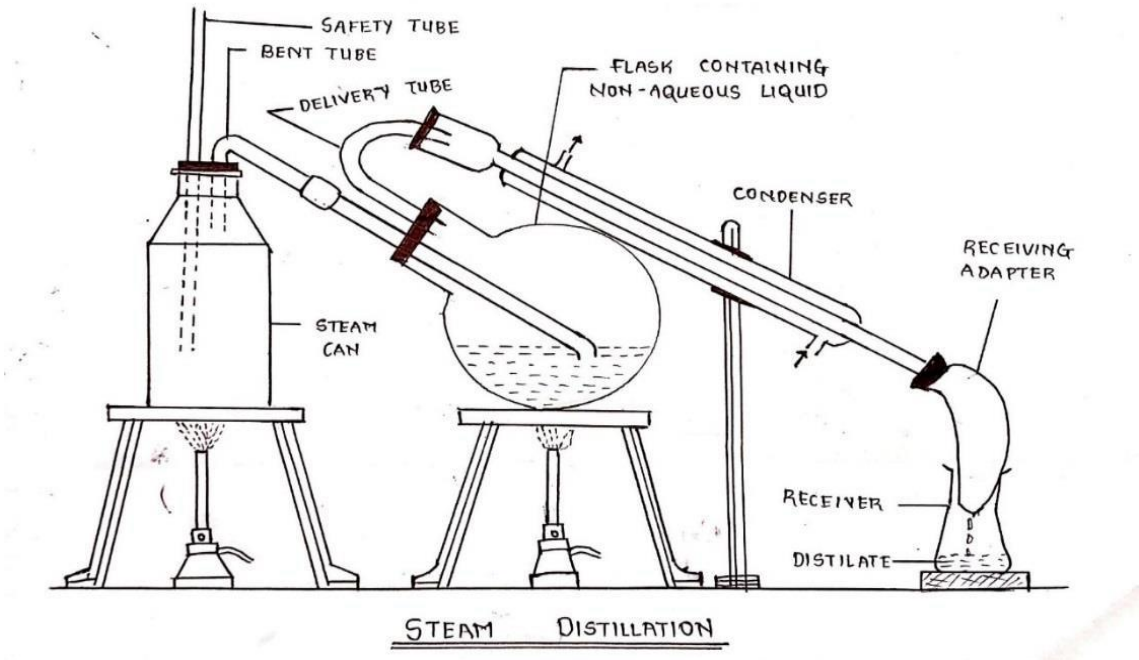
Disadvantages: (Any 3, 1.5 mark)

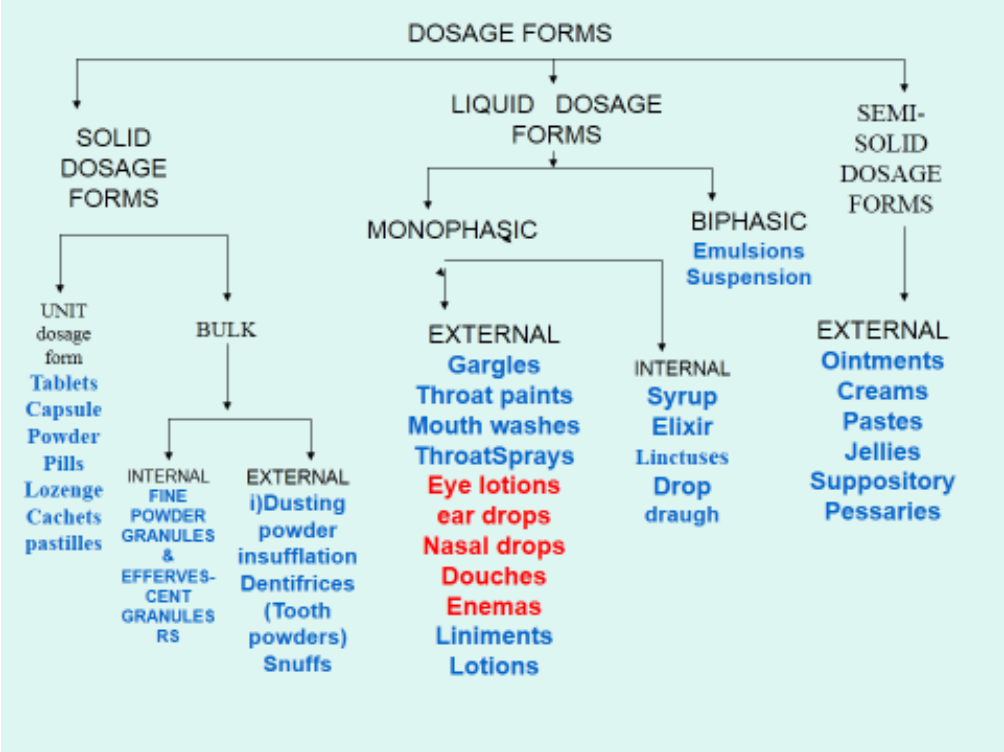
		1. Permeable to water vapour and atmospheric gases. 2. Cannot withstand heat without softening or distortion. 3. May interact with certain chemical to cause softening or distortion. 4. May absorb chemicals such as preservatives. 5. Relatively expensive. 6. Special type of gum or adhesive required for labelling.	
2	**e)**	**Give salient features of IIIrd edition of I.P.** ■ New analytical techniques like flame photometry, flurometry, electrophoresis and photometric haemoglobinometry were introduced. ■ Dissolution test for tablet introduced. ■ Disintegration test amended with modification. ■ A Microbial limit test prescribed for some pharmaceutical aids and oral liquid preparations. ■ Pyrogen test revised. ■ Gas liquid chromatography recognized as alternate method for alcohol determination. ■ Test for Viscosity modified. ■ New appendix "water for pharmaceutical use" has been introduced. ■ Drugs renamed e.g. acetyl salicylic acid-aspirin. ■ Many drugs omitted and new drugs added.	**(0.5 X 6 = 3M)**
2	**f)**	**How many tablets, each containing 8.75 grains of mercuric chloride will be required to make one quart of 0.05% solution?** 4.375 gr. in 1 fl ounce = 1% w/v solution 4.375 gr X 0.05 = 0.2187 gr required to get 1 fl.oz 0.05% 0.2187 gr x 40 = 8.748 gr≈ 8.75 grain required to get 40 fl.oz 0.05 % 8.75 gr/8.75 gr = 1 tablets Therefore, one tablet is required to prepare one quart of 0.05% solution.	**3M**
3		**Attempt any FOUR of the followings**	
3	**a)**	**Define and classify different types of tablets** **Definition(1M)** Tablets are solid unit dosage form containing medicament or medicaments usually	**(1+2= 3M)**

		circular flat or biconvex. OR Tablet is a solid unit dosage form prepared by compression. **Classification of tablets:(0.5X4=2M)** **1. Tablets ingested orally:** a)compressed tablet b)multiple compressed tablets c) multi-layered tablets d)sustained release tablets d)enteric coated tablets e)sugar coated tablets f)film coated tablets g)chewable tablets **2. Tablet used in oral cavity:** a) Buccal tablets b) Sublingual tablets c) Lozenge tablets and traches d) Dental cones **3. Tablets administered by other routes:** a) Implantation tablets b) Vaginal tablets **4. Tablets used to prepare solutions** a) Effervescence tablets b) Dispensing tablets c) Hypodermic tablets d) Tablet triturates	
3	**b)**	**Give principle, working and use of autoclave** **Principle:** • The steam has more penetration power than dry heat and thermal capacity of steam is more than thermal capacity of dry heat. • The method is useful for killing of bacterial spores. • The moist steam penetrate the spores and capsules of bacteria, rupture it and • Escaping protoplasma it coagulated. • The temperature conditions for autoclaving: 1 115^0C to 118^0C for 30 min. 2 121^0C to 124^0C for 15 min. 3 126^0C to 129^0C for 10 min. 4 134^0C to 138^0C for 5 min. **Working:** • A sufficient quantity of water is poured into the chamber after removing the perforated basket. • The level of water adjusted in such a way that it should not touch the bottom of perforated basket.	**(0.5+1.5+1 =3M)**

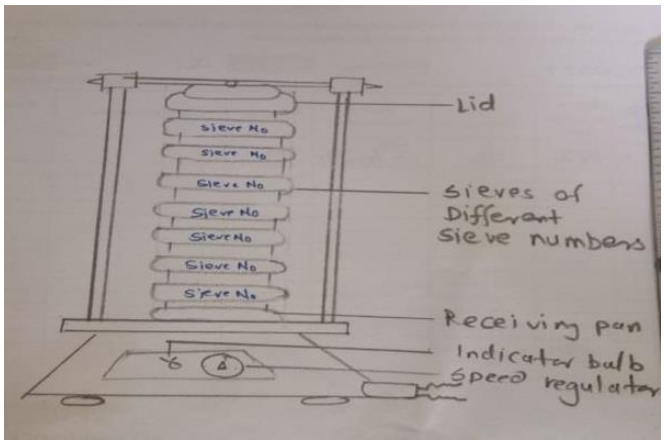
		• The material is placed in the basket and it placed in the autoclave. • Close the lid with wing nuts and bolts. • Switch on the heater. • Vent is opened and safety valve is set to required pressure. • When steam comes out for 5 min, then close the vent, the steam pressure stats rising it should be maintained to required level. • After the stated time, switch off the autoclave. • Allow to cool to about 40^{o}C. • Open the vent and allow the complete steam to pass from autoclave. • Lid is opened and sterilized material is taken out **Use: (0.5X2=1M)** • Sterilization of surgical dressings and surgical instruments. • Sterilization of containers and closers. • Sterilization of official injections	
3	**c)**	**Based on Darcy's law, discuss different factors which affect rate of filtration** This is also called as theory of filtration which gives idea about factors affecting rate of filtration through the filter medium. Any fluid while passing through porous medium offers resistance, the rate of filtration through the filter media is expressed in the form of an equation which is known as Darcy's law The equation is, $V = KA \Delta P/ \mu l$ 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 Thus, According to Darcy's law different factors which affect rate of filtration are: **(0.5X4=2)** **1. 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. **2. Pressure difference on the liquid and below the filter medium:** The rate of filtration of liquid is directly proportional to the pressure difference between the filter	**(1+2= 3M)**

		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. **3. 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. **4. 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.	
3	**d)**	**Define and discuss different types of container** **Container** is a device that holds the drug and it may or may not be in direct contact with the pharmaceutical preparations. **containers are divided into following types on the basis of their utility (0.5X4=2M)** 1. **Well-closed containers:** A well-closed container protects the contents from loss during transportation, handling, storage or sale etc. 2. **Single dose containers:** These containers are used to supply only one dose of medicament and hold generally parenteral products e.g. ampoules and vials. 3. **Multi dose containers:** These containers allow the withdrawal of dose at various intervals without changing the strength, quality or purity of remaining portion. These containers hold more than one dose. e.g. vials. 4. **Light-resistant containers:** These containers protect the medicament from harmful effects of light. Used for photo-sensitive medicaments. 5. **Air-tight containers:** These are also called hermetic containers. These containers have air-tight sealing or closing to protect the products from dust, moisture and air. 6. **Aerosol containers :** These containers have adequate mechanical strength in order to bear the pressure of aerosol packing	**(1+2= 3M)**

3	e)	**Draw a neat labelled diagram showing steam distillation at laboratory scale**  	**3M**
3	f)	**How many ml of 80%, 60% and 50% of alcohol to be mixed to obtain 100ml of 70% alcohol?** 80 20 parts of 80 % 60 70 20 parts of 60 % 50 10 + 10 = 20 parts of 50 % --- 60 parts Thus, 100 ml gives 60 parts X ml for 20 parts of 80%=33.33 ml X ml for 20 parts of 60%=33.33 ml X ml for 20 parts of 50%=33.33 ml Answer: One should thus mix 33.33 ml each of 80%, 60% and 50% alcohol to get 70% of 100ml alcohol	**3M**

4		**Attempt any FOUR of the followings**	
4	**a)**	**Define drug. Classify different types of dosage forms with examples** **Drug**- A chemical agent intended for use in the diagnosis, mitigation, treatment, cure or prevention of disease in man or in other animals.  	**(1+2=3M)**
4	**b)**	**Discuss working of freeze dryer.** **Working: steps involved in freeze drying are** 1. **Pre-treatment:** Solution is concentrated in normal vacuum tray dryer before introducing in the chamber this reduces drying by 8-10 times. 2. **Pre-freezing**: Ampoules, vials and bottles having aqueous solution are packed and frozen in cold shelves at a temp. below - 50^0C. 3. **Primary drying:** The material to be dried is spread to increase the surface area for sublimation.98-99% moisture removed. 4. **Secondary drying:** Remaining moisture is removed by vacuum drying done at 50-60^0C.It takes 10-20 hrs. 5. **Packing:** Packaging of product is performed carefully to protect it from moisture. The containers should be closed under aseptic conditions. Containers are labeled and packed in card-board boxes.after drying.	**3M**

4	**c)**	**Explain why there is need of different dosage form.** **Need of dosage forms :** 1. To protect drug substances from oxidation, hydrolysis, reduction etc.eg. coated tablets, sealed ampoules etc. 2. To protect the drug from destructive effect of gastric juice. eg. - Enteric coated tablets. 3. To provide a safe and convenient delivery of accurate dose. eg. - Tablet, Capsule. 4. To conceal the bitter taste or obnoxious odour of a drug substance.eg. – Capsule, coated tablets, flavoured syrups. 5. To provide optimum drug action in inhalation therapy.eg. Aerosols and inhalers. 6. To provide for the insertion of drug into body cavity. Eg. Suppositories &pessaries. 7. To provide maximum drug action from topical administration sites. Eg. Creams, ointments, ophthalmic preparations, ENT preparations. 8. To provide liquid dosage form of the drugs which are insoluble or unstable in different vehicles.eg. Suspension 9. To provide liquid dosage form of the drugs which are soluble in a suitable vehicle.eg. Solutions **10.** To provide drugs within body tissues. Eg. Injection xi. Sustained release action to control the release mechanism. Eg. Sustained release tablets, capsules and suspensions.	**0.5 X 6 = 3M**
4	**d)**	**Give advantages, disadvantages and applications of sterilization by ionising radiation**. **Advantages:** • The method is reliable and can be accurately controlled • No degradation of media during sterilization, thus it can be used for thermally labile media • Gamma rays have high penetration power thus can be used after packaging	**(1+1+1= 3M)**

		• Leaves no chemical residue • Administration of precise dosage and uniform dosage distribution • Immediate availability of the media after sterilization • Exposure time is less thus can be used for larger quantity **Disadvantages:** • This method is a more costly alternative to heat sterilization Requires highly specialized equipment • The process cannot be stopped once started • The radiations are harmful to the workers **Applications: this method can be used for sterilization of** • Plastic syringes, hypodermic needles, scalpels, surgical blades and adhesive materials. • Bones and tissue transplant, plastic tubing, catheters and sutures. • Sterilization of thermolabile medicaments.	
4	**e)**	**Mention different methods of size separation and explain any one.** **Different methods of size separation are:** 1. Sieving 2. Cyclone separator. 3. Air separator. 4. Elutriation. **SIEVING:** Diagram:  **Construction:** • In this method fine powder is separated from coarse by using sieve of desired	**1+2=3M**

number.

- In sieve separator sieves are arranged in descending order of size.
- The bottom sieve is attached to receiving pan.

Working :Different methods used: 1 Agitation 2 Brushing 3 Centrifugation

CYCLONE SEPARATOR:

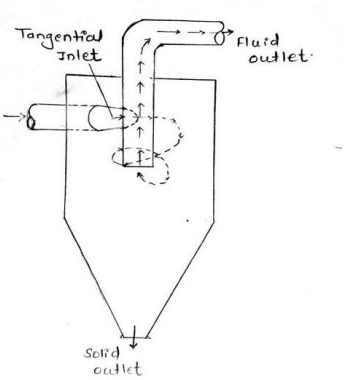


Fig- Cyclone separator

Construction-

Cyclone separator is size separation device

It consists of a cylindrical vessel with a conical base.

The upper part of the vessel is fitted with a tangential inlet and a fluid outlet.

At the base it is fitted with solid outlet

Working of cyclone separator

- The suspension of a solid gas (Usually air) is introduced tangentially at a very high velocity so that rotary movement takes place within the vessel.
- The fluid is removed from a central outlet at the top. The rotator flow within the cyclone separator causes the practices to be acted on by centrifugal force.
- The solid are thrown out to the walls. There after it falls to the conical base and discharge through the solid outlet.

AIR SEPARATOR:

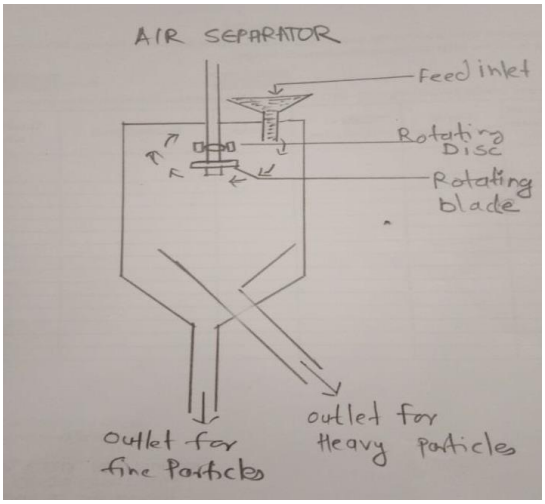
Construction:

- It consist of a cylindrical vessel with conical base
- The upper part of the vessel is fitted with a feed inlet and at base there are two outlets. One for fine and other for heavy particles.

- Rotating disc and blades are attached to the central shaft to produce air movement.

Working:

The sample of powder is passed through the feed inlet, which falls on the rotating disc. The rotating blades are attached to same shaft. The fine particles are picked up and are carried to the space, where air velocity is sufficiently reduced. The fine particles were dropped and collected at outlet. The heavy particles are removed at outlet for heavy particles.



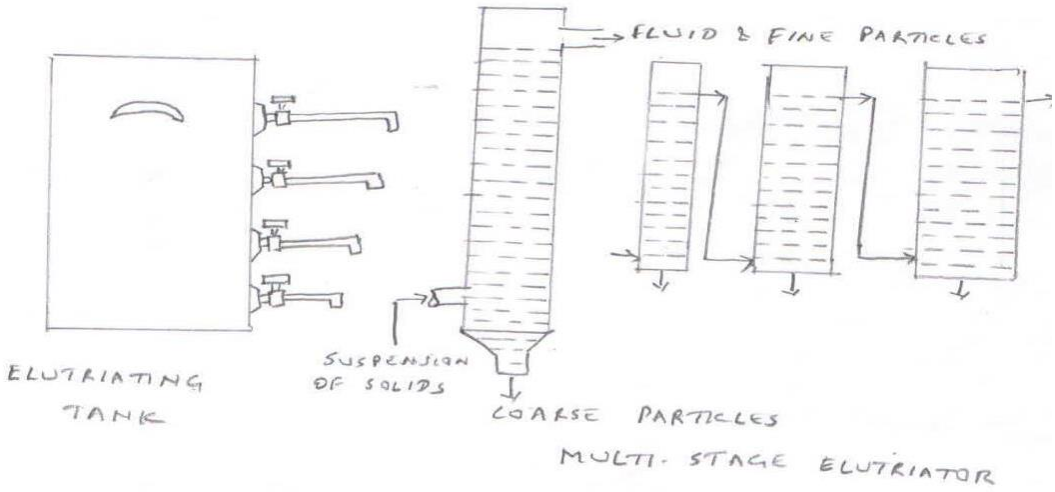
ELUTRIATION:

Construction

- The size separation of powder is based on the low density of fine particles and high density of coarse particles.
- The dry powder or paste is kept in an elutriating tank and mixed with large quantity of water.
- The solid particles are uniformly distributed in the liquid by stirring and then it is allowed to settle down.
- Depending on the density of the solid particles, it will either settle down or remain suspended in water.
- The sample is withdrawn at different heights through the outlets. These are dried and thus the powder with various size fractions is collected.

Working:

- The particles are suspended in a moving fluid, generally water or air.
- The apparatus consists of a vertical column with an inlet near the bottom for

		suspension, an outlet at the base for coarse particles and an overflow near the top for fluid and fine particles. • One column will give a single separation into two fractions. • If more than one fraction is required, a number of tubes of increasing area of cross-section can be connected in series. • The velocity of fluid decreases in succeeding tubes as the area of cross-section increases, thus giving a number of fractions. These fractions are separated and dried. **Application:** Elutriating tank is used to separate the coarse and fine particles of powder after levigation **Diagram:**  	
4	**f)**	**Write in brief about special applications of capsules.** **Special applications of capsules: (any three)** Applications of capsule: **1. Enteric coated capsule:** These capsules do not disintegrate in stomach (Acidic Medium) but break up in intestine (Alkaline medium). On commercial scale, a coating of cellacephate (cellulose acetate phosphate) and mixture of waxes with fatty acids and esters are given. Categories of drug needed coatings: Irritation to GIT • Destroyed in GIT • Specially intended to intestine	**(1 X 3 =3M)**

		• Required to produce delayed action **2. Sustained release capsule:** In order to maintain a proper blood concentration. • Preparation of coated pellets according to different release rate. • E.g. a capsule may be filled with mixture containing 30 % uncoated pellets for immediate release of the drug, 30 % each of the coated pellet, that release the drug 4 hour and 8 hour intervals and 10 % of neutral pellets are mainly used to fill capsule. **3. Rectal Capsule:** • Soft gelatine capsule may be used as substitutes for rectal and vaginal suppositories. • Soft gelatine capsule of various shapes and sizes available but pear shape commonly used. • Both solid and liquid medicament can be filled in to soft gelatine capsule. • Also base used for incorporating medicament is non-toxic, non-irritant and compatible with capsule shell. **4. Capsule containing ophthalmic ointments:** It must be sterile • It required to fill in single dose container • Soft gelatine commonly used • Capsule punctured by using sterile needle and then instilled into the eyes	
5		**Attempt any FOUR of the followings**	**12M**
Q.5	**a.**	**Define Pharmacopoeia. Discuss history of Indian Pharmacopoeia.** **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. **History of Indian Pharmacopoeia:** The government of India directed the Drugs Technical Advisory Board to list the drugs that are used in India, which are not mentioned in British Pharmacopoeia and also recommend the standards to be prescribed to maintain uniformity and the chemical tests to be used to establish identity and purity. The Government of India published the Indian Pharmacopoeial List in 1946 as a supplement to British Pharmacopoeia. The term	**(1+ 2= 3M)**

list in the title was ‘misleading’ in that, the book not only contained a list of drugs which were of substantial medicinal value but also laid down standards.

The Indian Pharmacopoeial List contained about 180 monographs and a number of appendices prepared on the lines of the British Pharmacopoeia. Approximately 100 monographs were on vegetable drugs growing in India and on their galenicals. `The drugs of plant origin such as artemesia, bael, berberis, cannabis, ispaghula, kaladana, kurchi, myrobalan,picrorhiza, punarnava, rauwalfia, vasakaetc.were included in it. Similarly several oils such as ajowan,cassia, chaulmoogra, neem and pudina were included it. The appendices gave detail for a number of determinations referred to in the monographs.

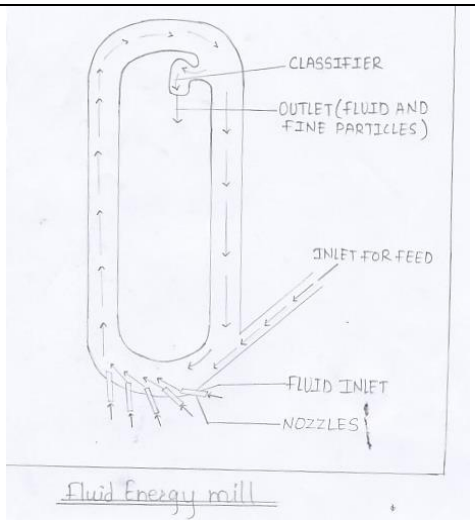
The Pharmaceuticals and Drugs Research Committee of the Council of Scientific and Industrial Research decided in February 1947 to compile a ’Brochure’ to highlight the information and clinical users of the important indigenous drugs of India. Later on it was decided to prepare a ’Codex’ instead of Brochure on the lines of the British Pharmaceutical Codex.

The first Indian Pharmaceutical Codex published in 1953.The Codex consisted of two parts. The part carried about 190 general monographs on natural product and drugs of vegetable and animal origin, and a few chemicals. The second part consisted of formulary of galenicals and other preparations.

After the publications of the Indian Pharmacopoeial List the Government of India, constituted an eleven member Indian Pharmacopoeial Committee in 1948, in their notification No. F.1-1/48-DS dated 23rd November, 1948, for preparing the Pharmacopoeia of India. The tenure of the office of the members of the Committee was five years. It was extended by one year vide Government notification no F.6-10/53-DSdated 21st November 1953. In compiling the monographs of the first Pharmacopoeia of India, help was taken from all available established scientific data in the modern Pharmacopoeia, such as British Pharmacopoeia, the United States Pharmacopoeia, and the international Pharmacopoeia and from scientific institutions interested in drugs and Pharmaceuticals products. The first edition of Pharmacopoeia of India was compiled and then published in 1955.

The second edition of Pharmacopoeia of India was compiled and then published in 1966. The third edition of Pharmacopoeia of India was compiled and then published in

		1985. The fourth edition of Pharmacopoeia of India was compiled and then published in 1996. The fifth edition of Pharmacopoeia of India was compiled and then published in 2007. The seventh edition of Pharmacopoeia of India was compiled and then published in 2010. The eight edition of Pharmacopoeia of India was compiled and then published in 2014.	
Q.5	**b.**	**Explain working of fluid energy mill with a neat diagram.** **Working:(2M)** 1. The material which is to be size reduced is fed in the grinding chamber from the bottom through the feed inlet. 2. The air or inert gas is introduced with a very high pressure through nozzles. 3 .Due to high degree of turbulence, impact and attritional forces between the particles there is size reduction. 4. The air moves at a very high speed in elliptical part carrying with it fine particles that pass through the outlet in a classifier and are collected. 5. The large particles are carried by centrifugal force to the end whereby they are further exposed to the moving air. 6. The design of the mill provides for the internal classification of the particles whereby lighter, finer particles are discharged and heavier particles are retained due to effect of centrifugal force to be reduced to smaller size. 7. Feed should be of 20 to 200 # size &mill produces particles of 1 to30 micron range to get a very fine powder even up to 5μ, the material is pre-treated to reduce the particle size to the order of 100# and then passed through fluid energy mill. **Diagram: (1M)**	**2+1= 3M**

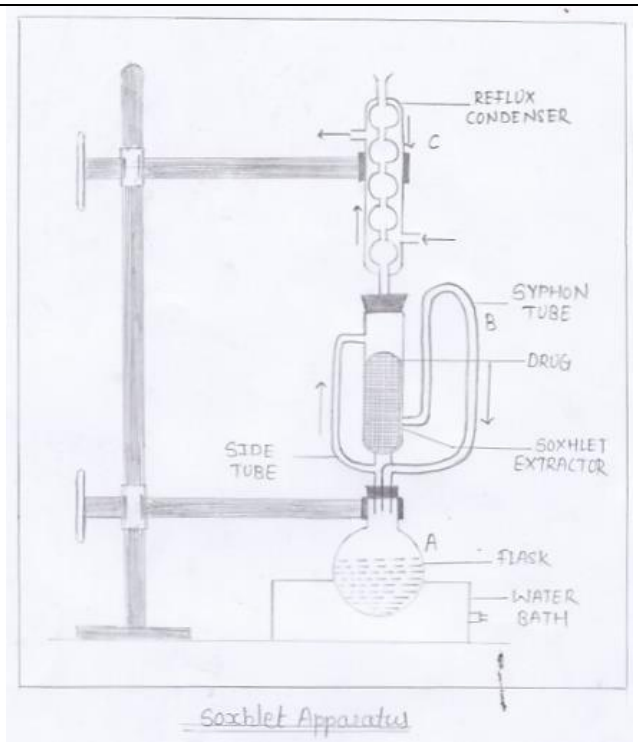
			
Q.5	**c.**	**Define evaporation. Explain any four factors affecting rate of evaporation.** **Definition: (01M)** Evaporation is the free escape of vapour from the surface of a liquid bellow its boiling point. **Factors affecting rate of evaporation:(0.5X4=2M)** **1. Temperature:** The rate of evaporation is directly proportional to the temperature of the liquid. The evaporation can be accelerated by increasing the temperature but it will cause decomposition of heat sensitive principles of many drugs. Many glycosides and alkaloids are decomposed at a temperature below 100oC. Hormones, vitamins, enzymes, antibiotics, malt extract need special treatment to avoid decomposition **2. Temperature and time of evaporation:** It has been observed that exposure to a relatively high temperature for a short period of time (as in film evaporators) may be less harmful than exposure to a lower temperature for a longer period. **3. Temperature and moisture content:** Some drug constituents decompose more readily in the presence of moisture if heated at a high temperature due to hydrolysis. To avoid this, the evaporation is done at a low temperature and then the final drying is done at a high temperature when only little moisture remains in it. **4. Types of product required:** The selection of the method and equipment required for evaporation depends upon the type of product required (liquid, semisolid or solid). **5. Effect of concentration:** During evaporation the upper layer tends to form a film and there is formation of precipitate in the product which results in lowering down the rate of evaporation. Therefore, efficient stirring is required which will prevent degradation of the product at the bottom due to excessive heat and also prevent deposition of solids.	**(1+2 =3M)**

		6. Surface area: The rate of evaporation is directly proportional to the surface area of the evaporator. **7. Vapour pressure of the liquid to be evaporated:** The rate of evaporation is directly proportional to the vapour pressure of the evaporating liquid. The rate of evaporation is maximum at its boiling point when the liquid has maximum vapour pressure.	
Q.5	**d.**	**Describe various stages of sugar coating.** **Steps of sugar coating of tablet:- (0.5X6=3M)** i) Sieving ii) Sealing iii) Sub-coating iv) Syrup coating v) Finishing vi) Polishing **i) Sieving :-** The tablets to be coated are shaken in a suitable sieve to remove the fine powder or broken pieces of tablets **ii) Sealing :-** • Sealing is done to ensure that a thin layer of water proof material, such as, shellac or cellulose acid phthalate is deposited on the surface of the tablets. • The shellac or cellulose acid phthalate is dissolved in alcohol or acetone & its several coats are given in coating pan. • A coating pan is made up of copper or stainless steel. • The pan is rotated with the help of an electric motor. **iii) Sub coating :-** • In sub coating several coats of sugar & other material such as Gelatine, Acacia etc. are given to round of tablet and to help in building up to tablet size. • Several coats of concentrated syrup containing acacia or gelatine are given. • After each addition of the syrup, dusting powder is sprinkled. • The dusting powder is a mixture of starch, talc & powdered acacia. **iv) Syrup coating :-** • This is done to give sugar coats, opacity &color to tablets • Several coats of the syrup are applied • Coloring materials & opacity agent are also added to the syrup	**(0.5X6=3 M)**

		• The process of coating is repeated until uniform colored tablets are obtained **v) Finishing :-** • Three to four coats of sugar are applied in rapid succession without dusting powder and cold air is circulated to dry each coat. Thus forms a hard smooth coat **vi) Polishing :-** • Beeswax is dissolved in volatile organic solvent & a few coats of it are given. • The finished tablets are transferred to a polishing pan is rotated at a suitable speed so the wax coated tablets are rubbed on the canvas cloth. • This gives a proper shining to the tablets	
Q.5	**e.**	**What is aseptic technique? State its importance.** **Definition: Aseptic technique** The method which is used to prevent the access of microorganism during the preparation of parenteral product and their testing are called "Aseptic Technique". **Importance of Aseptic Technique: (0.5X4=2M)** 1. It helps to maintain sterility of product. 2. It avoids contamination of product. 3. It prevents access of microorganism & particles. 4. It helps in filling and sealing of injectable. 5. It helps preparation of ophthalmic products. 6. Safety and efficacy of product can be maintained. 7. It helps to maintain required environment for testing of sterile products.	**(1+2M=3 M)**
Q.5	**f.**	**Mention different types of closures. Comment on materials used for making closures.** **Types of closures with examples: (0.5X3=1.5)** **1. Plug type.** **2. Crown cap.** **3. Push-fit cap.** **4. Screw closures.** **Materials used in pharmaceutical closures: (0.5X3=1.5)** **1) Rubber**	**(1.5+1.5= 3M)**

		• Cork is obtained from the bark of oak tree. • Cork is chemically inert and it does not impart any odour or flavour to the product. • Not used for liquid preparations because of danger of mould growth • Cork closures are rarely used nowadays & replaced by plastic or rubber closures. **2) Glass** • Glass closures are ideal but they mostly slip during transportation and handling. • Mainly used for reagent bottles in laboratories. **3)Plastic** • Plastic closures are nowadays commonly used • They are available in various shapes and sizes. • They are light in weight and are unbreakable. • Plastic closures must be tested for any extractable matter ,physiochemical & biological testing **4)Metal** • Made from tin plate and aluminium. • Aluminium closures are preferred because of their durability and also ease of conversion into desired shape. • Metal closures can be made pilfer-proof by using a liner. **5)Rubber** • Rubber is used mainly for the construction of closure meant for vials, transfusion fluid bottles. • Rubber, two types natural or synthetic,	
Q.6		**Answer any FOUR of the following:**	**16M**
Q.6	**a.**	**Discuss different official grades of powders according to I.P. 2010** **According to IP 2010 official grades of powders are as follows:** **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. **ii. Moderately Coarse powder:** A powder of which all particles pass through sieve no	**4M**

		22 with nominal aperture size 710um and not more than 40% pass through sieve no 60 with nominal aperture size 250um. i**ii. 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. **iv. Fine powder:** A powder of which all particles pass through sieve no 85 with .nominal aperture size 180 um. **v. Very fine powder:** A powder of which all particles pass through sieve no 120 with nominal aperture size 125 um. **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 **vii. Superfine powder:** A powder of which not less than 90% by weight of particles are less than 10 µm.	
Q.6	**b.**	**Classify different methods used for extraction. Draw a labelled diagram of soxhelt extractor** **Methods Of Extraction: (0.5X4=2M)** a) Infusion b) Decoction c) Maceration d) Percolation **e)** Digestion **Diagram of Soxhlet apparatus: (2M)**	**4M**

			
Q.6	**c.**	**Mention all Q.C. tests to be performed on tablets. Explain any one in detail.** **Q.C. Tests: (0.5X4=2M)** 1. Size and shape of tablet. 2. Appearance. 3. Content of active ingredient. 4. Uniformity of weight/weight variation test 5. Uniformity of content 6. Disintegration. 7. Dissolution. 8. Hardness test. 9. Friability 1. Shape of tablets: Circular with flat or convex faces. 2. Appearance: Uncoated tablet under lens either a relatively uniform texture or a stratified structure. No signs of coating. 3. Content of active ingredient: The amount of active ingredient in tablet is determined by doing the assay. Generally 20 tablets or such other number as may be indicated in the monograph are used in the assay. The result lies within the range for the content of	**(2+2=4M)**

active ingredient in the monograph. The stated limits are between 90 and 110%.

Weight of medicament in each tablet	Subtract from the lower limit for the sample of			Add to the upper limit for sample of		
	15	10	5	15	10	5
0.12 g or less	0.2	0.7	1.6	0.3	0.8	1.8
More than 0.12 g and less than 0.3 g	0.2	0.5	1.2	0.3	0.6	1.5
0.3 g or more	0.1	0.2	0.8	0.2	0.4	1.0

4. Uniformity of weight: Weigh 20 tablets selected at random and determine their average weight. Not more than 2 of the individual weights may deviate from the average weight by more than the percentage deviation given in the table and none should deviate by more than twice that percentage.

Sr. No	Average weight of a tablet deviation	Percentage
1	80 mg or less	10
2	More than 80 mg and less than 250 mg	7.5
3	250 mg or more	5

5. Uniformity of content: Percentage of medicament is calculated by doing assay for a particular drug. 20 tablets are taken, powdered and assayed. The average weight of medicament present in each tablet is calculated which is then compared with the desired weight. The pharmacopoeia has prescribed the limit in percentage of medicament per tablet in the monograph**.**

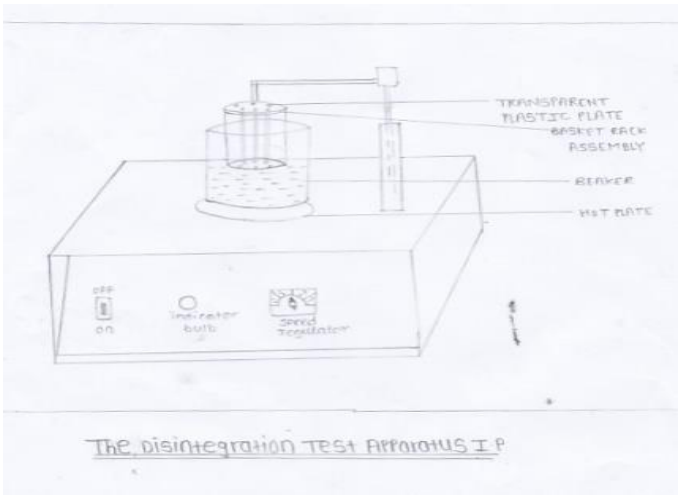
6. Disintegration test: Disintegration of a tablet means to break a tablet into smaller particles after swallowing. The time required to disintegrate the tablet is called disintegration time.

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 37^0C.

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.

Diagram:



The disintegration test Apparatus I P

7. Dissolution test: The test is done for measuring the amount of time required for a given percentage of drug substance in a tablet to go into solution under specified condition in vitro.

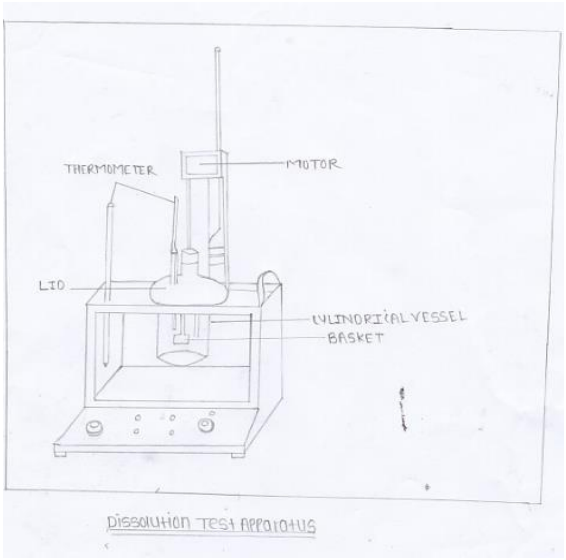
The apparatus consists a cylindrical covered vessel made of glass or other transparent material having 1000 ml capacity. The vessel is fitted with a lid having 4 holes, one for shaft of stirrer, second for placing thermometer and remaining two for removing the sample.

An electric motor which is capable of rotating the basket (woven wire cloth having aperture size 425 micrometer) in the vessel at varied speed between 25 and 150 revolutions per minute.

1000 ml of water at 37^0 C + 0.5 ^{o} C in placed and specified number of tablets are placed in the dry basket. The motor is started and the rotation speed is adjusted to 1000 rpm or as directed in the monograph. Withdraw the stated volume of solution from the vessel after 45 minutes or after the time specified in the monograph. Filter and determine the amount of active ingredient present in it. The tablets pass the test if for each of the five replicates; the amount of active ingredient in solution is not less than 70% of the stated

amount

Diagram:

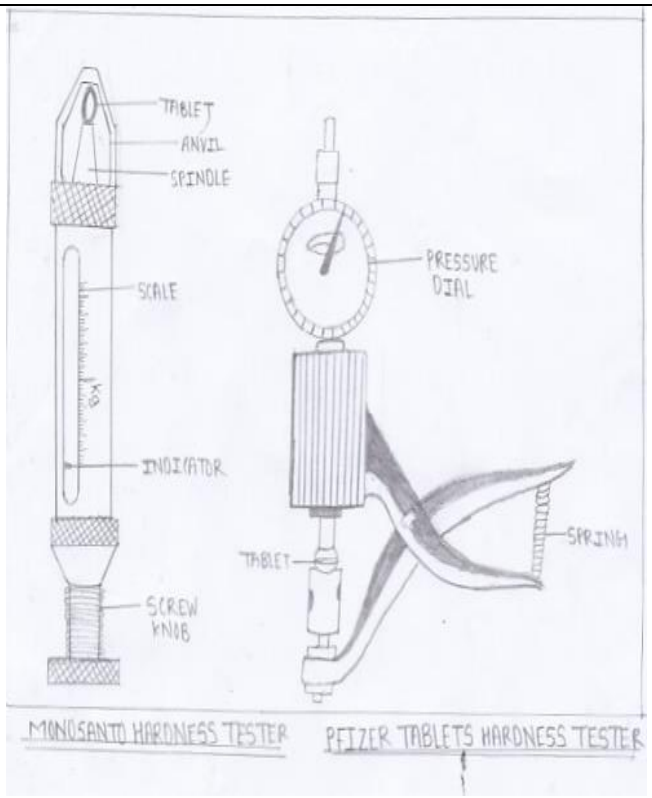


8. **Hardness test:** Manufacturers have set their own limit for the hardness. Monsanto hardness tester or Pfizer tablet hardness tester are the devices used for finding the mechanical strength of tablets.

Monsanto hardness tester has a graduated scale which gives the reading in kg/sq. cm. The tablet to be tested is placed between the spindle and anvil. The pressure is applied till the tablet breaks.

Pfizer tablet hardness tester is based on the principle of an ordinary plier. The tablet is placed between the jaw of the plier and the pressure is applied by pressing the handles with hand unit until the tablet breaks.

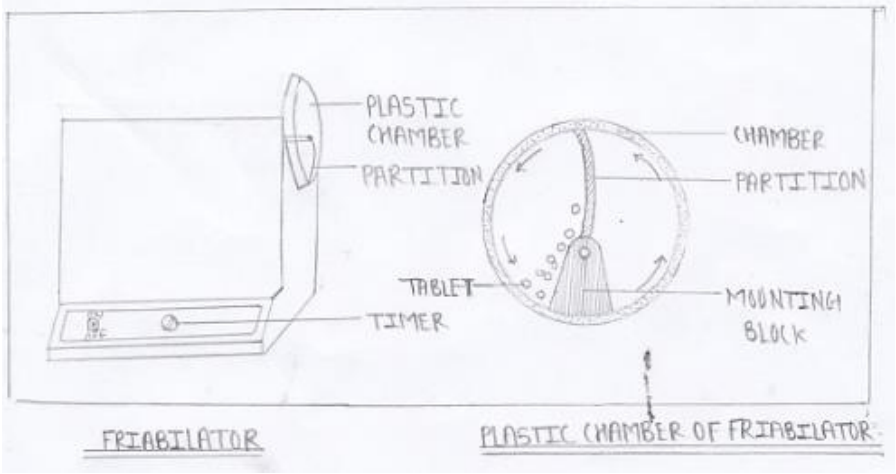
Diagram:



9. Friability test: This 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 1%.

Diagram:

			
Q.6	**d.**	**Define the term vaccine. Discuss the method of preparation of small pox vaccine using animals** **Definition: (1M)** Vaccines are antigenic preparations which stimulate antibody formation and producing immunity. Small pox vaccine is prepared by two methods 1) By using animals 2) By using Eggs By using eggs: **1) By using animals: (3M)** • 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 + glycerine mixed and stored at -100C to remove impurities. • Filling sealing and storage: filled in final container under aseptic condition and freeze drying.	**(1+3 = 4M)**

<table>
<tr>
<td>Q.6</td>
<td>e.</td>
<td>
What are NDDS? Differentiate between sustained and controlled release dosage forms.
NDDS: (2M)
New drug delivery system delivers or aimed at maximizing the drug effectiveness or minimizing the side effects. Some of the Novel dosage forms are:
1) Implants
2) Controlled drug delivery system
3) Sustained release system
4) Liposomes
5) Erythrocytes
6) Nanoparticles
7) Prodrugs
8) Film and strips.
Difference between Sustained and Controlled release dosage form: (0.5 X4=2M)
<table>
<tr><td>Sr.No.</td><td>Sustained Release</td><td>Controlled Release</td></tr>
<tr><td>1.</td><td>Onset of action is slow and duration of action is less.</td><td>Onset of action is fast and longer duration of action.</td></tr>
<tr><td>2.</td><td>Frequency of dosing is more.</td><td>Frequency of dosing is less.</td></tr>
<tr><td>3.</td><td>Dose concentration in plasma is not maintained.</td><td>Therapeutically effective and constant concentration of the drug in the plasma is maintained.</td></tr>
<tr><td>4.</td><td>The rate of release is not at predetermined rate.</td><td>The rate of release at predetermined rate.</td></tr>
<tr><td>5.</td><td>It prolongs the release of drug.</td><td>It controls the release of drug.</td></tr>
<tr><td>6</td><td>e.g. sustain release tables.</td><td>e.g. Transdermal patches.</td></tr>
</table>
</td>
<td>(2+2=4M)</td>
</tr>
<tr>
<td>Q.6</td>
<td>f.</td>
<td>Suggest instruments for following operations.
(i)Drying of thermolabile drug: Spray Dryer, Freeze dryer</td>
<td>4M</td>
</tr>
</table>

		(ii)Film coating of tablet (iii)Sterilization of powder (iv)Preparation of WFI I.P. (v)Size reduction of Brittle drug (vi)Mixing of ointment (vii)Classification of syrups (viii)Preparation of emulsion **(i) Drying of thermolabile drug:** Spray Dryer, Freeze dryer, vacuum dryer. **(ii) Film coating of tablet:** Tablet Coating Pan, fluidised bed coat. **(iii) Sterilization of powder:** Hot air oven. **(iv) Preparation of WFI I.P.:** Distillation unit **(iv) Size reduction of Brittle drug:** Ball Mill **(v) Mixing of ointment:** Triple Roller Mill, Planetary Mixer. sigma bled mixer etc. **(vi) Classification of syrups (read as clarification of syrup):** Meta filter, **(vii) Preparation of emulsion:** Silverson mixer homogenizer, colloidal mill, hand homogenizer.	