

IMPORTANT QUESTION- PHARMACEUTICS

Q. 1) What is immunity ?. classify it. Classify it Mention factor responsible for producing immunity. Write step involved in preparation of B.C.G vaccine.

Ans:- immunity refers to the body's ability to prevent the invasion of pathogens. Pathogens are foreign disease – causing substance such as bacteria and virus are attached to the surface of pathogens and stimulate an immune response in the body immune response is the body's defence system to fight against antigen and protect the body. Types:- (i) innate or native immunity. (ii) Acquired or adaptive immunity

1. Natural immunity :- it is god gifted which produce resist to disease.

a. Species :- Typhoid occur in men but not in fowls. B Races :- yellow fever occur in white man while negro are resistance to it. C. individuals:- some person are more resistant than other to cough, cold and skin infections.

2. Acquired immunity:- The immunity is acquired by antibodies. They are two types

A. Active immunity :- it is developed in a person due to formation of antibody by introduction of antigen in the body. → Active immunity is again divide in to two types :-

a. Naturally acquired active immunity :- acquired as a result of natural infection by pathogenic microorganism. Example:- when a patient recovers from the disease. Eg- small pox, polio, diphtheria he/ she become immune become whole life these disease.

b. Artificially acquired active immunity:- Acquired by introduction of vaccine or toxoids. eg- when vaccine are introduced in to body it stimulate body to produce antibodies and then person become immune to that disease.

2. Passive immunity :- it is acquired by introduction of readymade antibodies in to the body. → Passive immunity is again divide in to two types :-

a. Naturally acquired passive immunity :- in this immunity antibodies are transmitted from mother to foetus through placenta. eg- antibodies of chicken pox, diphtheria, measles are transmitted from mother which give immunity to infant for several months.

b. Artificially acquired passive immunity :- this type of immunity is produced by injecting readymade antibody preparations. These antibodies are produced in animal like horse and then injected to man.

• Factor responsible for immunity :-

1. Phagocytosis :- it is defined as ingestion of microorganism by some cells which microorganism become harmless. phagocytosis is caused by – wbc cells and cells of reticulo-endothelial cells (RES).

2. Antibody production :- B side phagocytosis body also produce antibodies. Which destroy pathogenic microorganisms and their toxins. antibodies are substance formed in the body due to stimulation of antigens.

3. Genetic factors :- genetic factor influence the host to antigen. Person responding to antigen are called responders. While person not responder called non responders. these difference are controlled by immune response (Ir gene) located in the short arm of 6th chromosome.

4. Age :- The embryo and the infant at birth are not fully immunologically competent. Full competent is achieved by about the age of 5-7 years for IgG and 10-15 years for IgA by the development of lymphoid organs.

5. Nutritional status :- Malnutrition affect both the humoral and cell mediated immunity. deficiency of amino acid and vitamin have shown to production of antibodies.

6. Route of antigen:- induction of immune response in a host depend on the route of administration of the antigen. subcutaneous, intramuscular and intravenous route of administration of the antigen induce a better immune response than oral or nasal route.

7. Dose of antigen:- the minimum critical dose of antigen

is essential to elicit an optimal immunological response. very high or small dose fail to stimulate the immune system. These phenomenon is called as immunological paralysis.

8. Adjuvants :- Adjuvant are substance they are mixed with an antigen enhance the immunogenicity of that antigen.

9. Hormones :- Certain hormone disorder enhance susceptibility to infections. Eg- diabetes mellitus, adrenal dysfunction are affect the immunity.

10. Environmental factors:- children living in rural area higher antibody response to the tetanus vaccine, small pox than urban areas.

• Preparation of B.C.G Vaccine (bacillus of calmette guerin vaccine):- it is a freeze dried preparation containing a living cell of a strain of Mycobacterium tuberculosis.

• Preparation:- bacilli are are grown on culture media not more than 14 days → culture media is filtered and cake is collected → cake is homogenized (grinding and transfer a sterile liquid → the above suspension is transferred to sterile container and freeze dried and sealed.

• STORAGE:- In light resistant glass container b/w 2 to 8°C.

• use:- As immunizing agent against T.B.

• Dose:- 0.1 ml by intravenous route.

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Q. 2.) Difference b/w Active immunity and passive – 5 marks.

Ans: (1) A.I – Antigen containing preparations produce active immunity. P.I – Antibodies containing preparation produce passive immunity.

(2) A.I – Produced actively by host P.I – Received passively by the host.

(3) A.I – Active participation of host immune system. P.I – No participation of host immune system.

(4) A.I – induced by antigen or infection. P.I – Produced by administration of antibodies.

(5) A.I – long lasting immunity. P.I – Transient protection.

(6) A.I – Generation immunological memory. P.I – Does not immunological memory.

(7) A.I – it has no side effect of vaccine. P.I – it may carry side effect.

(9) A.I – Development of negative phase. P.I – no negative phase

(10) A.P – immunological memory present. P.I – No immunological memory.

Question:-3. write detail note on pharmacopoeia of india.

Answer:- pharmacopoeia is derived from greek word 'Pharmakon' means drug and 'poiea' means to make. it is the official book issued by recognized authorities usually appointed by Government of each country. it comprises list of pharmaceutical substances, formulae along with their description and standards. etc.

• Pharmacopoeias are published or needed:-

1. To ensure uniformity in composition of drug.

2. To ensure purity of drug.

3. To ensure potency of drug.

4. To study official preparation of drugs.

5. To refer procedure for testing of drugs.

• Indian pharmacopoeia contains:-

a. Monograph:- they contains-

1. Main title

2. synonym

3. chemical formula

4. Category

5. dose

b. appendices:-

1. Description

2. Solubility

3. Standards

4. identification

5. Test for purity

• Pharmacopoeia is legally and official published book issued by rejoinal authorities usually appointed by the government of any country

• Indian pharmacopoeia set the standards of all drugs stated by the IPC are public under the title Indian pharmacopoeia have been prepare.

I.P written in English and its official titles of monograph is given in latin.

• List of pharmacopoeias :-

1. british pharmacopoeia

2. united state pharmacopoeia

3. european pharmacopoeia

4. japanese pharmacopoeias

5. Chinese pharmacopoeias

6. spanish pharmacopoeias

7. mexican pharmacopoeias

• First official

pharmacopoeias of india appeared in 1868 which was edited by Edward John Waring. In preindependence days british pharmacopoeias was used in india. in 1946 Government of india issued one list known as 'The Indian pharmacopoeial list'.

• Committee under chairmanship of sir R.N. Chopra along with other nine members prepared 'The Indian pharmacopoeial list'

• sir R.N. Chora along It was prepared by Dept. of health, Govt of india, delhi in 1946

• In 1948 Government of india appointed an indian pharmacopoeia committee for preparing "pharmacopoeia of india"

• Tenure of its committee was five years.

Indian pharmacopoeia committee under chairmanship of Dr B.N Ghosh published first edition of I.P in 1955. It is written in english and official titles of monograph given in latin. it covers 986 monographs.

2 nd edition of I.P was published in 1966 under the chairmanship of Dr. B. Mukherji. dose were expressed in metric system

3 rd edition of I.P Was published in 1985 with two volume and nine appendices.

4 th edition of I.P was published in 1986 under the chairmanship of Dr. Nityanand. it is effect from 1st december 1996 .it covers 1149 monographs and 23 appendices.

5 th edition of I.P was published in 2007 and addendum to this edition was published in 2008.

6 th edition of I.P was published in 2010 the 6th edition of I.P 2010 IS published by the indian pharmacopoeia commission (IPC) Ghaziabad in accordance with a plan and complete through the uniting efforts of its members, secretarial and laboratory over a period of About 2 years.

7 th edition of I.P was of the indian pharmacopoeia (I.P.2014) is published by the indian indian pharmacopoeia commission (ipc), this edition presented in four volumes this scope of pharmacopoeia has been extended to include additional anticancer drugs and antiretroviral drugs and formulations , product of biotechnology, indigenous herbs and herbal products and veterinary vaccines.

8 th edition of I.P was published in 2018. this edition was presented in four volume.

Q 4.) Difference b/w soft gelatin capsule and hard gelatin capsule.

Ans:- (1) S.G.C:- soft gels H.G.C:- Hard shell gelatin capsules (2) S.G.C:- it is one piece capsules H.G.C:- it is two piece capsule consist a body and a cap. (3) S.G.C:- Hermetically sealed (two) halves of gelatin are fused by heat and pressure. H.G.C:- sealed by interlocking or liquid sealing. (4) S.G.C:- it contain a semisolid or liquid drugs. H.G.C:- it contain a powder, granules or pellets. (5) S.G.C:- it shape like round oval and tube. H.G.C :- it is cylindrical in shape. (6) S.G.C :- Ratio of dry glycerin/Dry gelatin is 0.8: | H.G.C :- ratio 0.4: | (7) S.G.C:- Boundary wall soft and flexible. H.G.C :- Boundary wall firm and rigid. (8) S.G.C :- suitable for volatile drug substance. H.G.C :- Not suitable for volatile drug substance. (9) S.G.C :- use more preservative . H.G.C :- use less preservative (10) S.G.C :- No specific size are available. H.G.C:- 8 different size are available. (000, 00, 0, 1, 2, 3, 4, 5) Q.5) Difference b/w clarification and filtration: Ans:- Filtration - it is the process of separation of solid from from a fluid by passing the same through a porous medium that retains the solids but allows to fluid to pass through. Clarification - it is the process solids are present in very low concentration, i.e not exceeding 1.0 % w/v, the process of its separation from fluids is called is called clarification .

• Difference b/w filtration and clarification:- (1) Filtration:- filter medium is required. C.F – filter medium is not required. (2) F.T - useful for removal of large amount of solids C.F - useful for removal of small amount of solids (3) F.T - Any percentage of solids can be removed. C.F – only less than 0.15% of solids can be removed. (4) F.T – Bacterial

filtration can be possible. C.F - cannot be used for bacterial filtration. (5) F.T – useful for filtration of injection, eye drops. C.F – useful for filtration of syrup and honey. (6) F.T – Equipment used filter press, candle filter, filter leaf. C.T – Equipment used- Metafilter, stem line filter.

Question:- 12.Enlist additives/ excipients/adjuvants used in tablet with examples. Draw diagram of single punch compression machine.

Answer:- Additive:-. They are inert pharmaceutical material which mixed with API(active pharmaceutical ingredient) to form a dosage form.excipient have no pharmacological action but it helps stability in API. Excipient should compatible with API. 1.diluents:- the diluent is needed in the formulation of tablet, when the quantity of medicament in each tablet is very small and not possible to make a good tablet.Eg- lactose,sucrose,sodium chloride, dextrose. 2.Granulating agents:-they are used to convert the fine powder in to granules.this agent provide proper moisture to convert the fine powder in to damp mass,after passing through a sieve of suitable number form granules. Eg- water, alcohol, mucilage of acacia. 3.Binding agents:-these are used in granulation to provide proper strength to granules in order to keep the tablet intact after compression. Eg- gum tragacanth,gelatin,sucrose etc.4.Disintegrating agents:- these agent are added in the tablet formulation to ensure disintegrating of the tablet in to smaller particles when swallowed. Eg-sodium bicarbonate,citric acid tartaric acid etc. 5.Lubricants:- these are added to improve the appearance of tablet ,flow property of granules and to prevent sticking of the material to the dies and punches.Eg-Talc,Mg-stearate, and calcium stearate.6.Absorbing agents:- this agent are used to absorb volatile oil, liquid extract and tincture,which are included in the formulation of tablet. 7.Colours,flavours and sweetening agents:- The colours are used to improve the elegance of tablet.Flavours are volatile oils and hence they are added in the granules just before compression of tablets.Flavouring agents are dissolved in organic solvent and solution is sprayed on granules.Sweetening agents are used to improve the test of tablet. Eg sucrose,lactose,mannitol are commonly used. •Single punch compression machine:- single punch tablet press is also called as a eccentric press or single station press. • It is most simplest machine for tablet manufacturing.they are different parts. (1)Hopper :- Hopper may be one or more in number which serves two purposes. (a) Firstly to hold granulated feed. (b) Secondly to pass it the feed frame. For subsequent compressing the hopper can be filled manually or by using mechanical equipment. (2) Feeding mechanism :- The feeding mechanism helps in the guiding granulated feed from the hopper in to the die cavities in single punch a feed shoe which is connected hopper is laid down on the table (3) Tooling set :- • The basic mechanical and functional unit of tablet presses is the tooling set which compress of die cavity and a pair of upper and lower punches. • The tooling set comprises of a pair of upper and lower and a die cavity which is also called as station. • Dies that decide the size and shape tablet. • Punches of compressing the granulation within the die. • Cam track guide the position of the punches they are connected to the head of punches. • The resultant tablet are formed in the die cavity with their shaped and size. • It involves compression of only the upper punch. ⚙ Working :- The process of tablet

compression can be divided in to three stages. 1. Filling 2. Compression 3. Ejection. (1) Filling :- The lower punch falls within the die leaving a cavity in to which a particulate matter flows under the influence a gravity form a hopper. Through tablet are usually described in terms of weight. This die is filled by volumetric process. (2) Compression :- • The upper punch descends and its tip enter the die, confirming the distance separating the punch force decreases, either by movement of upper punch alone. • The porosity of the contents of the dies progressively reduced and the particles are force in to the over closer proximity to each other. (3) Ejection :- • The upper punch is with drawn from the die and show the force being applied to the tablet is removed. • The effect of this might to be cause deformed particles return to their former shape which would result in a decrease inter particulate contact and hence tablet strength. ⚙ Advantage :- 1. The machine structure is rational and small. 2. It very to operate, and it operate at a high utilalzaton ratio. 3. The machine capable of utilize a high amount of pressure to reduce the weight difference b/w the tablets while maintaining a low noise level. 4. The machine also provides a continuous control over the loading of the raw material and the thickness of tablet. Q7. Write a detail note on soft gelatin capsules. -10 marks. Ans:- Soft gelatin capsule:- • Soft gelatin capsule are one piece, hermetically (completely airtight) sealed, soft gelatin shell containing a liquid, a suspension, or a semisolid. • Soft gelatin are used to enclose liquid medicaments – oil, suspension, semisolid, ophthalmic product. Example :-Cyclosporine capsules. ⚙ Advantage:- (1) Easy to administer. (2) Easy to manufacture. (3) Liquid can be encapsulated (not water soluble) (4) Small to categorize possible. (5) Elegance, portability (6) Oder and taste masking. ⚙Disadvantage:- (1) Highly moisture sensitive. (2) Efflorescent material (material that may expand) cannot be incorporated, they may cause leaching. (3) Deliquescent material (tendency to become liquid) cannot be incorporated, that may cause hardening or brittle capsules. (4) Manufacturing procedure of soft gelatin capsules is complex as compared to other dosage forms. ⚙ Soft gel capsules shell:- • The capsule shell is basically composed of gelatin, plasticizer and water. • It may contain additional ingredients such as preservative, coloring and opacifying agents, flavorings sugar and medicaments to achieve desired effects. (1)Gelatin:- obtained from partial hydrolysis of collagen derived from the skin, connective tissue and bones of animals. (2) Water:- NMT45% W/W. (3) Plasticizer:- used to make the soft gel shell elastic and pliable(easily bent) Example:- glycerin, sorbitol. (4)Colour:- used in shell, has to be darker than colour of encapsulating material. • Colour may be natural or synthetic. (1) Opacifier:- usually titanium dioxide, may be added to produce an opaque shell, when the fill formulation is a suspension or to prevent photo degradation of light sensitive fill ingredients. (2) Chelating agents:- • iron is always percent in raw gelation and should not contain iron more than 15 PPM. • Additionally chelating agent may be used for preventing the reaction of iron with material or colours. ⚙ Shape of soft gelatin capsules:- (1) Oblong:- 0/3 0/4 0/5 0/6 0/8 0/11 0/14 0/15 0/16 0/17. (2) Oval:- 0/2 0/3 0/4 0/5 0/6 0/7.5 0/10 0/12 0/15 0/16 0/20 0/40. (3) Round:- 0/2 0/3 0/4 0/5 0/6 0/28 0/40. (4) Suppositories:- 0/5 0/10 0/15 0/17.5. ⚙ Manufacturing equipment for soft gelatin capsule:- • Soft gelatin capsule available from middle 19 century. • Originally, they were made one at time leather molds and later – iron molds- were used for shaping of

capsule. • Capsule are filled by machine dropper and sealed by hands with a glob of molten gelatin. • As technology advanced the individual iron molds gave way to multiple molding units. (1) Plate procees:- • Oldest commercial method of manufacture. • Involve pressing two sheets of gelatin together between two molds provided with depression. • One of the gelatin sheet is placed over mold and application of vacuum produce depression in gelatin sheet in to which active fill was then placed. • Second gelatin sheet was used over the first & both were passed together with fill material like sandwich. • Require 2-3 operator very tedious process. 2.Rotary die process:- • Late R.P scherer invented rotator die process. • Prior to this pharmaceutical company facing issue regarding content uniformity and weight variation. Injection wedges Ribbon Die roller mesh ----- Oil rolls • Colling drum temperature – 13-14°C • Ribbon thickness vary from ± - 10% • Gelatin wet shell thickness – 0.0022-0.45 inch. Gelatin tank Product material tank Product Pump BOX Cooling Convener belt drum • Product material tank contain capsule filling material. • Gelatin sheet is cut in to different size and shape. • Naptha are used for oil lubricant removing then wash and dry with infrared drying. • Moisture content allow up to 6-10 % . (2) Other instruments:- ⚙ Accogel technology:- • Develop in 1949 by de derle lab. Division of the American cyhamid company. ⚙ Accogel machine :- • Is unique in t it is the only equipment that accurately fill powder dry solids in to soft gelatin capsule. Moisture content determined by toluene distillation method. Q.7)what is levigation/MIXING. Enlist mixer used for mixing of semisolids. Write note on any one -- 10marks Ans :- Levigation:- The formation of paste by adding the large amount of water,by reducing the size of particle in to fine size,which is to be obtained as known as levigation. OR “Levigation” is a process reducing the particle size of a solid by triturating in a mortar or spatulating it on ointment slab or pad with a small amount of a liquid or melted base in which the solid is not soluble”. • Mixing is defined as a process that tends to result in a randomization of dissimilar particles with in a system. Or Mixing may be defined as the process in which two or more than two components are mixed in such a way that each with other uniformly. 0 0 + + Solid-solid Mixing-liquid-liquid -- Homogenous mixing Gas-Gas Solid-liquid Solid- gas -- Heterogenous mixing Liquid- Gas • The homogenous mixing means when two compnents of same phase mixed together and heterogenous mixing means mixing of two different component of different phase. • The mixing of gas in gas is very easy. • And the mixing of solid in solid is very difficult. ⚙ Objective of mixing:- 1.To make uniformity of materials it means all the ingredient well mixed together 2.After mixing to attain the same properties of material in through out the mixture. 3.To enhance the physicochemical properties of mixture such as dissolution, disintegration, weight variation etc. ⚙ Application of mixing:-the mixing process have wide application in the different dosage form such as. (1) in Granulation of tablet. (2) Mixing of ingredient before capsule filling. (3) In the manufacture of syrup. (4) In the mixing of ingredients in injection and ophthalmic preparation. ⚙ Mixing equipment:- for mixing process basically blender and propeller are used and on the basis of structure and function following mixture are used in mixing process. 1.Double cone blender. 2.Twin shell blender 3.Ribbon blender 4.Propellar 5.Sigmablade mixer 6.Plantery mixer 7.Turbines 8.paddles 9.Silverion

emulsifier. (1) Double cone blender:- Principle:- it is based on the principle of tumbling of powder by the action of blender. • It is based on convection of solid materials and the shear applied by the wall. • Construction:- • it consist of a double cone blender which are tapering two end. • This is fixed on a strong stand which is made up of iron. • A mortar is connected with blender which rotates with rotation speed of blender is 30 to 100 RPM (rotation per minute) • The volume of container is vary from 5 to 200kg. • Working:- • Only 50-60% material of its size is to be filled in to the blender and switch on the moter. • The blender start to rotate up and down and by principle of convection of shearing it mixed the powder. • Advantage:- • It show attrition (shout) less fragile substance can be mixed • It is available in various size. • Operation is very easy • Easy to load, unload and cleaning. • Disadvantage:- 1.It require high space for installation. 2.Material of large particle size cannot be blended 3. difficulty to carry transport. 4. Less stable in aqueous system,incompatability is faster in solution than solid dosage form. Q.5(b)What are sustained release dosage forms. Write advantage, disadvantages and application of the same. Ans:- Sustained release dosage form definition:- SRF'S describe the slow release of a drug substance from a dosage form to maintain therapeutic response for extended period (8-12 hours) of time. Time depend on the dosage form. In oral form it is depend on hours, and in parenteral it is in days and months Ex:- Aspirin SR, Dextrin SR. • Concept:-the goal's of SRDFS to obtain zero order release from the dosage form. • Zero order release is a release which independent of the amount of drug present in the dosage form. • Usually SRDF'S don't follow zero order release but they try to mimic Zero order release by releasing the drug in a slow first order fashion. • Pharmacological action is seen as the drug is in therapeutic range, problem occur when drug concentration is above/below therapeutic range. • The main aim of preparing sustained release formulation was intended to modify and improve the drug performance by • The duration of drug action • The frequency of dosing. • The required dose employed. • Providing uniform drug delivery • Technique for preparing SR formulations Types of preparation depend on (A)Drug modification :- (1) Complex formation (2) Drug adsorbate preparation (3) Prodrug synthesis (4) Ion exchange resin (1) Complex formation :- the rate of dissolution of solid complex in biological fluids and rate of dissolution of complex in the solution are considered and they depend upon PH and composition of gastric and intestinal fluids. (2) Drug-adsorbate preparation:- in this product is insoluble drug availability is determined by rate of disabsorption . (3) Prodrug synthesis:- They are inactive and need enzymatic hydrolysis for regeneration. Solubility, rate of prodrug must be lower than parent drug. (4) Ion exchange resin:- • They are water insoluble drug is bound to the resin by using chromatographic column or by prolonged contact. • Drug release from the complex depends on PH and property of resin. • Drug that is attached to the resin is released by exchanging with the ions present in the GIT. Resin ⁺ - Drug⁻ + X⁻ Resin⁻ - X⁻ +Drug Ex:- Biphetamine (B)Based on dosage from modification:- (1) Microencapsulation (2) Barrier coating (1) Microencapsulation:- • It is a process in which tiny particles are surrounded by uniform coating (microcapsule) or held in a matrix of polymer (microsphere). Spray drying is used which involve rapid evaporation of the solvent from the drug surface. (2)

Barrier coating :- • It this one quarter (1/4) of the granules are in non-sustained from for sudden drug release remaining part are coated for sustained release. • Both these granules are filled in hard gelatin capsule or compressed in a tablet and the release mechanism is by diffusion coating material used are fats, waxes. Matrix ("MONOLITHIC") DDS Drug is dispersed uniform in non-degradable matrix Drug Drug Drug increasing time Drug Drug • Advantages :- 1. Improved patient compliance • Less frequent dosing • Always whole decay coverage 2. Decrease local and systemic side effects. • GIT irritation • Local inflammation. 3. Improved efficiency in treatment • Uniform blood and plasma concentration • Es in fluctuation in drug level s.e uniform pharmacological response • Bioavailability of some drugs. • Special effect : SR Aspirin give symptomatic relief in arthritis after walking. 4. Economy • Disasvantages:- (1) Dose dumping:- • Quality of drug release causing dumping of drug which is turn leads to toxicity. (2) Reduced potential for accurate dose adjustment. • Administrating a fraction of drug is not possible (3) Need for additional patient education. • "don't crusher or chew the dosage unit" • "tablet residue may appear in stools" (4) Stability problem:- • To complexity of SRFs will lead to stability problem.

Question:- (8) Define the term filtration. Write darcy equation.Explain factor affecting the rate of filtration.

Answer:- Filtration are defined as the separation of solids from liquid by means of a filter medium, which retains the solid but allows the liquid to pass through.filter media are porous in which solid particles are deposited or entrapped.filter media are filter paper, cotton, sintered glass are used as filter media. — The factor affecting the rate of filtration are studied by a scientist named Darcy and he expressed in the form of an equation,which is known as Darcy law or darcy equation. Factor affecting the rate of filtration:- 1.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 because coarse filtering medium can be used to filter liquid coarse particle and it increase the rate of filtration. 2. Pore size of filter media:- the rate of filtration is directly proportional to the pore size of the filter media.the liquid having coarse particle require a coarse filtering media to remove them. So the rate of filtration is increased when a coarse filter medium is used for filtration. 3. Thickness of cake:-the rate of filtration is inversely proportional to the thickness of filter cake formed during the process of filtration. The filtration process are proceeds, the solid particle start depositing on the filter medium thus increase the thickness of the cake and decrease the rate of filtration. 4.Pressure :-the rate of filtration of liquid is directly proportional to the pressure difference between the filter medium and filter cake.the rate of filtration can be increase by applying pressure on the liquid being filtered or by decrease the pressure on the liquid being filtered or by decrease the pressure beneath the filter .5. Surface area of filter media :- the rate of filtration is directly proportional to the surface area of filter media.pleating the paper or using a fluted funnel increase the effective surface area of filter paper for filtration .6. Temperature of liquid :- temperature important role in the filtration. Viscosity is reduced by a rise in temperature and filtration of viscous oils,syrups etc. is accelerated by filtering them while they are still hot. 7. Nature of the solid material:-

the rate of filtration is directly proportional to the porosity of the filter cake. The porosity of filter cake depends on the nature of the solid particle to be removed from liquid.

Question:-8. Write application of drying in pharmacy. Draw diagram of fluidized bed dryer.

Answer:- Drying :- Drying is the process of removal of water content from drug material and reduce the weight.drying process is achieved by two method- first by thermal process as heat and second by non- thermal process like by squeezing(sponzy material),by absorption(dessiant) and by extraction process. •Application of drying :- 1. Preservation of drug products:- drying is necessary in order to avoid deterioration. A few example are:- blood products,tissue undergo microbial growth, effervescent tablets, synthetic and semi synthetic drugs undergo chemical decomposition .2. preparation of bulk drugs:- drying is the final stage of processing. Eg- dried aluminium hydroxide,spray dried lactose. 3. Improved characteristics:-Drying produces materials of spherical shape, uniform size, free flowing and enhanced solubility.granules are dried to improve the fluidity and compression characteristics. These are essential for production of tablet and capsules. 4.improved handling:- removal of moisture makes the material light in weight and reduce bulk. The cost of transportation will be less and storage will be efficient.if moisture is present , size reduction of drug is difficult. Drying reduces moisture content. 5. Reduction in transport cost 6. Purification of crystalline products. 7. Prevention of corrosion. •Fluidized bed dryer(FBD) :- •Principle :- In a FBD Hot air or gas is passed through a bed of solid particles at a velocity higher than the velocity of settling , so the particles remain in suspended air for longer duration so the hot air in contact uniformly with solid material. •Construction:- on the basis of construction the FBD are two types- vertical FBD, Horizontal FBD.The construction of vertical FBD is made up of stainless steel and plastic. And a detachable container is placed at the bottom in which solid particles is placed. The container is perforated wire mesh to support the placing the material. The capacity of FBD is vary from 5 to 200 kg. •Working:- First of all the solid wet particles is placed over the detachable container and fit inside the FBD.now switch on the FBD and allow to air go inside with the very high velocity. Due to high velocity moves upward in air bag and remain suspended in air for some times. After drying the solid dry particles fallen down in chamber and some of them are adhere in air bags which is removed by shaken. •Advantage:- 1.it is fast process,less time than tray dryer. 2. handling time is short 3. The thermal container are mobile making handling simple and reduce labour costs. 4. The thermal efficiency is 2 to 6 times greater than the tray dryer. heating time of heat sensitive materials is minimized. 5.the product obtained after FBD is free flowing in nature 6.drying takes place from individual particles and not form the entire bed , therefore drying occur mostly at constant rate and there is no chance of overheating. •Disadvantage:- 1.formation of fines by attrition caused by high turbulence. Care must therefore taken to avoid seggeration and loss of fine while collecting them by bag filters. 2.generation of electricity charge on particle due to vigorous movement of particles in hot dry air. •Application:-1. For drying granules. 2. It can be used for drying, mixing and granulation process. 3.it is modified for coating of granules.

Question:-9. Define homogenization/MIXING. Write note on silverson mixer homogenizer

Ans:-Mixing:-mixing is the process in which two or more components are mixed so that each particle of one component is in contact with each particle of other component. Homogenization:- it is the process by which the large globules or particle in a coarse emulsion or suspension or semisolid preparation are broken to small globules or particles by passing the samples under pressure through a narrow orifice as a result the final product is stable and uniform. ●The main objective are :- 1.Simple physical mixing of materials to form a uniform mixture. 2.To promote the chemical reaction to get uniform products. 3. dispersion of solid in liquid to form suspension or paste. Dispersion of two immiscible liquids to form an emulsion ●Silverson mixer homogenizer:- ●Principle:-it work on the principle of combination of mixing and homogenization. ●Construction:- consist of emulsifying head to which no of blades are attached. It is surrounded by a fine mesh sieve made up of stainless steel.the head is rotated by small mortar which rotate the blade at very high speed. ●Working:- The emulsifying head is immersed in the liquid to be emulsified. The liquid are mixed and sucked through the fine mesh and oil id reduced in to fine globules in this process. The process of mixing occur the high speed rotation of blade.The mixed materials is then peeled out a great force and thus the process of homogenization occurs. ●Advantage:- 1.silverson mixer is available in different size to handle the liquids ranging from a few millilitre to several thousand litre. 2.it can be used for batch operations. It is also used for continuous operation by incorporating in to a pipeline through which the immiscible liquid flow. ●Disadvantage :- occasionally , there is a chance of clogging of pores of the mesh. ●Application:-silverson mixer is used for the preparation of emulsions and creams of fine particle size.

Question:-5. what is size reduction. Draw diagram, write advantage disadvantages of ball mill.

Answer:- size reduction:-Size reduction is the process of reducing (vegetable mass,chemical substance) in to small unit mass i.e coarse particles or fine particles. ●Principle:- The ball mill work on the principle of the combined effect of impact and attrition. ●Construction:- The consist of a hollow cylinder which mounted on the metallic frame in such a way that it can be rotate on its longitudinal axis.the cylinder contains balls that occupy 30 to 50% of the mill volume.the ball size depend on the size of feed and the diameter of the mill.balls are made up of steel,iron or stoneware and act as grinding medium. ●Working:- the drug to be ground and put in to the cylinder of the mill in such a quantity that is filled to about 60% of the volume.A fixed number of balls are introduced and the cylinder is closed the mill is allowed to rotate on its longitudinal axis. The speed of rotation is very important. ●Advantage:- 1. It can produce fine powder 2. ball mill is used for both wet and dry grinding process. 3.installation,operation, and labour cost are low. 4.toxic substance can be ground, as the cylinder is closed system. 5. the mill is closed system used for sterile products and oxygen sensitive product ●Disadvantage:- 1.The ball mill is a very noisy machine .2. The mill is a slow process. 3. Soft, fibrous cannot be milled by ball mill. ●Application:- 1. For fine grinding with a particle size range of 100 to 5mm or less. 2. for production

of opthalmic and parenteral products . 3. for milling dyes , pigments, and insecticides at low speed.

QUESTION:-6.Draw diagram ,advantage, disadvantage and application of Fluid energy mill (FED).

Answer:-Fluid energy mill(FED) :- ●Principle:- FED is based on the principle of impact and attrition. Milling takes place because of high velocity collisions b/w the suspended particles. ●Construction :-It consist of an elliptical pipe which has height of 2 meters and diameter ranging from 20 to 200 mm. the mill surface may be made up of either soft stainless steel or tough cremic.grinding nozzles are placed tangential and opposed to the intial flow path of powder.venturi feeder is provide in the path of the air flow. An outlet with a classifier is filled to allow the escape of air. ●Working:-The air or inert gas is introduced with a very high pressure through the nozzles. Solids are introduced in to air steam through inlet. Due to high degree of turbulence,impact and attrition force occur b/w the particals.the fine particles are collected through a classifier. Mill reduces the particle size to 1 to 20 micron to get a very fine powder even up to 5 micron. The material are pretreated to reduce the particle size to the order of 100 mesh and then passed through the FED. ●Advantage:- 1. It has no moving parts heat is not produced during milling. 2. It is rapid and efficient method for reducing powder to 30 mm or less 3. No contamination is possible. 4.A maximum degree of size reduction occur with the mill. 5.it is suitable for drugs, which are sensitive to oxygen,since inert gas can be used as fluid. ●Disadvantage:-1. Not suitable for milling of soft, sticky and fibrous material. 2. equipment is expensive. 3. the feed should be pretreated to reduce the particle size to the order of 100 mesh. ●Application:- 1. To reduce the particle size of most of the drugs such as antibiotics and vitamins.

Question:-8.Discus glass as a material for packaging

Answer:- packaging is the process by which the pharmaceuticals are suitably placed so that they should retain their therapeutic effectiveness from the time of their packaging till they are consumed. ●Glass:- Glass container are most common material,which are widely used in pharmaceutical industry for almost all type of dosage forms.glass is composed of sand,soda ash,lime stone and cullet,Si,Al,K,Ca,Mg,Zn and Ba are generally used in to preparation of glass. 1. Type-1 glass:- composition:- Neutral glass,borosilicate glass. ●Advantage:- 1.it posses a high hydrolytic resistance. 2.it is inert type of pharmaceutical glass. 3.it has the lowest coefficient of thermal expansion(suitable for sterilization by heat for ampoule and vials. ●Disadvantage:-1.it has vary glass transition temperature so need complicated processing .2. it is expensive. ●Use:- 1. Type-1 glass is suitable for packaging for all pharmaceutical preparations. 2.it is widely used as glass ampoules and vials to packaging fluid for injection. Type-2 glass:- soda-lime glass.- soda(Na_2CO_3) is used to decrease the glass transition temperature of silica.soda increase the water solubility of silica and lime(Cao) is used to increase hydolytic pressure. ●Advantage:-this glass has lower melting point than type-1 glass and thus easier to produce and consequently cheaper ●Uses:- type-2 glass is used for aqueous preparations,eye preparations, and other dropper bottles. 3.Type-3 treated soda lime glass:-is made from commercial soda-lime glass that has been de-alkalized or

treated to remove surface alkali.the dealkalized process is known as sulfur treatment.sulfur treatment neutralize the alkaline oxide on the surface ,rendering the glass more chemically resistant.acceptable for more more products accept blood products and aqueous pharmaceutical with ph less than 7. Type- 4 NP(General purpose soda lime glass):- in general purpose soda lime glass used for oral and topical preparations. It is suitable for solid products,some liquids and semi solid and not for parenteral. Type-5 Coloured glass:- These glass is obtained by adding small amount of metals during fusion of glass.ther are used for light sensitive products which don't allow the uv- rays to pass through it. Type-6.Neutral glass:- it is the another variety of glass available in between soda lime glass and borosilicate glass-1. It is resistant to alkalies. 2.resistance to weathering 3. Withstand to autoclaving 4. It is used for manufacture of multidose vials and transfusion bottles etc. ●Advantage of glass:-1.it is hygenic and suitable for sterilization. 2.they are relatively non-reactive. 3.they can accept a variety of closures 4.they are used for high speed packaging lines. 5. they are transparent.6.they have good protection power. 6. They can be easily labelled. 7. They are available in various shape and size. 8.they can withstand the variation in temperature and pressure during sterilization. 9. they do not deteriorate with age .10.they are impermeable to atmospheric gass and moisture. ●Disadvantage:-1. It is relatively heavy. 2. Glass is fragile and easily broken. 3. Relase alkai to aqueous preparation. 4. photosensitive drugs cannot be protected in the transparent glass container is required in this case. 5.A glass is a chemical substance , sometimes it react with the product contained inside it. ●PLASTIC:- "According to british standards institutes plastic represents:- "A wide range of solid composite materials which are largely organic,usually based upon synthetic resin or upon modified polymers of natural origin and possessing appreciable mechanical strength.at a suitable stage in their manufacturing,mmost plastic can be cast,molded or polymerized directly in tshape. ●Classes of plastics:-They are two types of plastic,reflecting their behavior with respect to individual or repated exposure to heating and cooling①1. Thermoplastics:- They are capable of being shaped after intial heating solidifying by cooling.resistant to breakage and cheap to produce and provide the right plastic are chosen will provide the necessary protection of the product in a attractive containers. Eg- polystyrene,polyethylene and polyvinyl chloride. 2.Thermosets:-They need heat for processing in to a permanent shape.During heating such material from crosslinks b/w the linear chains,resulting in solidification and loss of plastic flow. Eg:-phenolic,urea and melanine are thermosets. ●Uses:- used for many types of pack including:- rigid bottles, for tablets and capsules,squeezable bottle for eye drops and nasal sprays,blister and strip packaging. ●Advantage:- 1.they are light in weight and can be handled easily. 2.they are poor conductor of heat. 3.they have sufficient mechanical strength. 4.they can be transported easily .5. they are unbreakable. 6.they are available in various shape and sizes. 7.they are resistant to inorganic chemicals. ●Disadvantage:- 1. They are permeable to water vapour and atmospheric gass. 2.they cannot withstand heat without softening or distoring. 3. They may interact with certain chemicals to cause softening or distortion. 4. They may absorb chemical subrsance,such as preservatives for solution. 5. They are relatively expensive. consist of facing

and backing facing is in contact with the products and backing provide questioning effect.

Question:-9. what is sieve number.write gradation of powder according to I.P and write different sieving methods.

Answer:- Sieve number:-sieve number is the no of holes present in the sieve within one inch length of the sieve mesh called sieve number.in one inch length all mesh present just like 10 mesh present. The degree of coarseness or fineness of a powder is expressed by reference to the nominal mesh aperture related to the size of sieve used for measuring the size of powder. In according to Indian pharmacopoeia powder are graded in to five parts a/c to based on particle size and based on character. 1.Coarse powder:-it is the powder all the particle sieve through which sieve no-10 all particles must pass but sieve through which not more than 40% of particle pass through sieve no-44 is called coarse powder. 2. Moderately coarse powder :- it is the powder all the particle sieve through which sieve no-22 all particles must pass but sieve through which not more than 40% of particle pass through sieve no-60 is called moderately coarse powder. 3.Moderately fine powder :- it is the powder all the particle sieve through which sieve no-44 all particles must pass but sieve through which not more than 40% of particle pass through sieve no-85 is called moderately fine powder. 4.Fine powder:-are those powder all the particles must pass through sieve no-85 are called fine powder. 5.Very fine powder:- are those powder all the particles must pass through sieve no-120 is called as very fine powders.

Question:-11. Define extraction process. What are different extraction methods. write steps involved in percolation process.

Answer:- Extraction is defined as the treatment of the plant or animal tissue with solvent ,whereby the medicinally active constituents or API are dissolved and most of the inert matter remain undissolved. Menstrum:- solvent used for extraction. Marc:- are insoluble material that remain after extraction. •Types of extraction process:- 1. Infusion:-In infusion process the drug is keep in contact with water for stated period usually 15 minutes with occasional stirring and finally filtering off the liquid.The marc is not pressed. The boiling water is commonly used as solvent since it has a greater solvent action than cold water. 2.Decotion:-In this process of extraction the crude drug is boiled in a specified volume of water for a definite time ,it is then cooled and strained or filtered .after boiling , the liquid is strained and water is pass through the content of the strainer to make the required volume.this procedure is suitable for extracting water- soluble ,heat stable constituents. Eg – tea,coffee. 3. Digestion:-In digestion process drug is extracted by heating at a particular pressure in the digester.in extraction process hot water taken not boiled water. 4.Maceration:- In maceration process the drug is placed with the whole of the menstrum in a closed vessel for 7 days with frequent agitation untill soluble matter is dissolved then mixture is pass through sieve or by decantation after standing. Eg :-Tincture of orange and Tincture of lemon .5.Percolation:- it is continuous downward displacement of the solvent through bed of crude drug material to get extract.they are used in the preparation of tincture and fluid extracts. •Write steps

involved in percolation process:-Percolation is the process in which a communicated drug is extracted by the passage of suitable solvent through the column of a drug packed in the percolater. Stages of percolation:- 1.Size reduction of drug:- The drug is powered before packaging in to percolator to provide uniform packing. 2. Imbibition:- Imbibition means moistening of drug before pack in to percolator. Imbibition is necessary because it allow the swelling of drug thus prevent blockage of percolator. B.it help in uniform packing of drug. C.it help to remove air from packed drug. 3.Packaging of drug in percolator:- imbibed drug can be sieved to break lump or mass.moistened glass wool is placed at the bottom. Then whole quantity of drug is slowly packed in to the percolator.A piece of filter paper is placed on the packed drug. Washed sand is then placed on the filter paper to prevent distribution of top layer. Then sufficient quantity of menstrum is added in the percolater.when the liquid starts coming from percolater,outlet is closed.again sufficient menstrum is added. 4.Maceration:- the drug is kept in contact with menstrum for 24 hours. The menstrum penetrate in to tissue of drug and dissolve active constituent. 5.Collection of percolater:- After 24 hours outlet is opened and percolate is collected.marc is pressed and added to percolate and volume is adjusted with menstrum. 6.Clarification:-Finally to get clear solution,clarification is done.

Question :- 5.a (2017-i)

Maceration with their modification:- for unorganized drugs. Eg- gums, resins,oleo-gum resins.in this process ,the unorganized drug is placed with 4/5 volume of menstrum in closed vessel for 7 days.at this period shaking is done occasionally. After the stated period the liquid is filtered and not necessary to marc.after the final volume is adjusted with the remaining quantity of 1/5 th volume of menstrum through the filter. •Double maceration process:-it is carried out in the same way as simple maceration process but menstrum used in divided in to two parts.in this process drug is macerated twice by using the menstrum which divided in two parts in a such manner that the same volume used for each maceration.the volume of menstrum required is calculated as follows. →Volume of menstrum required for first maceration=Total volume of menstrum- volume to be retained by the drug+volume retained by the drug/2 →Volume of menstrum required for second maceration=Total volume of menstrum- volume of menstrum used in first maceration. In this process the whole drug is macerated for 48 hours with quantity of menstrum for first maceration.strain the liquid and press the marc after 48 hours,the again macerated for 24 hours with remaining quantity of maceration for 2nd maceration.strain the liquid and press the marc after 24 hours. The mix the liquids obtained from two maceration and allow to stand for 14days then filter.Eg-concentrated infusion of orange,concentrated compound infusion of chirata. Triple maceration process:- this process are same as simple maceration process but menstrum used in three parts.in this process drug is macerated thrice by using the menstrum which divide in to three parts in such a manner that the same volume for each maceration. In that the drug is macerated for one hour with a part of the menstrum required for first maceration and strained. Macerated again for one hour with a part of menstrum for 2nd maceration and strained.Macerated again for one hour with a part of the menstrum for third maceration and

strained and after that marc is pressed lightly.then combine the liquid obtained from 2nd and 3rd maceration and evaporate it to a specific extent.then mix it with the liquid obtained from 1st maceration and alcohol 90% equal to 1/4th of the volume of the finished product.then adjusted the volume with water. Allow the solution for 14 days then filter. Volume of menstrum required for 1st maceration= Total volume of menstrum- volume retained by the drug+ volume retained by the drug/3 Volume of menstrum required for 2nd and 3rd maceration=Total volume of menstrum - volume of menstrum used in first maceration/2 Eg:- cocentrated infusion of quassia, liquid extract of senna.

Question- 6.a)Difference b/w maceration for organized drugs and maceration of unorganized drugs. S.NO
Maceration process for organized drugs M. of unorganized drugs
1 Drug along with the whole of the menstrum is used in maceration process. 1 Drug along with 4/5 of the menstrum used in maceration process. 2. The period of maceration is 7 days 2.the period of maceration is 2-7 days as specified. 3. Mix the pressed liquid with the macerate and clarify by substance or filtration. Filtrate is not adjust to volume. 3.Filter the liquid and pass the remaining 1/5th of menstrum through filter to make up the final volume. 4. Strain off the liquid and press the marc. 4.Decant the liquid. Marc is not pressed 5. Example of tinctures made by this process are-a.Tincture of orange and Tincture of lemon 5.Example of tinctures made by this process are-a. compound tincture of benzoin and Tincture of tolu.

Q.1(a) Define the following terms:-

Ans:- (i) Drug - • Drug is any substance is intended is used as or orally applied, a topically for the purpose of used of mitigation, treatment prevention cure and diagnosis of disease and disorder and maintain the good quality of health is known as drug. • Drug are chemical compound intended for used in diagnosis,treatment prevention of disease. (ii)Emulsion – • Emulsion is a biphasic liquid preparation containing two immiscible liquid (continuous phase and dispersed phase) made miscible. • The liquid which is converted in to minute globules is called as dispersed phase and the liquid in which the globules are dispersed is called the continuous phase. Dispersed phase Continuous Two immiscible liquids:- • Dispersed phase (internal phase) • Continuous phase (External phase) (iii)Suspensions :- • Suspension are the biphasic liquid dosage form of medicament in which finely divided solid particles ranging from 0.5 to 5 micron are placed in dispersed in a liquid or semisolid vehicle with aid of single or combination of suspending agent. H₂O Sand • The mixture still has undissolved solid particles settled at the bottom with some particles still floating. (iv)Dosage forms :-Dosage form are the means by which drug molecules/ API are delivered to site of action within the body to produce optimum desired effects and minimum adverse effects. (v) Creams :- • Creams are homogenous, semisolid preparations consist of opaque emulsion system. • Cream is divided in to two types namely as i. Aqueous creams ii. Oily creams (vi) Syrup :- • Syrup is concentrated or saturated solution of sucrose in purified water. 0 – 0 – 0 – 0 – 0 – 0 – • The concentration of sucrose is 66.7% w/w and due to that it is a viscous preparation . • The syrup which contain medical substance called as a medical syrup and those containing aromatic or flavoured substance

known as flavoured syrup. (vii) Tinctures :- • Tinctures are alcoholic preparations containing the active principle of vegetable drugs. • In another way tincture is typically as alcoholic extract of plant or animal material or solution or of a low volatility of substance. they are obtained by maceration, decoction, digestion extraction process. (1) Pastes :- • Paste are homogenous semisolid preparations containing high concentration of insoluble powdered substance (usually not less than 20%) dispersed in a suitable base). • They are mainly used as antiseptic, protective, soothing dressing. • Paste should be stored and supplied in container made of material which don't allow absorption or diffusion of content. (2) Lotions :- • Lotions are usually aqueous alcoholic or oil, liquid preparations. • They are intended for external application without friction or rubbing the affected area. (3) Liniments :- • Liniments are liquid or semi-liquid preparations meant for external application to the skin. • They are usually applied to the skin with friction and rubbing of the skin. 2016-(i) (1) Elixirs :- • It is clear, sweetened, aromatic hydroalcoholic preparation meant for oral use. • The medicated elixirs are generally contained potent drug like as antibiotics anti histamine or sedative where as non-medicated elixirs contain flavored. (2) Filter cake :- • The deposition layer of solid on the filter medium called filter cake. • When liquid contain high solid loads, cake filtration is often used as a physical filtration technology. (3) Slurry :- • A slurry is a mixture of solid denser than water suspended in liquid, usually water. The most common use of slurry is as a means of transporting solids the liquid being a carrier. (4) Filtrate :- • It is the clear liquid passing through the filter. • Filtrate is the part of filtration process filtration is the process of separating suspended solid matter from a liquids, by causing the liquid to pass through pores of some substance, called a filter the liquids which has passed through the filter is called filtrate. (5) Straining :- • When object of filtration is to remove large visible particles using a coarse filtering medium like muslin cloth, glass wool etc. such process is known as straining collation. 2017-(i) (1) Tablets :- • Tablet are unit dosage from consisting of active ingredient and suitable pharmaceutical excipients. • They may vary in size shape hardness, weight, disintegration, dissolution characteristics in other aspect. (2) Capsules :- • Capsules are solid unit dosage form in which one or more medicament enclosed within a shell. • Types :- 1. Hard gelatin capsule (powder, granule, bled, tablet) 2. Soft gelatin capsule. (liquid or semisolids). (3) Immunological products :- • Immunological products are the preparations which are meant for the prevention of disease, such as vaccine or for the treatment of diseases. • Such as antitoxin and antiserum or for the diagnostic purposes Eg:- bacterial toxin, these are biological products and they are proteinous in nature • These immunological products are storage below the room temperature. 2018-(ii) (1) Filtration :- it is the process in which insoluble solid are removed from the liquid by passing through a porous medium in which solids are retained and liquid is allowed to pass. (2) Clarification :- When solid are present in a very small proportion (not exceeding 1.0% w/v), the process of its separation from liquids is called clarification. (3) Filter media :- • the surface upon which solids are deposited in a filter is called as filter medium. • Different material just like woven material, perforated steel metal and membrane filter media are used for filtration. 4. Suppositories:- they are semisolid dosage form used they

deliver medication in to a body orifice where it dissolved or melt to exert local or systematic effects.

Question:- 4.a. Discuss factors affecting extraction process. (2014-1)

Answer:- :- Extraction is defined as the treatment of the plant or animal tissue with solvent, whereby the medicinally active constituents or API are dissolved and most of the inert matter remain undissolved. • Menstruum- solvent used for extraction. • Marc:- are insoluble material that remain after extraction. → They are different factor affecting extraction process:- 1. Nature of the drugs:- on the basis of nature of drug they are two forms. the first form are fresh in this condition maceration will be performed and 2nd form are dried the percolation is best. in another way they plant part is soft form the maceration and hard part percolation is best. 2. Cost of the drugs:- The cost of the drug is high percolation best because solvent because solvent is not waste in this process and in another condition drug is chiefly maceration is best 3. Stability of drugs:- The selection of extraction process is related to stability of drugs. stability is related to heat sensitive and heat stable in heat sensitive condition temperature is affected the drug are decompose or degrade the percolation and infusion are best. In another condition drug are heat stable the decoction and digestion are best in this process the drug is not affected by temperature 4. Therapeutic value of drugs:- Therapeutic value is related to concentration of drugs. in therapeutic condition drug concentration is less percolation is best. in non-therapeutic condition just like vitamin, tonic the concentration is high maceration is best 5. Nature of the solvent :- Nature of solvent is related to alcoholic and aqueous. in aqueous condition maceration will be best. in alcoholic solvent the percolation will perform. in alcoholic condition evaporation fast and container are covered with cover. 6. Concentration of the products:- They are related to dilute. the dilute condition solvent is more maceration will perform. in non-dilute condition solvent is lighter the percolation is best. 7. Temperature:- When solute is not readily soluble or penetration of solvent in to cellular tissue is slow, hot solvent extraction is necessary for prolonged period. Example:- Extraction of fixed oil from seeds, as the temperature increases, the solubility of most material increases further diffusivity also increases which result in high extraction rate. therefore hot extraction permit high yield of extractives. 8. Method of leaching:- The choice of method also depend on the economic considerations and mentioned in the monograph of official preparations. 9. Physicochemical properties of solvents:- The solvent used are water, butanol, isopropanol, amyl acetate, butyl acetate, hexane, carbon tetrachloride, chloroform and alcohol. if the product is polar in nature, then the solvent must be polar for extraction. but these polar solvent have significant solubility in aqueous phase. water, alcohol and mixture of two are widely used for tincture and liquid extracts. 10. Size reduction and nature of raw material:- the crude drug is related to size reduction before extraction. size reduction is expensive and produce heat. the extent of size reduction is important for thinly sliced material, crushed or broken material and different grade of powder.

Question:- 4 (b) Write short note on soxhlet process or hot continuous extraction process. Answer:- • PRINCIPLE:- They are based on hot continuous process. in this process

powdered drug is placed on syphon tube and the solvent is vapour form. the vapour is passed through the drug and extract is obtained in the round bottom flask (RBF). • Construction:- Apparatus contain 4 parts:- 1. Round bottom flask (RBF). 2. Soxhlet extraction tube:- in this tube three parts are present-a. Thimble:- Thimble are separated from soxhlet extraction tube, then powdered drug is filled and cotton layer is covered because drug is not over flow. B. Adapter:- c. Condenser:- they are attached with water in and out because condenser is cold. • Working:- 1. Firstly crude drug is obtained in powdered form through drying or different size reduction apparatus. 2. Secondly the soxhlet extraction tube thimble are separate then powder drug fill then cotton is pressed because not drug overflow, then thimble tube are placed on soxhlet extraction tube. 3. Attach all part of soxhlet apparatus. 4. Heating mantle start and produce heat. 5. Heating the RBF (Round bottom flask) vapour is passed through drug thimble. vapour is also passed through side tube, condenser. 6. vapour is passed through condenser then vapour is flow through drop by drop on thimble the drug will viscous solution is formed 7. Thimble drug are filtered then drop by drop flow through rbf flask. 8. this process is repeated again and again. 9. This process complete in 24 hours because these process are called as hot continuous extraction process. 10. powdered extract filled RBF flask. • Advantage:- 1. The extraction process is rapid. 2. It require small volume of menstruum. 3. The system use same portion of solvent repeatedly which is being pass through the sample every time, thus the process save solvent by recycle it over the sample. 4. This process is automatic and continuous. 5. Process is time saving to prepare the extract about 500 gram of drug. the duration is required less than 24 hours. 6. process is useful for exhausted extraction of plant material with specific solvent for example defatted plant material is done by using petroleum ether as a solvent • Disadvantage:- 1. The extraction process is not suitable for the drug containing thermolabile constituents. 2. It require high pure solvent or constant boiling mixture hence costly. 3. it is not suitable for the extraction of unorganized drugs. repeatedly, equilibrium between liquid and vapour is set up at each stage, which ultimately result in the separation of more volatile component.

QUESTION :- Discuss factor affecting size reduction process. (2016-1)

Answer:- size reduction is defined as the process of reduction of material to smaller pieces to coarse particles or to powder. • Objective of size reduction:- 1. to subdivide aggregate of solid particles. 2. to increase the stability of suspension and emulsion. 3. to enhance the solubility of slowly soluble drugs. fine particles are having high degree of solubility than the coarse particles. 4. to facilitate uniform mixing which gives more homogenous mixture. • They are different factor affecting size reduction:- 1. Hardness:- Hardness is related to surface property of material the material may be very hard. but if it is brittle also. Hardness is measured by Moh's scale have been devised to different material have different hardness. The scale range from 1 to 10 or from graphite to diamond. up to 3 are soft and above 7 are hard, those b/w 3 and 7 are described as intermediate. hardness of material related to toughness of the material. 2. Moisture content:- moisture content affects number of properties affecting the size reduction process. Eg:- hardness, toughness or stickiness. For the size reduction process, the

material should be dry or wet and merely damp. dry grinding require less than 5% moisture content while wet grinding needs more than 50% moisture content.

3. Material structure:- this factor is inherent property of materials some are homogenous in character but a majority shows some special structures. eg. mineral substance have lines of weakness along which the material splits to form flake like particles while vegetable drugs have a cellular structure giving fibrous particles.

4. Softening temperature:- in all size reduction process heat is generally generated which may cause some substance to soften. the temperature at which this occurs called softening temperature. it is a common problem in case of material like stearic acid, drug containing oil or fat and any other waxy substance. to avoid this problem the mill has to be cooled either by water jacket or by passing through of air through the equipment.

5. Stickiness:- stickiness cause considerable problem in size reduction. such material may adhere to the grinding surface or the meshes of screen may become blocked. the material containing gum and resin may present difficulty in size reduction. if the method used generate heat. to avoid this problem complete dryness is necessary. The addition of inert substance may also solved the problem.

6. Abrasiveness:- this is the property of hard materials, particularly those of mineral origin. this property of material may contaminate the final powder during the grinding of the material. in case of grinding mill more than 0.1 % contamination of metal worn has been noted.

7. Ratio of feed size to product size:- To get a fine powder in a mill it is required that fairly small feed size should be used. they are necessary to carry out the size reduction process in several stages using different equipment. Eg- preliminary crushing followed by coarse powder and then fine grinding.

8. Bulk density :- The output of the size reduction of material in a machine, depend upon the bulk density of substance.

9. Purity required:- Various mill used for size reduction often causing the grinding surface to wear off and thus impurities comes in the powder. If a high degree of purity is required, such mill must be avoided. Moreover, the mill should be thoroughly cleansed b/w batches of different material in order to maintain purity.

10. Physiological effect:- Some drugs are very potent. during the size reduction in a mill, dust is produced which may effect on the operator. in such cases, the enclosed mill may be used to avoid dust.

Question:- 4 (a) Define size separation. Explain construction and working of cyclone separator (2017-1).

Answer:- Size separation is a unit operation that involve the separation of a mixture of various size of particles in to two or more portion by means of screening surface. They are different equipment used for size separation- air separator, elutriation method, bag filter and cyclone separator.

●Cyclone separator:- Principle:- In cyclone separator, centrifugal force is used to separate solid from fluids. depend on fluid velocity, the cyclone separator can be used to separate all types of particles. but in case of air movement obtained by means of rotating disc and blades. the improve the separation the stationary blade are used. By controlling this blades and speed of rotation. it is possible to vary size at which separation occurs.

●Construction:- it consist of cylindrical vessel with a conical base. in the upper part of the separate the vessel is fitted with feed inlet and at the base they are two outlets, one for light particle and other for heavy particles. the rotating disc and rotating blades are attached

to the central shaft, to produce air movement.

●Working:- The sample powder is passed through the feed inlet, which fall on rotating disc. the rotating blade are attached to the same shaft. these produce a current of air as shown by arrows. the fine particles are pick up and are carried in to space, where air velocity is sufficiently reduced. the fine particles are dropped and ultimately collected at an outlet meant for fine particles. the heavy particles which fall downward are removed at an outlet meant for heavy particles.

●Uses:- 1. cyclone separator is used to separate the solid from gasses. 2. it is also used for size separation of solid in liquids. 3. it is used for separating the heavy or coarse fraction from fine dust.

Question:- (4b) Write a note on Triple roller mill (2017-1)

Answer:- Mixing is defined as the process in which two or more component are mixed so that each particle of one component is in contact with each particle of other component. they are different equipment used for mixing of powder, liquids and semisolids. Mixing of semisolid is done for preparing ointments, cream, pill masses and wet masses for making granules. Equipment used for mixing of semisolid in case the quantity is large the following equipment are used for mixing of semisolids- Triple roller mill, agitator mixer, planetary mixer.

Triple roller mill:-

●principle:- The differential speed and the narrow space b/w the roller develop high shear over the material. the shear cause crushing of aggregates, particles and also distributes through drug uniformly through out the semisolid base.

●Construction:- The mill consist of three roller which are made of a hard abrasion material. these roller are arranged in such a way they come very close to each other. these roller are rotated at different rate of speed. the material coming b/w the rollers is crushed depending on the gap b/w them and difference in rate of movement of the two surface.

●working:- As shown in figure the material after passing through hopper comes b/w roller 1 and 2 and is reduced in size in the process. The gap b/w roller 2 and 3 is usually less than b/w 1 and 2, further crushes and smoothes the mixture which adhere to roller 2. A scrapper is arranged in such a way, that it can remove the mixed material from the roller no. 3 and does not allow the material which has not passed b/w both sets of the roller to reach the scrapper.

●Use:- The triple roller mill is very useful for the purpose of mixing of solid powder in ointment base.

●Advantage:- triple roller mill is suitable for continuous process. Extremely uniform dispersion is obtained.

QUESTION:- 3(A) Enlist mechanism of size reduction with examples of mill

Answer:- Size reduction:- Size reduction is the operation carried out for reducing the size of bigger particle in to smaller one of desired size and shape with the help of external force.

●Objective of size reduction:- 1. increase the surface area because in most reactions involving solid particles, the rate of reaction is directly proportional to the area of contact with a second phase. 2. Break a material in to small particle in order to separate the valuable among the two constituents. 3. Achieve intimate mixing. 4. To dispose solid waste easily. 5. To improve handling characteristics.

●ADVANTAGE OF SIZE REDUCTION:- 1. Content uniformity. 2. uniform flow. 3. uniform mixing and drying. 4. increase surface area or viscosity. 5. improve rate of absorption, smaller the particle greater is absorption. 6. Improve dissolution rate.

●DISADVANTAGE:- 1. Drug

degradation. 2. contamination.

●Mechanism of size reduction:- The mechanism of size reduction may vary with the nature of material. therefore each drug require a separate The theoretical strength of a crystalline material can be calculated from interatomic attractive and repulsive force. the strength of material in reality is found to be many time. this discrepancy is explained in terms of flaws of various kinds. the strength of material depend upon the distribution of flaws and is a statistical quantity varying within fairly wide limits. Particle are amorphous and crystalline, these flaws to a definite degree. the constitute weak part in the particle. when sufficient stresses such as impact, shear and compression are applied, the weak flaws develop in to cracks, which eventually lead to cleavage. the smaller particle are obtained with additional surface area. when stress in the form of attrition is applied, the particle surface chip and produce smaller particle. generally drug are easy to grind. the operation is classified as fine grinding (#200) and superfine grinding (particles of few micro metre).

●HAMMER MILL:-

- Principle:- The hammer mill operate on the principle of impact b/w rapidly moving hammers mounted on a rotor and the powder material.
- CONSTRUCTION:- It consist of a stout metal casing, enclosing a central shaft, to which four or more swinging hammers are attached. The lower part of the casing consist of a screen, through which material can pass and collect in a suitable receiver, when the desired degree of size reduction is reached.
- Working:- The hammer are allowed to be in continuous motion (8000 to 15000 revolution per minute). The feed material is placed in to the hopper, which flows vertically down and then horizontally, while hammer are continuous motion. these rotating hammers beat the material to yield small particle. then these particle pass through the screen. due to tangential exit, the size of particles is considerably smaller than the aperture of screen is seen in figure. screen are interchangeable, so that any grade of fineness can be achieved. the hammer act as a centrifugal fan. so that large amount of air drawn through the mill.
- Application:- it is useful in powdering of barks, leaves, roots, crystal and filter cake. the mill has provide to be especially useful for granulation. when the hammers are provided with cutting edges.
- ADVANTAGE:- 1. Hammer mill is easy to set up (install), dismantle and clean up. 2. A product of desired shape and size can be obtained by simply varying in motor speed, hammer type, size and shape of mesh. 3. hammer mill occupy small space and operated continuously. 4. hammer mill is operated in closed environment, dust can be reduced and explosion hazardous can be prevented. 5. it is efficient in function and can grind different types of material.
- DISADVANTAGE:- 1. Heat build up during milling is more, therefore product degradation is possible. 2. wearing of mill and screen is more with abrasive material. 3. the screen may get clogged. 4. hammer mill cannot be employed to mill sticky, fibrous and hard materials. 5. the rate of feed must be controlled carefully otherwise the mill may be choked, resulting in loss of efficiency or even damage the mill.

Question(4a) Explain significance of size reduction in pharmacy. (2017/2).

Answer:- Size reduction is a process of reducing large solid unit mass (vegetable or chemical substance) in to small unit masses. i.e coarse particle or fine particles. → they are different significance of size reduction in pharmacy:-

1. Content uniformity:- mixing of different ingredients can be effective, if the particle size is uniform and small. Particle of optimum size are desirable for effective mixing, as the size of particle is small, the no. of particles per unit weight (dose) is large. The larger the no. of particles, better is the mixing. The better content uniformity can be obtained for a given dose. This is particularly important in formulations containing potent and low dose drugs.

2. Uniform flow:- Small particle size and controlled size distribution promote the flow of powder in to dies during compression of tablets. The same principle used in production of capsules.

3. Effective extraction of drugs:- smaller particles allow rapid penetration of menstruum or solvent in to tissue or cells of vegetable animal origin (liver and pancreas). As a result, extraction or leaching of active constituents become effective and complete in preparation of galenicals. The time required for extraction can be short. Normally fine powder preferred for compound powders, while moderately coarse powder are used for preparation of tinctures.

4. Effective drying:- Drying of a granular mass can be rapid and effective. If the size of granule is small and uniform such techniques are used for production of tablets. Similarly drying of medicinal plant part can be quick and fast after size reduction.

5. Improved physical stability:- In case of emulsion and suspension the rate of sedimentation decreases to a large extent if particle size is small.

6. Improved dissolution rate:- Size reduction increases surface area which facilitates intimate contact of solid particles and gastric or intestinal juices, thus the rate of dissolution enhances. For example, size reduction of griseofulvin led to development of oral dose regimen with a dose half that of the originally marketed product.

7. Improved dissolution rate:- The smaller the particle size, the faster is the absorption, because of enhanced dissolution. Keeping in the view of the advantages, pharmacopoeias specify particle size as a quality control tool. For example, griseofulvin (antifungal antibiotic) should have surface area of not less than 1300 to 1700 meter square per kilogram (as per I.P). If it is less the absorption of drug decreases.

8. Bioavailability:- As particle size decreases the rate of absorption increases. Hence size reduction ensures good bioavailability. e.g:- griseofulvin.

9. To facilitate filtration:- Rate of filtration depends upon the size of particles to be separated.

Question:- (8a) Enlist different manufacturing defects in tablets. Explain any one in detail. (2019-2). Answer:- Tablet is solid dosage form containing medicinal substances with or without suitable diluents, prepared either by compression or moulding. → They are many manufacturing defects in tablet:-

1. Capping, lamination and chipping

2. Picking and sticking

3. Mottling

4. Weight variation

5. Hardness

6. Double impression

1. Capping, lamination and chipping:- “capping” refers to the separation of top or bottom part of tablet from the main body. Whereas “lamination” refers to the separation of tablet in to two or more distinct layers. When a small portion of the tablet comes off it is called ‘chipping’. → The reason for these defects may be:-

1. Entrapment of air among the granules during compression.

2. The granulation may be dry.

3. The concave or beveled edges or punches gradually curve and inward with use and form claws then can pull the top of the tablet loose.

4. Wear in the area of compression.

5. Improper setting of sweep of blade may also cause chipping.

2. Picking and sticking:- Material is removed or picked up by the upper punch from the upper surface of tablet. In case of sticking, the material

sticks to the wall of the die. Reason for picking and sticking:-

1. Use of worn out dies and punches.

2. Use of small quantity of lubricants.

3. Presence of moisture in the granule.

4. Excess of powder in the granule. → DEFECTS CAN BE REMOVED BY:-

1. A new set of dies and punches.

2. A proper quantity of lubricants in the granule.

3. Dry granules

3. Mottling:-

1. Mottling means an unequal distribution of colour on the surface of a coloured tablets.

REASON:- Migration of dye in the granules during the process of drying.

2. Using the different coloration of medicament and excipients.

• DEFECTS CAN BE AVOIDED BY:-

1. Drying the granule at low temperature.

2. Using the dye which can mask the colour of all the ingredients of tablet formation.

4. Weight variation:- During the compression of granules in a tablet machine, the tablet does not have uniform weight.

• REASON:-

a. Granules are not uniform in size.

b. Presence of excess amount of powder in the granules.

c. No proper mixing of lubricants.

d. No uniform flow of granules from the hopper to die.

5. Hardness:- Hardness depends on the weight of material and the space b/w the upper and lower punches during the stage of compression. If volume of material varies or distance b/w punches varies, the hardness will also vary.

6. Double impression:- The defects occur when the lower punches has a monogram or some other engraving on it. During compression, the tablet receives an imprint of the punch. This defect related to in the machine, lower punch moves slightly upward before ejection of a tablet and second imprint of the tablet. This can be controlled the undesirable movement of lower punch.

Question :- 2020(1) (4a) Enlist filtration device used for sterilization. Write a note on any one. -10 marks

Answer:- Filtration:- The separation of solid from a liquid by means of a porous medium that retains the solid but allows the fluid to pass. They are different devices used for filtration :-

Membrane filter, sintered glass filter.

:-

MEMBRANE FILTER :-

• Principle :- It works on the principle of surface filtration. (Trap particles larger than the pore size on the top surface of the filter).

• Construction :- Membrane filters are made of thin and flat membrane of cellulose derivative and cellulose nitrate. These filters are brittle when in dry condition and can be stored for an indefinite period. The filters are between 50 and 150 micron and available in size up to 60 cm². These membrane filters have 400 to 500 million pores per square centimeter of filter surface.

• Working :- Take a mixture to be filtered → pass it through membrane filter → particles larger than pore size retain on the surface of membrane filter → liquid passes through the membrane filter → collect the filtrate in suitable container.

• Uses :- → Membrane filters are mainly used for sterilization of both aqueous and oily liquids. → Separate solids from fluids. → Separate heavy or coarse particles from fine particles.

• Advantage :-

1. It is fast process.

2. It can be used for sterilization of thermolabile substances.

3. It can operate with pressure.

• Disadvantage :-

1. It can be used for filtration of organic solvents such as alcohol, ketones, esters and chloroform.

:-

SINTERED GLASS FILTER :-

• Principle :- It works on the principle of surface filtration. (Trap particles larger than the pore size on the top surface of the filter).

• Construction :- These are made of borosilicate glass. → Borosilicate glass is finely powdered, sieved and particles of desired size are separated. It is then packed in to a disc mould and heated to a temperature at which adhesion takes place between the particles. → The disc is then fused to a funnel of suitable shape and size. → The sintered glass

filters are available in different pore sizes. → The sintered glass filters are also available in stainless steel which has greater mechanical strength.

• Working :- Take the mixture to be filtered → pass it through sintered glass filter under reduced pressure → particles larger than the pore size retain on the surface of filter → liquid passes through sintered glass filter → collect the filtrate in suitable container.

• Uses :- → They are used for bacterial filtration. → They are used for filtration of parenteral injections, ophthalmic solutions and potent drugs.

• Advantage :- → Easy to clean. → A very small amount of medicament is absorbed in the surface of filter medium. → It can operate with pressure.

• Disadvantage :- → They are expensive. → They are fragile. → They cannot be used for large volume due to less surface area of filtration.