TIRUPATI COLLEGE OF POLYTECHNIC AND PHARMACY, RATIA

D. PHARMACY FIRST YEAR

PHARMACEUTICS-1 (2111)

Section A

Fill in the blanks with answers. Each question carries one mark. 1x10=10

1) **Insufflators** are used to introduce the medicated dusting powder into the body cavities.

2) The first Indian Pharmaceutics Codex was published in **1953.**

3) **Amber coloured** containers are used for storage of photosensitive pharmaceutical products.

4) Ball mill works on principle of **impact** and **attrition**.

5) In the sieving method, the powder is passed through a set of sieves which are arranged in **descending order** according to the pore size

6) In CGS system, the viscosity of the liquid is measured in **centipoise.**

7) The rate of filtration is **directly** proportional to the surface area of filter media.

8) The sublimation process reduces **bulk** and **weight** of the drugs and hence **increases** the potency of drugs.

9) **Fractional distillation** is used for separation of two miscible liquids.

10) Proper drying prevents **deterioration** of the products.

11) The majority of bacterial vaccines are stored at a temperature between **2^{o} c** to **8^{o} c.**

13) Glass wares are sterilized by **dry heat sterilization** whereas injections are sterilized by **moist heat sterilization.**

14) The largest size of capsule is represented by the number **000.**

15) The film coating on tablets is done to make them **water proof** before sugar coating.

16) Continuous hot percolation process is also called as **Soxhlet Extraction.**

17) The immunity which is produced by injecting a vaccine in the body is called **artificial acquired active immunity**

18) The process of extraction in which drug is kept in contact with menstrum for 15 minutes is called **infusion.**

19) Substances used to increase the weight of tablets, are called **diluents.**

20) The most widely used gaseous sterilizing agent in pharmacy is **ethylene oxide.**

21) The animals required for manufacturing of polio vaccine is **monkey.**

22) In case of aqueous creams, the emulsion used are of **oil/water (o/w)** type, and in case of oily creams, these are of type **water/oil (w/o).**

23) In general, the disintegration time of uncoated compressed tablet is **15 minutes.**

24) The rise in temperature **decreases** the surface tension.

25) Simple syrups are **saturated** solution of sucrose in water having a sucrose concentration **66.7% w/w.**

26) The Schick test is done to detect the immunity or susceptibility to **diphtheria.**

27) The serum containing antibacterial antibodies is called **antiserum.**

28) The rate of filtration is **inversely** proportional to the viscosity of liquid.

29) Filter candles are also called as **ceramic candles** and are made up of **unglazed porcelain** and **kieselguhr.**

30) The throat sprays are sprayed from a special type of **atomizer** called **nebulizer.**

31) The first U.S.P. was published in **English & Latin** language.

32) Roller mill works on the principle of **compression** and **shearing action.**

33) In cyclone separator, the powder is separated depending on its **centrifugation** and **sedimentation.**

34) The membrane filter has **400** to **500** million pores per square centimeter of filter surface.

35) In film evaporators the material is spread as **a film** on the heating surface to provide a large **surface area.**

36) The **Monteux test** is done to detect the immunity or susceptibility to **tuberculosis.**

37) In moist heat sterilization the bacteria are killed by **coagulation of protoplasm.**

38) BCG contains living culture of **bacillus of calmette and guerin strain of *Mycobacterium tuberculosis*.**

39) Surface tension is expressed in **dynes/cm.**

40) The new edition of British Pharmacopoeia is published after every **5** years.

41) The first edition of Pharmacopeia of India was published in **1955.**

42) Silicone treated glass is used to prepare containers to store **alkali sensitive** products.

43) Milk is sterilized by **pasteurization.**

44) Comminution helps to increase **rate of absorption** of the drug.

45) **Cyclone separators** are used to separate the suspension of a solid in a gas (air).

46) In homogenizer the coarse emulsion is converted into fine emulsion by passage under **pressure** through a narrow **orifice.**

47) When a drug is extracted by heating at a particular pressure the process is called **digestion.**

48) The liquid boils when its **vapour pressure** is equal to the atmospheric pressure.

49) The enteric coated tables are made to disintegrate in the **intestine.**

50) **Phagocytosis** means the ingestion of bacteria by certain cells of the body which make them harmless.

51) Syrups containing aromatic flavored substances are known as **flavored** syrups.

52) Very fine powder passes through **120** no. sieve.

53) Liquid or paste is filled in **soft gelatin capsules.**

54) The rate of filtration is **inversely** proportional to the thickness of the cake formed during filtration.

55) In colloidal mill the rotor rotates at a speed of **3000 to 20000 r.p.m.**

56) The Indian Pharmacopoeial list was published as a supplement to **British Pharmacopoeia.**

57) Containers meant for storage of injectables are made of **Type I & Type II glass.**

58) The solution to be sterilized is packed in final containers and heated at 80^0 C for one hour on **3 successive days** in **tyndallization** method.

59) The output of size reduction of material in a machine depends on **bulk density.**

60) Press coating is done in **Drycota rotary** tablet machine.

61) Vacuum oven is operated at the pressure of about **0.03 to 0.06 bars.**

62) The **hygroscopic** drugs cannot be filled in hard gelatin capsules.

63) The process of extraction where the drug is boiled with water of stated period of time is called **decoction.**

64) Particles size reduction **increases** the surface area of solid substances.

65) Distillation is the method of **separating** substances, which differ in their **vapour pressure.**

66) Soft gelatin capsules are used for administration of **hygroscopic & liquid drug.**

67) A substance which can kill bacteria are called **bactericidal agent.**

68) Lozenges are so designed to exert a local effect in the **mouth & throat.**

69) The preparation of syrup of Tolu Balsam involves a process of **extraction.**

70) Ball mill is used for **size reduction.**

71) Thermolabile solutions are sterilized by **moist heat sterilization.**

72) LAL test is used to detect **pyrogens** in injection.

73) Seitz filters are made up of **asbestos fibre, cellulose & alkaline earth such as magnesium compound**.

74) The official grade of moderately fine powder is **only 40% should pass through sieve no. 85.**

75) Rate of evaporation depends upon **temperature of liquid.**

76) Distillation of two immiscible liquid is called **steam distillation.**

77) Sigma arm mixer is used for mixing **semisolid** preparation.

78) Edge runner mill works on the principle of **shearing & crushing.**

79) Propellant used in aerosol is **chloro-flouro carbons.**

80) Surgical dressings are sterilized by **moist heat sterilization.**

81) Tablets that are placed under the skin are called **skin implants.**

82) Drying by the process of sublimation is called **Freeze Drying.**

83) An example of living bacterial vaccine is **B.C.G. vaccine.**

84) Modified hot maceration process is called as **Digestion.**

85) The typhoid disease causative micro-organism is ***Salmonella typhi*.**

86) The antibodies capable of neutralizing the exotoxin is called **antitoxins.**

87) Cork used in pharmaceutical packaging industry is obtained from the bark of **oak** tree.

88) Air-tight containers are also called **hermetically sealed container.**

89) In dry heat sterilization method, bacteria are killed due to **oxidation.**

90) Microcapsules provide the **controlled release** dosage form.

91) The implants are useful in **hormone** therapy.

92) Sintered glass filters are made of **borosilicate** glass and filtration is done **under reduced pressure.**

93) Drying is used to remove **liquid** and **moisture** from the solid substances.

94) UV light is used for sterilization of air to prevent **contamination** in hospitals.

95) Collapsible tube made from lead is not used for pharmaceutical packing due to **lead poisoning.**

96) IP stands for **Indian pharmacopoeia** and BP stands for **British pharmacopoeia.**

97) **Enteric** coated tablets do not disintegrate in the stomach.

98) The smallest size of capsule is represented by the number **5.**

99) Autoclave is used for sterilization of **surgical dressings and surgical instruments.**

Fill in blanks from Meterology

1) 1 pound = **16** ounce

2) 1 gallon = **160** fluid ounce

3) 1 gm = **1000** mg. = **15.43** grains

4) 1 pint = **568** ml = **20** fluid ounce

5) 1 ounce = **31.10** gm = **8** drachms

6) 1 teaspoonful = **4** ml.

7) 1 fluid drachm = **60** minims. = **4** ml = **1/8** fluid ounce

8) 1 teacupful = **4** fluid ounce = **120** ml

9) 1 liter = **1000** ml.

10) 1 kilogram = $\mathbf{10^6}$ mg

11) 1 quart = **40** fluid ounce = **1200** ml.

12) 1 milligram = $\mathbf{10^{-3}}$ gram.

13) 1 ounce = **0.125** drachm = **30 ml.**

14) 1 pint = **20** fluid ounce

15) 1 kilogram = **2.20** pounds.

16) 1 liter = **35.19** fluid ounce

17) 1 Pound = **450** g = **16** ounce.

18) 1 grain = **64.78** mg

19) 1fluid ounce = **480** minims = **30** ml.

20) 1 drop = **1** minims = **0.06** ml.

21) 1 scruple = **20** grains

23) 1 drachm = **60** grains

24) 1 centigram = **0.01** gm

25) 1 ml = **15** Minims.

26) 1 tablesponful = 15 ml.

27) 1 Decagram = **10** grams.

28) 1 tumblerful = **240** ml.

Definitions-

1) Capsules: Capsules are solid dosage form of medicament in which the drug is enclosed in either a hard or soft soluble container or shell made up of gelatin.

2) Nanoparticle: Nanoparticles are sub-nanosized colloidal structures composed of synthetic or semi-synthetic polymers. Nanoparticles are consists of a drug & a carrier to deposit drug at target site. Their size range is 200-500 mm.

3) Microcapsules: These are tiny capsule containing material (such as an adhesive or a medicine) which released the medicament when capsule is broken, melted, or dissolves. They may consist of single particles or cluster of particles.

4) Evaporation: It is removal of large amount of water from solutions is called evaporation. It provides dry/viscous products.

5) Disinfection: It is a process used to inactivate all the pathogenic microorganisms but not the bacterial spores. For example chloride is used as a disinfectant in water.

6) Lotions: They are liquid preparation for external use. They are applied without friction with the help of cotton wool. Lotion may be alcohol preparations. Example: Calamine lotion.

7) Mixing: Mixing is the process in which two or more than two substances are combined or mixed together to produce the synergistic effect.

8) Insufflations: These are the medicated dusting powders meant for introduction into the body cavities such as nose, throat, ear and vagina.

9) Tablet: These are solid unit dosage form containing medicament, usually circular in shape and may be flat or biconvex and available in coated and uncoated forms.

10) Elixir: Elixirs are sweet aromatic preparation and are usually colored. The main ingredient of elixier is ethyl alcohol, water, flavoring agent.

11) Phagocytosis - It means the ingestion of bacteria or any foreign particle by certain cells of body, which make them harmless.

12) Toxoids - When toxins are treated with chemicals such as formaldehyde, their toxic properties are destroyed without causing any loss of antigenic property. These are called as toxoids. **Example:** Tetanus Toxoid.

13) Vaccine- Vaccine is preparation containing antigens which stimulate the body to produce antibodies. This is artificially induced system to provide immunity to body.

14) Sterility- The absence of viable microorganisms is called sterility, which can be done by physical, chemical or mechanical methods.

15) Viscosity- The property of a liquid which gives its resistance to flow is called viscosity.

16) Sieve- Sieves for pharmaccopoeial testing are constructed from wire cloth with square meshes, woven from wires of brass, stainless steel or any other suitable material having particular sieve no. but not bacterial spores.

Section-B **3x5= 15**

Each question carries three marks.

Question No. 01. Why lime soda glass is not used for storage of parenteral products?

Question No. 02. Differentiate between simple maceration and double maceration.

Question No. 03. What are the advantages of effervescent granules?

Question No. 04. What is the importance of size reduction process in Pharmacy?

Question No. 05. What are the applications of drying?

Question No. 06. Classify various types of vaccines.

Question No. 07. What are factors which cause variation in the percentage of medicament in each tablet?

Question No. 08. How does the presence of moisture interfere with the process of size reduction?

Question No. 09. Find the concentration of boric acid required to produce a solution of iso-osmotic with lachrymal secretion. Molecular wt. of boric acid is 62 gm and it is non-ionizing.

Question No. 10. Prepare 400 ml of 45% alcohol from 95% alcohol.

Question No. 11. Why are granules preferred for compression than powders?

Question No. 12. Why is glycerin used as a base in throat paints?

Question No. 13. Differentiate between sterilization and disinfection.

Question No. 14 What are the ideal characteristics of a good container.

Question No. 15. Distinguish between cream and ointment.

Question No. 16. Write down the difference between film coating and enteric coating.

Question No. 17. Write down the difference between suspension and syrup.

Question No. 18. Write down the difference between mouthwash & gargles

Question No. 19. Write down the Difference between sera & vaccines.

Question No. 20. Write down the difference between maceration & percolation.

Question No. 21. Write five points about importance of particle size reduction.

Question No. 22.Write about objectives of mixing process.

Question No. 23. Write note on reserve percolation process.

Question No. 24. Why maceration is done in closed vessel?

Question No. 25. Write in brief about storage of immunological products?

ANSWERS

Question No. 01. Why lime soda glass is not used for storage of parenteral products?

Answer: Lime soda glass is not used for storage of parenteral products because it contains higher concentration of alkali oxides and can impart alkalinity to aqueous preparations stored in it. Other disadvantage of soda glass is its low mechanical strength and its loss of brilliancy on repeated use. Flakes separate more easily from the surface of soda lime glass as compared to the other type of glasses. It is not resistant to sudden changes in temperature.

Question No. 02. Differentiate between simple maceration and double maceration.

Answer:

S. No.	Simple Maceration	Double Maceration
01.	The drug is macerated with the whole of the menstruum.	The menstruum is divided into two parts.
02.	The period of maceration is 7 days.	The drug is macerated for 48 hours in the first maceration followed by a second maceration for 24 hours.
03.	After maceration, strain the liquid and press the marc.	Strain the liquid after each maceration and press the marc.
04.	Mix the pressed liquid with the strained liquid and then filter. Volume is not made up.	The pressed liquid is mixed with the strained liquids of both macerations and then the volume is adjusted by adding more of menstruum.
05.	The final volume is not made up.	The final volume is made up in double maceration process.

Question No. 03. What are the advantages of effervescent granules?

Answer: The effervescent granules are the specially prepared solid dosage form of medicament meant for internal use. They contain a medicament mixed with citric acid, tartaric acid and sodium bicarbonate. Sometimes saccharin or sucrose may be added as s sweetening agent. Before administration, the desired quantity is dissolved in water; the acid and bicarbonate react together producing effervescence.

Advantage: 1) The carbonated water produced from release of carbon dioxide serve to mask bitter & saline taste of drugs.

2. Carbon dioxide stimulates the flow of gastric juice and helps in absorption of medicament.

Question No. 04. What is the importance of size reduction process in Pharmacy?

Answer: Importance / significance or objectives of particle size reduction are as follows:-

1) Particle size reduction leads to increased surface area which results in increased solvent action.

2) To allow the rapid penetration of solvent, in case of crude drugs for the extraction of active constituents from vegetable and animal drugs.

3) A uniform powder can be obtained because particle size reduction helps in uniform mixing of drugs.

4) Rate of absorption of drug can be increased because smaller the particle size greater will be the absorption.

5) The rate of sedimentation of suspensions decreases to a large extent by reducing the particle size of the drug. Therefore size reduction improves the stability of dosage form like suspensions.

Question No. 05. What are the applications of drying?

Answer: Applications of Drying:

1) In the Pharmaceutical industry it is used as a unit process in the manufacturing of granules which can be dispensed in bulk or converted into tablets or capsules.

2) Drying can also be used to reduce the bulk and weight of the material, thereby lowering the cost of transportation and storage.

3) It helps in the preservation of crude drugs from mould growth.

4) It helps in the size reduction of crude drugs. The presence of moisture in the crude drug does not allow it to get powered easily.

5) Drying is also used in the processing of materials. For example: The preparation of dried aluminium hydroxide.

Question No. 06. Classify various types of vaccines.

Answer: Vaccines are the substances which are administered in the body to produce resistance against infectious diseases. They are mainly used for prophylactic treatment. Vaccines may be prepared from living, attenuated or killed bacteria, viruses or rickettsia. Type of vaccines:

(1) Simple vaccines: These vaccines contain only one species of microorganism.

(2) Mixed vaccines: These vaccines contain two or more than two species of micro organisms.

(3) Univalent vaccines: These vaccines contain only one strain of a species.

(4) Polyvalent vaccines: These vaccines contain two or more strains of the species of microorganisms.

Question No. 07. What are factors which cause variation in the percentage of medicament in each tablet?

Answer: The following are the main factors which are responsible for variation of medicament in each tablet.

1. Weighing of material before granulation and during the process of granulation.
2. Variation in the weight of an individual tablet.
3. Error of random sampling.
4. Analytical error and purity of medicament.

Question No. 08. How does the presence of moisture interfere with the process of size reduction?

Answer: The presence of moisture in the material influences a number of its properties such as hardness, toughness or stickiness which in its turn affects the particle size reduction. The material should be either dry or wet. It should not be dump. The material having 5% moisture in case of dry grinding and 50% moisture in wet grinding does not create any problem. The material should not be merely dump for the process of size reduction to be carried out efficiently.

Question No. 09. Find the concentration of boric acid required to produce a solution of iso-osmotic with lachrymal secretion. Molecular wt. of boric acid is 62 gm and it is non-ionizing.

Answer: By applying the formula:

w/v percent of boric acid required = 0.03 x gram molecular weight of boric acid

=0.03 x 62

= 1.86%

Therefore 1.86 gm of boric acid is required to make 100 ml solution isotonic with lachrymal secretion

Question No. 10. Prepare 400 ml of 45% alcohol from 95% alcohol.

Answer: Volume required = 400 ml, Percentage of alcohol required = 45%

Percentage of alcohol used = 95%

By applying the formula:

$$\text{Volume of stronger alcohol to be used} = \frac{\text{Volume required x Percentage required}}{\text{Percentage used}}$$

= 400 x 45/95

=3600/19= 189.47ml = 190 ml

190 ml of 95% alcohol is diluted with water to produce 400 ml. The strength of dilute alcohol will be 45%.

Question No. 11. Why are granules preferred for compression than powders?

Answer: Granules are preferred for compression than powder because:

1. Granules flow evenly through the hopper of the tablet machine. Hence tablets of uniform weight are produced.
2. The granules may be bigger or smaller but are uniform in composition. Therefore, separation of smaller granules at the bottom is not going to change the composition of the tablets.
3. Granules have more knitting power. Hence, on compression, the granules form a sound tablet.
4. The granules being heavier do not blow out of the die and therefore do not stick to the machine.

Question No. 12. Why is glycerin used as a base in throat paints?

Answer: Paints are the liquid preparations intended for application to the skin or mucosa of mouth and throat. Skin paints generally have a volatile solvent which evaporates quickly to leave a dry film of medicament. Throat paints are generally more viscous liquid preparations used for mouth and throat infections. Glycerin is commonly used as a base because, being viscous, adheres to mucous membrane for a long period which increases the contact of medicament with the mucous membrane that results in longer duration of action. Further glycerin also provides sweet taste to the preparation. The commonly used throat paints are boroglycerin, phenol glycerin, tannic acid glycerin, compound iodine paint (Mandle's paint)**.**

Question No. 13. Differentiate between sterilization and disinfection.

Answer:

S. No.	Sterilization	Disinfection
01.	It is a process in which all the viable microorganisms are destroyed	It is a process used to inactivate all the pathogenic microorganisms.
02.	It is capable to destroy resistant spores	It cannot destruct resistant bacterial spores.
03.	Sterilization can be done by physical, chemical and mechanical methods.	Disinfection is usually carried by use of chemical agents.
04.	Sterilization process can be used on food products & medicinal agents	Disinfection cannot be used on eatables & medicines and they are more harmful and strong to human body.

Question No. 14. What are the ideal characteristics of a good container.

Answer: 1) The material must not interact physically or chemically with the substance which is retained, so as to change the strength, quality or purity of the substance.

2) It should help in maintaining the stability of the product against the environmental factors which cause its deterioration.

3) The material used for making of container must be non-toxic.

4) It should not impart any taste or odour to the preparations.

Question No. 15. Distinguish between cream and ointment.

Answer: Cream is viscous semi solid emulsions which are meant for external use. Creams are of two types that is oil in water and water in oil. e.g. neomycin cream

Ointment is semisolid preparations meant for application to the skin or mucous membrane. Ointment bases are oleaginous bases and absorption bases etc. e.g. Sulphur ointment

Question No. 16. Write down the difference between film coating and enteric coating

Answer: Film coating tablets are coated by a single or mixture of film forming polymers. Polymers such as PEG 400, carbowax are used.

Enteric coating: This coating is given to the tablets in order to ensure that these tablets will not disintegrate in the intestines. Cellulose acid phthalate, polyvinyl acetate phthalate etc polymers are used.

Question No- 17. Write down the difference between suspension and syrup.

Answer- Suspension is liquid dosage forms in which an active drug is dispersed in a liquid phase normally used due to better availability. There are two types of suspensions: flocculated and non-flocculated. e.g. Insulin zinc suspension.

Syrup is a concentrated mixture of sugar and purified water. There are two types of syrups: medicated syrup and flavored syrup. e.g. Tolu syrup

Question No- 18. Write down the difference between mouthwash & gargles

Answer-

S. No.	Mouthwashe	Gargles
1	Mouthwashes are aqueous solutions with a pleasant taste and odor used to make clean the buccal cavity.	It is a aqueous solutions used to prevent or treat throat infections.
2	It is dispensed in white fluted bottles.	It is dispensed in clear, fluted glass bottles closed with a plastic screw cap.
3	Mouthwashes label should clearly indicate the proper directions for diluting before use.	Gargles container should be labeled for external use only. The direction for proper dilution should be stated on the label.

Question No-19. Write down the Difference between sera & vaccines.

Answer:

S.No	Sera	Vaccine
1	The clear pale yellow liquid that separate from the clot in the coagulation of blood.	It is an antigenic substance prepared from causative agent of a disease or a synthetic substance used to provide immunity against one or several disease.
2	It does not contain bacteria or toxin.	It contains dead or weak bacteria or toxins.
3	Sera provide immunity for short time.	Vaccines provide immunity for long time.
4	By sera patient acquired immunity immediately.	By vaccines patient gain immunity after a period.

Question No-20. Write down the difference between maceration & percolation.

Answer- Maceration: The main purpose of maceration is to obtain softer substance in a liquid medium. It takes a long time to complete the process. It does not require specific equipment for the procedure.

Percolation: The main purpose of percolation is to extract particular substance into a liquid. It takes very little time to complete the process. It requires equipment such as a filter.

Question No. 21. Write five points about importance of particle size reduction.

Answer: Importance / significance or objectives of particle size reduction:

1) To increase the rate of solution because particle size reduction leads to increased surface area, this in result increased solvent action.

2) To allow the rapid penetration of solvent.

3) To get a uniform powder because particle size reduction helps in uniform mixing of drugs.

4) To increase the rate of absorption of drug. The smaller the size, greater will be the absorption.

5) To improve the stability of dosage form like suspensions.

Question No. 22.Write about objectives of mixing process.

Answer: The main objective of mixing 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

4) Dispersion of two immiscible liquids to form an emulsion.

Question No. 23. Write note on reserve percolation process.

Answer: Reserve percolation process: In this process, a $3/4^{th}$ the volume of the finished preparation, is reserved and the percolation process is continued till the drug is completely exhausted.

Advantages: The reserved part of the percolate which contains the maximum amount of dissolved active principles is not subjected to heat, only the dilute portion is evaporated. Hence, the major portion of the active constituents of the drug is saved from deterioration.

The process is economical as the whole of the percolate is not evaporated.

Question No. 24. Why maceration is done in closed vessel?

Answer-: It is a process of extraction in which the properly crushed drug is soaked in the menstruum until the cellular structure is softened and penetrated by the menstruum and the soluble constituents are dissolved. Alcohol or water is used as menstruum. Closed vessel is used to prevent evaporation of the menstruum and avoid batch to batch variations. Closed vessel also prevents the deterioration of the preparation of the drug

Question No. 25. Write in brief about storage of immunological products?

Answer: All the immunological products are liable to degradation on storage either due to the destruction of living cells or due to the denaturation of proteins. As the degradation is accelerated by temperature, it is essential to store these preparations at temperatures between 2 and 8°C.The bacterial vaccines and anti-toxins should not be allowed to freeze as serious deterioration may occur due to mechanical damage by ice crystals or the adverse effects of high local concentrations of inorganic salts. The viral vaccines like small pox and poliomyelitis are however, more stable at or below their freezing point. As the light usually accelerates the degradation process, it is essential to protect all immunological products from light. Light resistant containers are however not used as they obscure the observation of any changes in the preparation. Freeze dried preparations should be stored similarly but either under vacuum or under an inert gas.

SECTION- C 5x5 =25

Each question carries 5 marks.

Question No. 01. Write a short note on Cyclone Separator.

Question No. 02. Give in brief the method of preparation of small pox vaccine.

Question No. 03. Write a short note on different types of maceration.

Question No. 04. Write a note on thermal resistance of microorganisms.

Question No. 05. What are isotonic solutions?

Question No. 06. Write advantages and disadvantages of pills.

Question No. 07. Mention the various grades of powder.

Question No. 08. Differentiate between soft gelatin and hard gelatin capsules.

Question No. 09. Write note on filter aids.

Question No. 10. Differentiate between dry and moist heat sterilization.

Question No. 11. Enumerate the various factors affecting the size reduction.

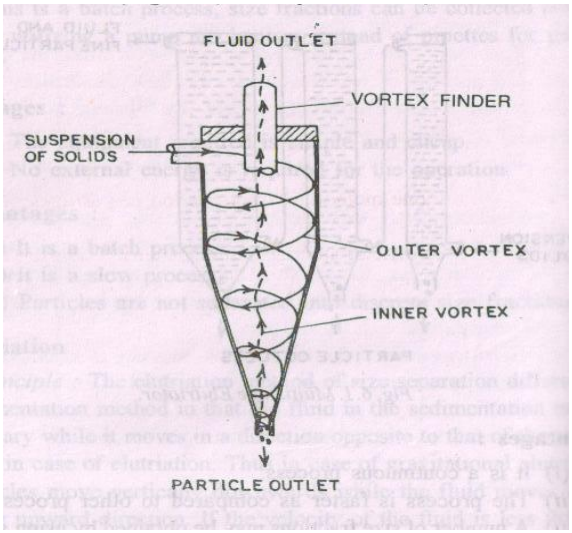
Question No. 12. Describe Water for Injection & Sterile Water for Injection I.P in detail.

ANSWERS

Question No. 01 Write a short note on Cyclone Separator.

Answer: Principle: In cyclone separator, the centrifugal force is used to separate solids from fluids. The separation depends upon particle size and density of particles.

Construction: It consists of cylindrical vessel with a conical base. The upper part of the vessel is fitted with a tangential inlet and a fluid outlet and at the base it is fitted with solid outlet.



Cyclone separator

Working: The suspension of a solid in gas 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 rotatory flow within cyclone separator causes the particles to be acted on by centrifugal force. The solids are thrown out to the walls; thereafter falls to the base and discharged out through solids outlet.

Question No. 02. Give in brief the method of preparation of small pox vaccine.

Answer: Smallpox vaccine is almost white powder which reconstitutes to yield a viscid, straw colored liquid. It consists of the living virus of vaccinia, of strain capable of protecting man against smallpox. To prepare small pox vaccine two methods are used.

1. by using animals: i) Selection of animals- Usually healthy calves or sheep are selected for the production of smallpox vaccines.

ii) Preparation of animals for scarification- The selected animals are thoroughly scrubbed, washed and disinfected.

iii) Scarification and inoculation- The scarified area is then rubbed with a seed virus of known potency.

iv) Incubation- The inoculated area is allowed to incubate for the next 4 to 5 days.

v) Harvesting- The animal is taken to the operation table and killed. The abdomen and flanks are then washed with sterile water and contents of pustules are withdrawn with help of a sharp edge instrument.

vi) Purification- The withdrawn contents are first pooled mixed with equal volume of glycerin and finely ground to form a homogeneous mixture.

2. By using Eggs: - Hen's eggs which have been incubated for 12 days are selected. A small cut of the shape of triangle is made in the shell which is lifted up gently to expose the chorio-allantoic membrane. This membrane is inoculated with seed viruses of known potency. The cut portions are sealed with a suitable technique like application of paraffin wax then incubated for 72 hours. After this chorio-allantoic membrane is added to sterile saline solution. The material is ground to obtain a homogenous product which is then transferred to sterile capillary tube

Question No. 03. Write a short note on different types of maceration.

Answer. **Type of maceration:**

i) Simple maceration for organized drugs: Organized drugs are those drugs which drugs have a specific cell structure like roots, stems, leaves, flowers etc. In this process the extraction of drug is carried out by placing the solid drugs in contact with whole of the menstruum in a closed vessel for 2-7 days with occasional stirring .The liquid is strained and marc pressed and finally adding the expressed liquid to the strained liquid. The combined liquids are clarified by decantation or filtration. Final volume is not adjusted.

ii) Modified maceration for unorganized drugs: Unorganized drugs are those drugs which have no cellular or tissue structure. In this process the extraction of drugs is carried out by placing a weighed amount of drug in contact with $4/5^{th}$ of the menstruum in a closed vessel for 2-7 days with occasional shaking. After the specified period the clear liquid is decanted or filtered, the marc is not pressed; volume is adjusted by passing remaining of 1/5th of the menstruum through the marc.

iii) Multiple maceration:

a) Double maceration process: In this process, the drug is macerated twice by using the menstruum which is divided in to two parts in such a manner that the same volume is used for each maceration.

b) Triple maceration process: In this maceration process, the drug is macerated thrice by using the menstruum which is divided into three parts in such a manner that the same volume is used for each maceration. .

Question No .04 Write a note on thermal resistance of microorganisms.

Answer- The microorganisms show varying resistance to different methods of sterilization.

1. Thermal death time- It may be defined as the time required to kill a specific type of microorganisms at a given temperature under specific conditions. It depends on the factors like temperature, pH, presence of bactericide and the resistance of microrganism against. . There is a considerable variation in thermal death time between different types of bacterial spores. Therefore an adequate margin of safety should be kept to kill the most resistant species of microorganism and spores. It can be done by exceeding temperature and time for which it is applied more than the known thermal death time of most of the spores.

2. Death rate of microorganisms- There is no direct method to determine the time when the sterility will be achieved. It is because; the number of living microorganism is so small, so accurate determination becomes impossible due to very high errors in taking the sample. The reliable approach is to plot a graph between survivors against time of exposure.

3. Decimal reduction time- It is defined as the time in minutes required to reduce the number of viable organisms by 90%. It is one of functions to indicate the efficiency of sterilization.

Question No 05. What are isotonic solutons.

Answer- Isotonic solutions: Osmosis is the flow of solvent from low concentration of solute to high concentration of solute through a semi permeable membrane. The solutions having same osmotic pressure are known as iso-osmotic solutions. When a R.B.C. cell is placed in contact with a solution that has same osmotic pressure as that of blood plasma, the cell wall will neither swell nor shrink. It means it will retain its tone and therefore the solution is said to be isotonic. It is not necessary that solutions, which are

isoosmotic, will also be isotonic. Parenteral preparation should be iso-tonic with blood plasma, but there can be some flexibility depending on the route of administration and quantity of solution to be injected.

Question no. 06. Write a advantage and disadvantage of pills.

Answer: Advantages:1) Pills provide an accurate, stable dose of the drug with least variability.

2) They are easy to be swallowed or administered.

3) These are an economical dosage form.

4) Of all the dosage form, pills are easiest and cheapest as regard of packing and transport.

Disadvantages: 1) Some drugs are difficult to compress into pills form due to their amorphous nature or low density character.

2) Bitter tasting drugs and drugs with objectionable odour require special treatment like coating or encapsulation which may increase the cost of the dosage form.

3) Drugs with poor wetting and slow dissolution properties are difficult to convert into pills which will provide poor drug bioavailability.

4) Drugs with high doses are difficult to formulate as pills.

5) Drugs that are liquid at room temperature cannot be formulated in this dosage form.

Question No. 07. Mention the various grades of powder.

Answer: Grades of Powder: The I.P. specifies 5 grades of powder:-

1) Coarse powder: - A powder of which all the particles pass through sieve no. 10 and not more than 40% pass through sieve no. 44.

2) Moderately coarse powder: - A powder of which all the particles pass through sieve no. 22 and not more than 40% pass through sieve no. 60.

3) Moderately fine powder: - A powder of which all the particles pass through sieve no.44 and not more than 40% pass through sieve no. 85.

4) Fine powder: - A powder of which all the particles pass through sieve no. 85.

5) Very fine powder: - A powder of which all the particles pass through sieve no. 1

Question No. 08. Differentiate between soft gelatin and hard gelatin capsules.

Answer:

S. No.	Hard Gelatin Capsules	Soft Gelatin Capsules
01.	It consists of two parts body and cap.	It is a single unit after sealing the two half of the capsule.

02.	They are cylindrical in shape.	They are available in round, oval or tube shape.
03.	It consists of gelatin, titanium dioxide, coloring agent and plasticizer.	These are prepared from gelatin, plasticizer and preservative.
04.	It is used only for solid medicament.	It is used for filling of solid, liquids or semisolids.
05.	Capsules are sealed to ensure that medicaments may not come out of capsule due to rough handling.	Filling and sealing of soft gelatin capsules are done in a combined operation on machines.

Question No. 09 Write note on filter aids.

Answer: These are the substance, which reduce the resistance of the filtrate to flow. These are added to the preparation in concentration from 0.1 to 0.5% before filtration. An ideal filter aid should possess the following qualities.

i) It should be able to remain suspended in the fluid.

ii) It should be free from impurities.

iii) It should be inert to the liquid being filtered.

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

The object of the filter aid is to prevent the filter medium from becoming blocked. Filter cake must be light, porous inert various filter aids are used like cellulose asbestos, carbon, diatomaceous earth. They are used according to their advantage and chemical composition.

Question No .10 Differentiate between dry and moist heat sterilization.

Answer-

S. no.	Moist heat sterilization	Dry heat sterilization
01.	In moist heat sterilization steam is used which also penetrates in bacterial spores and cause coagulation of protoplasm part of bacteria.	In dry heat sterilization the microorganism are killed due to oxidation of bacteria.
02.	This method is used for killing bacteria and bacterial spores.	Only bacteria are killed by this method. Spores are not killed.
03.	Surgical dressing, rubber and plastic containers can be sterilized easily without any deterioration.	Oily material, powders, which get spoiled during moist heat sterilization, can be sterilized easily.
04.	Temperature of sterilization is 121 to 124 °C for	Temperature of sterilization is 160°C for one

	15 minutes.	hour.
05.	This method is suitable for most of the medicaments as the temperature of sterilization is comparatively low for shorter duration, however the medicaments that get deteriorated in the presence of moisture cannot be sterilized.	This method is not suitable for most of the medicaments as the temperature of sterilization is very high for long duration. However the medicaments that get deteriorated in the presence of moisture can be sterilized.

Question No. 11: Enumerate the various factors affecting the size reduction.

Ans. Size reduction: It is the process of reducing drugs into small particles or fine powder. Crushing, grinding, milling and pulverization all are the synonyms of size reduction.

Factors affecting size reduction:

(a) Method of size reduction: The selection of the method of size reduction depends upon the physico-chemical properties of the dosage forms.

(b) Hardness: Hardness of a material depends upon its surface properties that can be determined with the help of Moh's scale. This scale gives the no. from 1 to 10. It is difficult to reduce the particle size of a hard material (moh's no. 7) and soft material having the moh's no.3

(c) Toughness: It is more difficult to reduce the size of a soft and tough material as compared to the hard and brittle material.

(d) Stickiness: Stickiness causes the adhering of the material to the grinding surface. Mainly this problem occurs in the case of gummy and resinous material.

(e) Moisture content: Moisture content has a great effect on the hardness, toughness and stickiness which effects the size reduction of a drug. Moisture content below the 5% is suitable for the dry grinding and greater than 50% is suitable for the wet grinding.

(f) Purity required: Certain size reduction equipments involves considerable wear and tear of grinding surface. So it should be avoided if high degree of purity is required.

(g) Bulk density: The capacity of most of the batch mills depends upon the volumes. The volume of a material depends upon the bulk density of it.

(h) Temperature: In case of the thermolabile drugs that may undergo degradation and very fine powder may explode if there is an excessive increase in the temperature occurs.

Question No. 12. Describe Water for Injection & Sterile Water for Injection I.P in detail.

Answer- Water for injection: Water which is free from volatile and non volatile impurities, microorganism and pyrogen is called water for injection. It is obtained by distilling potable water, purified

Question No 09- What is Pharmacopoeia. Explain Indian pharmacopoeia.

water, or distilled water from a neutral glass or suitable metal still fitted with an efficient device for preventing the water drops to go along with water vapors into the condenser. the first portion of the distillate is rejected which contains volatile impurities. The remainder is collected in suitable containers, previously rinsed with freshly distilled water and closed so as to avoid contamination. It contains no added substances. It need not be sterile but it should comply with the test for pyrogen.

Sterile water for injection I.P: It is water for injection which is sterilized and suitably packed. It contains no anti microbial agent or other added substance. It has ph is 4.5 to 7.5 it must comply with the rests for sterility, it should also comply with the requirements of the tests for carbon dioxide, chloride, sulphate, nitrates and nitrites, ammonium, calcium and heavy metals. It must comply with the test for pyrogen. Sterile water for injection should be stored in single dose containers not larger than of one liter in size.

SECTION – D **10x3=30**

Each question carries 10 marks.

Question No. 01. Define sterilization. Discuss briefly various methods of sterilization. .

Question No. 02. Discuss ball mill in detail.

Question No. 03. Discuss fluid energy mill in detail.

Question No. 04. Write a short note on evaluation of tablets.

Question No. 05. Describe the construction and working of filter press.

Question No. 06. Define aerosols and discuss their packaging. Give advantages and disadvantages of aerosols.

Question No. 07. Define distillation and its type. Write a short note on fractional distillation.

Question No. 08. What is Pharmacopoeia? Explain Indian pharmacopoeia.

Question No. 09. Write a short note on the manufacturing defects in tablets.

Question No. 10. What is freeze drying?

ANSWERS

Question 01: Define sterilization. Discuss briefly various methods of sterilization. .

Ans. Sterilizations: Sterilization may be defined as process of removing or destroying all the living microorganisms present in any preparation or part thereof. Various methods of sterilization are used to prepare the pharmaceutical products.

Methods of sterilization:

(1) Physical methods: All microorganism including spores, can be killed by the application of heat. Heat can be applied in different forms in sterilization.

(a) Dry heat sterilization: In dry heat sterilization the microorganisms are destroyed due to oxidation of essential cell constituents. Dry heat sterilization is mainly done by "Hot air oven".

Hot air oven: It is used for sterilization of pharmaceutical products and other materials. It is double walled chamber made of steel. This method is used for sterilization of those substances, which get spoiled during moist heat sterilization. According to pharmacopoeia sterilization by dry heating is effected by heating at a temperature of 160^0 C for 1 hour for most of the equipments.

Uses:

1) This method is used to sterilize the glass wares.

2) This method can be used for the equipments like mortar pestle, ointment tubes and surgical equipments.

3) Fixed oils, ointment base, liquid paraffin and wool alcohol can also be sterilized by this method.

4) This technique can also be used for surgical catguts and gelatin sponge.

(b) Moist heat sterilization: This method is more effective than dry heat method, due to the fact that steam has more penetration power than dry heat. The moist heat penetrates the spores and capsules of bacteria, rupture it and escaping protoplasm is coagulated. Generally the holding temperature in moist heat sterilization is 121^0C to 124^0C for 15 minutes. In this method the instrument used for sterilization is "**Autoclave**". In which steam is used for sterilization. Other methods of moist heat sterilization are tyndallisation, pasteurization and sterilization of vaccines

Advantages:

1) Autoclaving destroys microorganisms more efficiently than dry heat sterilization.

2) Equipments or parts of rubber and plastic, such as, nylon and polyvinyl chloride can withstand the temperature and pressure required for moist heat sterilization.

3) Sterilization can be done after packing the pharmaceuticals preparations in its final container.

Disadvantages:

1) This technique is not suitable for oils, fats, ointments, powders and oily injection and aqueous and alcoholic preparation.

2) It cannot be used for sterilization of plastic which get spoiled at 115-116^{0}C for 30 minutes.

(c) Radiation Sterilization: Direct sunlight can destroy microorganism on account of its ultra violet rays of long wavelength. Ultra-violet rays for sterilization can be produced by passing a low current at high voltage through mercury vapour in an evacuated glass tube.

Sterilization by ionizing radiation: The ionizing radiations are x-rays and γ-rays. These are lethal to bacterial cell and destroy the nuclei of the bacterial cell. Gamma rays are produced from radioisotopes such as Cobalt-60 or Cesium-137. The material to be sterilized is packed in the final container and then exposed to ionizing radiations.

(2) Chemical methods:

(a) Sterilization by heating with bactericide: This method is used for sterilizing aqueous preparations, which are unstable at higher temperature. The medicament is dissolved or suspended in a suitable solution of bactericide. The preparation is then transferred into its final container, which is then sealed so as to exclude microorganisms and the final container is then heated at 98-100^{o}C for 30 minutes in boiling water.

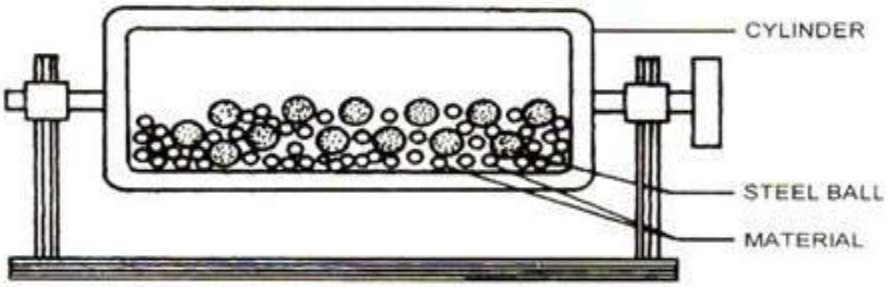
(b) Gaseous sterilization: In this process sterilization is done with a chemical in gaseous state. Formaldehyde was used in olden days but now ethylene oxide is used for sterilization.

(3) Mechanical methods: The solution containing thermolabile medicament can be sterilized by filtration through bacteria proof filters. These filters retain the bacteria and sterile filtrate is collected in sterilized receiver. Various filters used for sterilization are: (i) Membrane filters (ii) Ceramic filters (iii) Sintered glass filters (iv) Seitz filter (v) Sintered metal filters. Only important one membrane filter is discussed here.

Question 02: Discuss ball mill in detail.

.**Answer - Principle**: It works on the principle of impact and attrition.

Construction: It consists of a hollow cylinder, which is mounted on metallic frame in such a way, that it can be rotated on its longitudinal axis. The length of the cylinder varies usually 1-3 meters in diameter. The cylinder contains balls that occupy 30-50% of the mill. The balls are made up of the same material as that of the cylinder. These balls act to grind the material. If the pebbles, rod or bars are present at the place of balls, then they are called as pebble mill, bar mill or rod mill respectively. The mill usually contains the balls of different size so the efficient reduction in particle size takes place. The upper size of the cylindrical vessel is fitted with the tightly closed lid through which the material can be introduced.



Ball Mill

Ball mill operation

Working: The drug to be grounded is put into the cylinder of the mill and mill is rotated. The speed of rotation is very important. At low speed, the mass of balls will slide or roll over each other and size reduction does not take place. At high speed, balls will throw out to the walls by centrifugal force and no grinding will occur. At 2/3 speeds, the centrifugal force just occurs with the result that the balls are carried almost to the top of the mill and then fall. After suitable time, material is taken out and passed through sieve to get a powder of uniform size.

Uses: 1) The mill used to grind brittle drugs to fine powder.

2) It can also be used for wet grinding also**.**

Advantages:

1) It can produce very fine powders.

2) It can be used for continuous production if sieve is attached.

3) Suitable for wet and dry grinding.

4) It can also be used to grind toxic materials.

Disadvantages:

1) It is very noisy machine.

2) Wear and tear occurs from the balls.

Question No : 03 Discuss Fluid energy mill in detail.

Answer- Principle: It works on the principle of impact and attrition.

Construction: It consists of a hollow loop of pipe, which has a diameter of 20 to 200 mm depending on the overall height of loop, which may be upto about 2 m. The lower part of the loop has the nozzles through which a fluid, generally compressed air is injected at very high pressure. The mill has an inlet and outlet for the entry and exit of the material. For the collection of the reduced particles a cyclone separator is also present at the outlet.

Working: The air or inert gas is introduced with a very high pressure through the nozzles. Solid are introduced into air stream through inlet. Due to high degree of turbulence, impact and attritional forces occurs between particles. The fines particles are collected through classifier.

Uses:

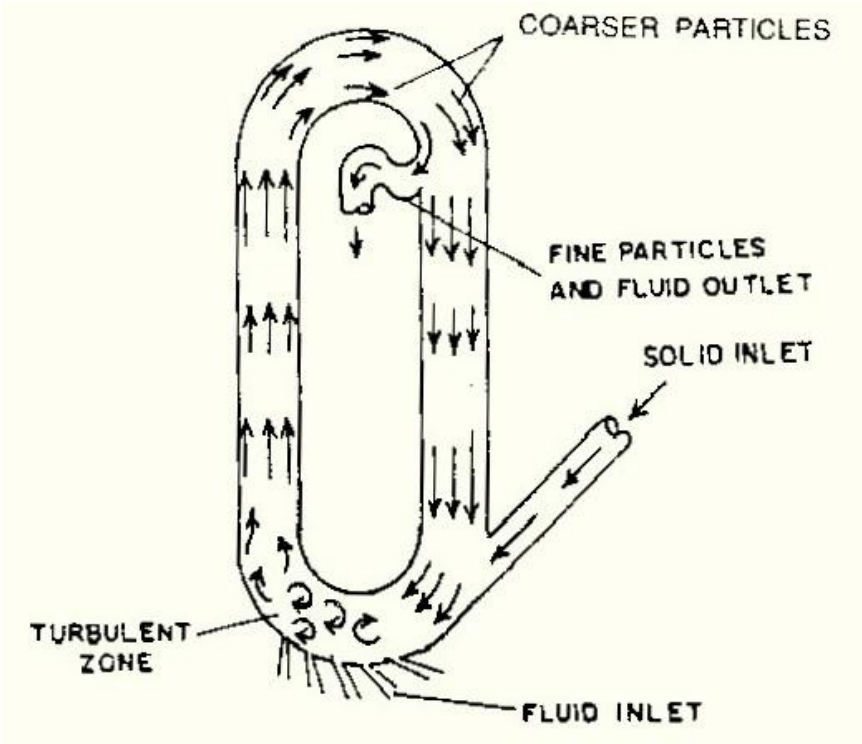
1) The mill is used to grind heat sensitive material to fine powder.
2) It is used for coating of fine particles.

Advantages:

1) The particle size of powder can be controlled due to the use of a classifier.
2) There is no wear and tear in the mill.

Disadvantages:

1) Process is not economical,
2) Premilling is also required.



Fluid Energy Mill

Question No: 04 Write a short note on evaluation of tablets.

Ans. (a) Evaluation of tablets (quality control of tablets):

The various tests are carried out to maintain quality control of tablets as prescribed in pharmacopoeia. These are as follow:

1) Shape of tablets: In the pharmacopoeia the shape of the tablets is defined as circular with flat or convex faces.

2) Appearance: When broken section of an uncoated tablet is examined under a lens, uniform texture of single layered tablet or a stratified texture in multilayer tablet. Coated tablets will appear with a smooth and colored surface.

3) Uniformity in weight: It is desirable that every drug or tablet should have uniform weight. Little variation is liable to occur but large variation cannot. Test for uniformity in weight: 20 Tablets are selected and determined their average weight and not more than two tablets vary from average weight by more than the percentage deviation given in the table:

Average weight of tablet	***Percentage deviation***
(i) 80 mg or less	10
(ii) More than 80 mg but less than 250 mg	7.5
(iii) 250 mg or more	5

4) Uniformity in content: Tablet must comply with the requirement for uniformity of content specified in the individual monograph. The percentage of medicament is calculated by doing assay for a particular drug, by the method that is given in pharmacopoeia. If any drug does not comply with test, it is rejected.

5) Measurement of hardness or mechanical strength: Mechanical strength determines the strength or hardness of a tablet. It is necessary to ensure that the tablets should withstand the normal risk of handling and transportation. The instruments which are used for testing the hardness of tablets are ***Monsanto hardness tester*** and ***Pfizer hardness tester***

6) Friability test: During the course of compression of tablet, a sufficient pressure is applied on the granules, so that tablet can withstand wear and tear during transportation. In this test a tablet friabilater is used. The apparatus consists of a plastic chamber, which is divided into two parts and it revolved at a speed of 25 r.p.m. 20 tablets are weighed and placed in the plastic chamber. The chamber is rotated for 4 minutes or 100 revolutions. During each revolution tablet falls from the distance of 6 inches. Loss in weight is indicated by weighing the tablets after 100 revolution. The tablet is considered to be of good quality if the loss of weight is less than 0.8%.

7) Disintegration test: Disintegration of a tablet means breakdown of the tablet into smaller particles after swallowing. The time required to disintegrate the tablet is called "Disintegration Time". The rate of disintegration depends upon type of tablet. In this test the instrument used is known as Disintegration apparatus. If a tablet does not comply with the test time, it is rejected or again tested if any error exits in testing.

8) Dissolution test: Dissolution test is generally performed to determine the amount of active ingredient dissolved in the specified time. The dissolution media and time is specified in particular monographs in I.P. Generally two types of dissolution apparatus are used for the dissolution of tablets and capsules.

Question No. 05 . Describe the construction and working of filter press.

Answer- Filter press: There are two basic forms of the filter press but only the plate and frame press has a wide application in pharmaceutical industries.

Plate and frame filter press:

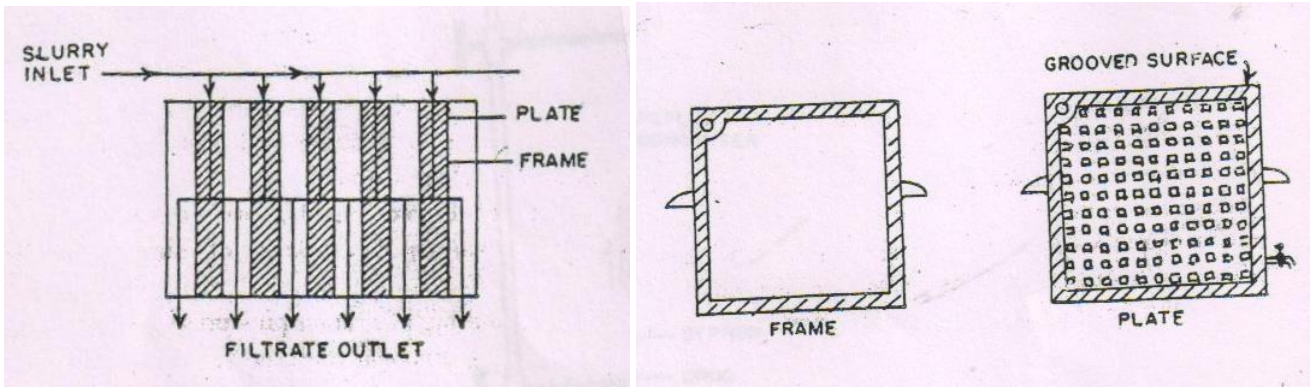
Construction: It consists of plates and frames. The frame is open and is used as an inlet for the material to be filtered. Plate is supported by filter cloth. The filter cloth is fitted on each side of the plate. Plates and frames are placed alternatively.

Working: i) the filtering liquid enter the frame under pressure from the feed channel.

ii) The filtrate passes through the filter medium on to the surface of the plate.

iii) The filtrate is collected in the plates from common outlet pipe.

iv) The cake is deposited in the frames. The process of filtration is continued until the frames are filled with filter cake. Then the process is stopped, the frame is emptied.



Principle of operation of filter press

Advantages:

1) The filtering media can be used repeatedly.

2) Operation and maintenance is simple.

3) It requires less space and provides large surface area for filtration.

Disadvantages:

1) It is not a continuous process.

2) Leakage between plate and frame can take place.

Question No. 06. Define aerosols and discuss their packaging. Give advantages and disadvantages of aerosols.

Ans. Aerosols may be defined as disperse phase system in which very fine solid particles or liquid droplets or gaseous phase get dispersed in the gas, which acts as a continuous phase. This is also known as pressurized system because medicaments come out of container when pressure is applied on valve.

Packaging of Aerosols: The aerosols products can be filled in aerosol containers by two ways:

(a) Cold-fill process (b) Pressure- fill process

(a) Cold-fill process:

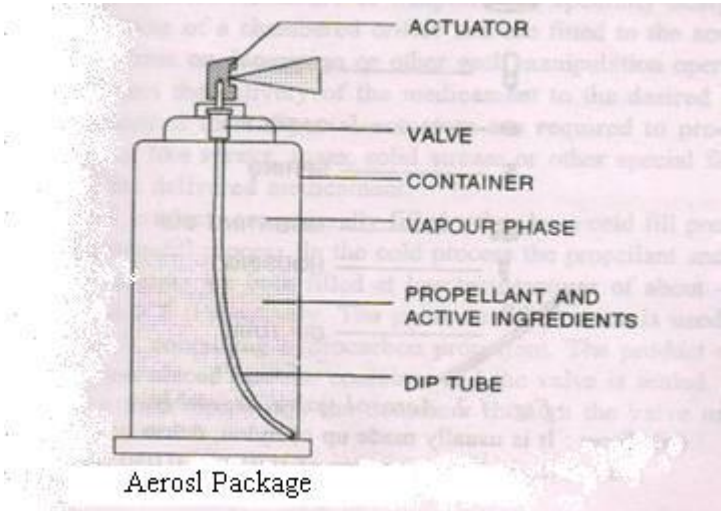
1) This process is used to fill metered aerosol products using a fluorocarbon propellant. By lowering the temperature of a propellant below its boiling point, the propellant becomes liquid at atmospheric pressure.

2) The active ingredients and propellant are cooled to a low temperature of about -30^0 F to -40^0 F.

3) The active ingredients are generally cooled to below 0^0 C in order to reduce loss of propellant during the filling operation. The chilled active ingredients are poured into chilled container and propellant is added.

4) Sufficient time is given for the propellant to partially vaporize, in order to expel the air present in the container.

5) The valve is fitted on to the container which is placed into a water bath so that the contents are heated to 130^0 F (54^0C) in order to check any leakage and strength of container.



Aerosl Package

b) Pressure-fill process: This process is used for filling aerosols containing hydrocarbon propellant. The product concentrate is placed into the container and the valve is sealed. The propellant is forced through the valve under pressure. After this the container is immersed in a water bath at 130^0 F (or 54^0C) in order to check any leakage and strength of the container. It is essential that the air present in the container must be expelled before filling the contents into the aerosol container.

Advantages:

1) The medicament can be delivered directly to the affected area.
2) Absence of air prevents oxidation of product.
3) The hydrolysis of medicament can be prevented.
4) Drug can be given by oral inhalation.
5) Sterility of the product is maintained.
6) The application of medicament is easy.
7) Drug decomposition does not take place.

Disadvantages:

1) Aerosol packaging process is costly.
2) Sometimes propellants are toxic.
3) Cooling effect of volatile propellants may cause discomfort

Question No. 07. Define distillation and its type. Write a short note on fractional distillation.

Answer;- Distillation: Distillation is the process of converting liquid into its vapours by heating and reconverting it again into liquid by condensing the vapours. It is a method of separating substances which differ in their vapour pressure. Steam distillation is used for the separation of two immiscible liquids or preparation of volatile oils.

Type of Distillation Processes: 1. Simple distillation: It is a process of converting a liquid into its vapour in a distillation still, transferring the vapour to another place and condensing it again into liquid

.**2. Distillation under reduced pressure:** The boiling point of the liquid may be lowered to the desired temperature by reducing the pressure on its surface.

3. Fractional distillation: It is used for the separation of miscible liquids, such as alcohol and water.

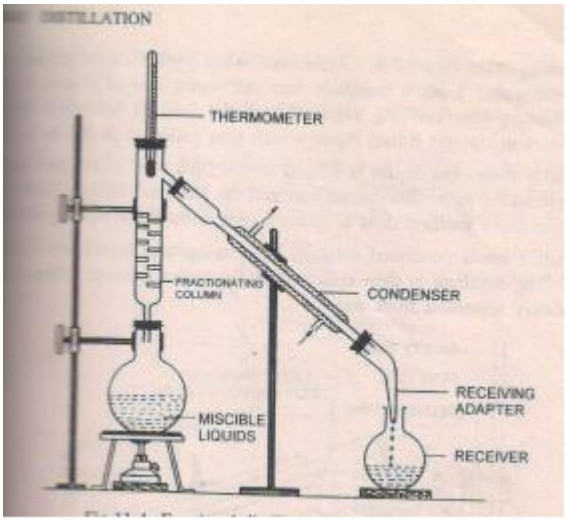
4. Steam distillation: It is used for the separation of two immiscible liquids or preparation of volatile oils.

5. Destructive distillation: This is also known as dry distillation. It is mainly used in industry for obtaining many valuable products from wood and coal.

Fractional distillation

Theory: When a substance is dissolved in a liquid, the vapors pressure of the liquid is lowered. When two miscible liquids are mixed together, each will act as solute or solvent for the others. So, when a mixture of

two such liquid is heated, the vapour pressure of each is lowered. The pressure exerted by each liquid in the mixture is known as partial pressure. The liquid boils when the sum of partial pressure is equal to the atmospheric pressure. The vapours arising from two miscible liquids at boiling point are richer in the component exerting the greater partial pressure.



Apparatus used for laboratory scale- Fractionating column is fitted between the distillation flask and the condenser. Fractionating column is used for continuous separation of two miscible liquids. Long fractionating column is used in the mixture where the boiling point is quite close to each other and short fractionating column is used in those cases where there is a considerable difference in the boiling point of the mixture of miscible liquid. The mixture of miscible liquid is heated in the still. The vapors formed are allowed to pass through the fractionating column, where a part of the vapor is condensed and while returning to the still comes into an intimate contact with the rising vapor resulting in further fractionation of the liquid being distilled.

Application- 1 Alcohol is purified from the mixture of alcohol ans water obtained from fermentation tank.
2. It is used for the separation of miscible liquids such, as, alcohol ans water, acetone and water, chloroform and benzene.

Question No 08- What is Pharmacopoeia. Explain Indian pharmacopoeia.

Answer- The books containing the standards for drugs and other related substances are known as pharmacopoeias.

Indian Pharmacopoeia (I. P.): In 1946 the Government of India published the Indian Pharmacopoeial list which served as a supplement to British Pharmacopoeia. This list included the drugs which were of substantial medicinal value and were later on included in the Pharmacopoeia.

The first edition of Indian Pharmacopoeia was published in 1955 and a supplement of it was published in 1960.

The second edition of Indian Pharmacopoeia was published in 1966 and a supplement of it was published in 1975.

The third edition of Indian Pharmacopoeia was published in 1985. A working group was constituted by the committee to prepare monographs, appendices and general notes which were finalized by the pharmacopoeia committee. The same were published in the form of the pharmacopoeia of India in 1985, in two volumes, volume I and volume II by the controller of publications, Delhi on behalf of government of India, ministry of health and family welfare. The volume I contains legal notices and preface, acknowledgements, introduction, general notices and monographs from A to P. the volume II contains monographs from Q to Z, appendices, contents of appendices and index.

The 4th edition of I.P. was published in 1996. It contents 1149 monographs and 123 appendices and available in two volumes.

Fifth edition of I.P. (2007): Fifth edition of I.P. was published in 2007. It is expanded in the three volumes.

Vol. 1: This volume gives the information about the general topics.

Vol. II: This volume provides the information about the pharmaceutical aids, dosage forms and general knowledge about the herbs and herbal products.

Vol. III: This volume provides the complete knowledge about the drugs, human used materials and products

Question No. 09. Write a short note on the manufacturing defects in tablets.

Answer: The following defects occurs during the compression of granules into tablets.

1. Capping- It is the partial or complete separation of upper or lower surface of the tablets. The reason for this defect usually may be excessive fines in granules which entrap air in a tablet.

ii) Defective punches and dies.

These defecst can be removed by- i) Setting the dies and punches properly.

ii) Regulate the speed of tablet machine.

iii) To reduce the percentage of fines.

2. Picking and Sticking: In picking the material is removed or picked up by the upper surface of the tablet. In case of sticking the material stick to the wall of the die. These defects appear due to use of worn out dies and punches, by use of small quantity of lubricants by presence of moisture in the granules.

These defects can be removed by using: i) A new set of die and punches and ii) Dry granules.

3. Mottling: Mottling means an unequal colour on the surface of coloured tablets. This defect occurs due migration of dye in the granules during the process of drying and use of different coloration of medicament and excipients.

These defects can be avoided by: i) Drying the granules at a low temperature.

ii) Using the dye which can mask the colour of all the ingredients of tablet formulation.

4. Weight variation- During the compression of granules in a tablet machine, the tablet does not have a uniform weight. The reason for these defects is- i) Granules are not uniform in size (ii) No proper mixing of lubricants. (iii) Variation in the speed of the tablet machine.

These defects can be avoided by correcting and checking the above mentioned points.

5. Hardness variation- Hardness variation is a problem having the same causes as weight variation. In this case the tablet does not have a uniform hardness. Hardness depends on the weight of the material and the space between the lower punches during the stage of compression.

6. Double impression: It is due to the undesirable movement of the lower punch having the monogram. During compression the tablet receive an imprint of the punch. Due to some defect in the machine, the lower punch moves slightly upward before ejection of a tablet and gives a second, though light, imprint on the tabet. These defects can be removed by controlling the undesirable movement of the lower punch.

Question No. 10. What is freeze drying?

Answer- Freeze drying: In freeze-drying process, there is removal of water vapors from a frozen material by sublimation. Therefore it is also called sublimation drying process or lyophilization.

Theory: In this process, the material is frozen in a suitable container connected to a high vacuum system, so that the vapour pressure of water vapours is reduced to less than that of the material being dried. It reduces the temperature and pressure to values below the triple point. Under these conditions, ice sublimes directly to vapour state. The water vapours are removed from the system by condensation in a condenser maintained at a temperature lower than temperature of a frozen material. The process is mainly used for drying of biological products such as antibiotics, blood products, and vaccines.

Parts of freeze dryer:

(i) A chamber for vacuum drying (ii) A vacuum source (iii) A heat source (iv) A Vapor removal system

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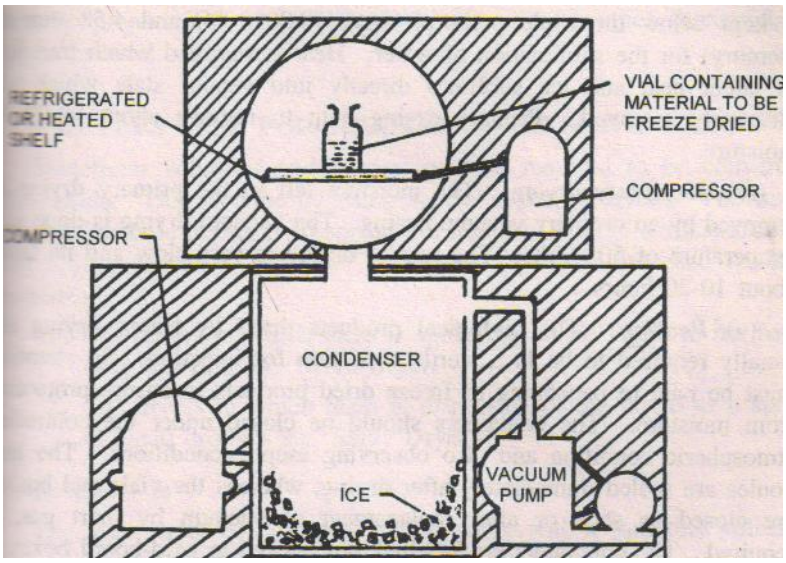

Freeze Dryer

Working: The working of freeze dryer involves the following steps.

1) Pre-treatment: This step is done to reduce the volume of the solution to be introduced into the container which has limited capacity. The solution is pre-concentrated under normal vacuum tray drying.

2) Pre-freezing: This is done to solidify water. The ampoules, vials and bottles in which aqueous solution is packed, are frozen in cold shelves at a temperature below -50^0C.

3) Primary drying: the material to be dried is spread to increase the surface area for sublimation. Heat is supplied which transfers as latent heat and ice sublimes directly into vapor state which are ultimately removed.

4) Secondary drying: The moisture left in the primary drying is removed by an ordinary vacuum drying. The vacuum drying is done at a temperature of 50^0C-60^0C.

5) Packing: The biological products dried by freeze drying are packed in sterile container under sterile conditions **Advantages:** 1) The product obtained is light and porous having excellent solubility.

2) The heat sensitive material can be dried.

3) The loss of volatile material is minimum.

4) The sterility of the product is maintained.

Disadvantages: 1) The process is very expensive.

2) The product obtained by freeze-drying is hygroscopic.