JRG College of Pharmacy

JRG COLLEGE OF PHARMACY

BOARD SOLVED QUESTION

WITH ANSWER

Year : 2022

Subject : Pharmaceutics

Subject Code : ER20-11T

Subject In-Charge : Ms. Monali Padhi

ODISHA STATE BOARD OF PHARMACY

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D. Pharm Part (I)

ER 2020

2022(I)

DO NOT WRITE ANYTHING ON YOUR QUESTION PAPER EXCEPT YOUR ROLL NO. QUESTION PAPER CONTAINING ANYTHING WOULD BE TREATED AS MALPRACTICE

Subject: PHARMACEUTICS (Theory)

Full Mark -80 **Time -3 hrs**

1. **Long type questions (answer any six)** [6x5=30]
   - i. Define Immunity. Write down the details about small pox vaccine. (1+4=5)
   - ii. Define tablet. Write down the details about excipients used in tablet preparation with suitable examples. (1+4=5)
   - iii. Discuss different methods for identification of types of emulsion. (5)
   - iv. Define Q.A & Q.C. Write briefly about cGMP. (2+3)
   - v. Write down the principles, construction, working and application of Ball Mill with labelled diagram. (1+1+1+1+1=5)
   - vi. Write down different quality control tests for tablets. (5)
   - vii. Write down different methods used in formulation of parenteral preparations. (5)
2. **Short type questions (answer any ten)** [10x3=30]
   - i. Write the ideal properties of filter aids. Give two examples of filter aid.
   - ii. Write a short note on homogenisation.
   - iii. Write a short note on Soxhlet extraction.
   - iv. Write a short note on sterilization.
   - v. Differentiate between flocculated and deflocculated suspension.
   - vi. Write notes on factor affecting size reduction.
   - vii. Define diffusible solid & indiffusible solid.
   - viii. Write down the difference between liniments and lotions
   - ix. Write short note on fusion method of preparation of suppositories.
   - x. Differentiate between calibration and validation.
   - xi. Write a short note on effervescent granules.
3. **Objective type Questions, Answer all from both sections, Each carries One mark** (20x1)

(A) DEFINE THE FOLLOWING

i) Impact ii) Co-solvent. iii) Colloidal suspension. iv) enteric coated tablet v) Microencapsulation vi) Clarification vii) Lyophilisation viii) Sieve number ix) Mottling x) Opsonin. xi) Pharmacopoeia xii) Elixir xiii) Tablets xiv) Poultice xv) Extraction

(B) ANSWER THE FOLLOWING.

- i. Give two major differences between emulsion and suspension.
- ii. Differentiate between 'purified water' and 'water for injection'.
- iii. Write advantages of evaporating pan.
- iv. Give two examples of wetting agent.
- v. What is prodrug.

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(ii) Define immunity. Write down the details about small pox vaccine.

A) Immunity is the ability of the body to defend itself against disease-causing organisms. Everyday our body comes in contact with several pathogens, but only a few results into diseases. The body has the ability to release antibodies against these pathogens & protects the body against disease. This defence mechanism is called immunity.

Small pox vaccine :-

- The term vaccine derives from the latin word for cow, reflecting the origins of small-pox vaccination.
- In 1796, British physician Edward Jenner demonstrated that an infection with the relatively mild cowpox virus conferred immunity against the deadly smallpox virus.
- The small-pox vaccine is used to prevent smallpox infection caused by the variola virus
- 1958 to 1977, the WHO conducted a global vaccination campaign that eradicated smallpox, making it the only human disease to be eradicated.
- small pox vaccines produced & successfully used during the intensified eradication program are called 1st generation vaccines in contrast to small-pox vaccine developed at the end of the eradiction phase.

- second & third generation vaccines are co. produced using modern cell culture techniques & current standards of good manufacturing practices.
- In 2002, World Health Assembly resolution ss.16 urged member states to share expertise, supplies & resources to rapidly contain a public health emergency.
- Due to widespread vaccination, smallpox was declared eradicated by the WHO in 1980, the first human disease to be eradicated globally.
- While generally safe, the vaccine can have side effects, including mild reactions & rare severe complication.

e.g:- vaccinia infection.

i) Define Tablet write down the details about excipients used in tablet preparation with suitable examples.

→ Tablet is a unit solid dosage form containing medicaments usually circular in shape. prepare by the method of moding & compression.

Excipients used in tablet preparation:

Excipients is inert substances which is added along with medicaments.

(1) Diluents (2) Glidants (3) Lubricants
(4) Disintegrants (5) colouring agent (6) flavouring agent
(7) sweetening agent (8) Anticaadherents
(9) granulating agent (10) Binding Agent.

(1) Diluents :-

- Added when quantity of active ingredient is small or difficult to compress.
- The tablet size should be kept above 2-3 mm & weight of tablet above 50 mg.
- carbohydrates such as sugars, starches & cellulose used as diluent & also function as binders during wet granulation.

e.g:- Lactose, calcium phosphates, kaolin.

(2) Glidants :-

→ Glidants are added to formulation to improve the flow properties of the material which is to be fed into the die cavity.
→ Improve the flow property of the material.
→ Always added in dry state.

e.g:- colloidal silica, talc.

(3) Lubricants :-

Reduce the friction by interposing an intermediate layers between the tablet constituents & the die wall during compression & ejection.

(4) Anti adherents :-

Reduce sticking or adhesion of the tablet granules or powders to the faces of punches or the die walls.

e.g :- starch, magnesium stearate.

(5) Disintegrants :-

These are added to induce breakup of the tablet when it comes in contact with aqueous fluid & this process of disaggregation of the particles before the drug dissolution occurs, is known as disintegration process & the excipients which induce the process are known as disintegrants.

e.g :- Starch, explotab

⑥ Binding Agents :-

used in granulation to provide proper strength to the granules, in order to keep the tablet intact after compression.

e.g:- Gum acacia, gelatin, etc.

⑦ Granulating Agent :-

→ These are used to convert to fine powder into granules.

→ A granulating agent provided the proper moisture to convert fine powder into dump mass after passing through a sieve, from granules.

e.g:- gelatin solution, acetone

⑧ Flavouring agent :-

usually limited to chewable tablets, lozenges or other tablets intended to dissolve in the mouth.

e.g:- Orange syrup, vanilla, etc.

⑨ Sweeting agent :-

used to improve the taste of the tablets.

e.g:- sugars like mannitol, saccharin

⑩ Colouring Agent :-

- Makes tablet more esthetic for appearance
- Identification for the user.
- e.g:- sunset yellow FCF, curcumol, etc.

(iii) Discuss different methods for identification test of emulsion.

Emulsion :-

An emulsion is a biphysic liquid preparation containing two or more liquid that are usually immisble in which one is present as droplets of microscopic & ultramicroscopic size throughout the orders.

The methods commonly used to prepare emulsion can be divided in two & categories

A) Trituration Method :-

This method consist of dry gum method & wet gum method.

1) Dry gum Method :-

- In this method the oil is first triturated with gum with a little amount of water to from primary emulsion
- The trituration is continued till a characteristic 'clicking' sound is heard & a thick white creamed is formed
- once the emulsion is formed then remaining quantity of water slowly added to form final emulsion)

2) wet gum method :-

- In this method first gum & water are triturated together to form a mucilage.
- The required quantity of oil is then added gradually in small proportions with through trituration to form primary emulsion.
- once the primary emulsion has been formed remaining quantity of water is added to make the final emulsion.

(B) Bottle Method :-

→ This method is employed for preparing emulsions containing volatile & other non-viscous oils.

- In this method, oil, or vector is 1st shaken thoroughly with the calculated amount of gum.
- Horse of water is added in small portions with constant agitation after each addition to produce the final volume.

Identification of Emulsion :-

① Dilution Test :-

→ Dilution of an emulsion either with oil or with water can reveal its type

- The test is based on the principle that more of the continuous phase can be added into an emulsion without causing the problem of its stability.
- Thus an o/w emulsion can be diluted with water & a w/o emulsion can be diluted with oil.
- Addition of water to a w/o emulsion & oil to o/w emulsion would crack the emulsion & lead to separation of the phase.

② Conductivity Test :-

- In this test a pass of electrodes connected in a bulb & electric source are dipped into an emulsion.
- If the emulsion is o/w type, water conduct the current ~~between~~ & the bulb get lit due to passage of current between two electrodes.

- If the emulsion is w/o type, oil does not conducts the current & bulb does not glows.

③ Dye solubility test :-

- emulsion is mixed with a water soluble dye & observed under the microscope.
- If the continuous phase appears red, then it means that the emulsion is o/w type as water is the external phase.
- If the scattered globules appears red & continuous phase colourless, then it is w/o type.

④ fluorescence test :-

- Many oils exhibit fluorescence when exposed to uv light.
- Therefore o/w emulsion show spotty pattern) while w/o emulsion gives fluorescence.

⑤ Cobalt chloride test :-

filter paper socked in a cobalt chloride solution & allowed to dry turns form blue to pink on exposure to o/w emulsion.

⑥ filter paper Test :-

→ The test is based on the fact that an o/w emulsion will spread out rapidly when dropped onto filter paper.

- In ~~contact~~ contact a w/o emulsion will migrate only slowly.
- This method should not be used for highly viscous

(iv) Define Q.A & Q.C. write in brief about cGMP

Quality Assurance :-

According to WHO, quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of product with regard to pharmaceuticals. Quality Assurance can be divided into major areas: development, quality control, production distribution & inspection.

Quality control :-

QC is a procedure intended to ensure that a manufactured product adheres to a defined set of quality criteria or meet the requirement of customer.

current good Manufacturing practise (cGMP)

- cGMP should be designed to be flexible to allow each manufactoring to decide individually how to implement the necessary controls by using scientific processing methods & testing procedures.
- The 'c' in GMP means current & up to date technologie

Basic Requirment of cGMP :-

- personal
- premisses & Industrial layout
- sanitization & Hygiene
- water treatment system.
- qualification
- Equipment matterial

CGMP Principle :-

- Manufacturing facilities must maintain a clean & Hygiene manufacturing area.
- Controlled environment conditions.
- Prevent cross contamination foods & drugs.
- Manufacturing process are clearly defined.
- Instruction & procedure are written in clear language.
- Record of manufacturing complete History note on diary with Batch no.

(V) Write down the principles, construction, working & application of Ball Mill with labelled diagram

Principle :-

- A ball mill is a type of grinder used extensively mechanical process & for the size reduction of a wide variety of materials.
- It's construction & working principle are based on the rotation of a horizontal cylinder filled with both grinding media & the material to be ground which leads to the reduction in size of the material through impact & attrition.

construction :-

1) cylinder :-

The container which holds the grinding media & the material to be ground. It's internal surface may be either smoother or lined with

abrasion resistant materials such as steel or rubber to reduce wear.

② Grinding Media :-
Balls made of steel, ceramic or rubber. The diameter of these balls can range from a few millimeters to several inches depending on the application.

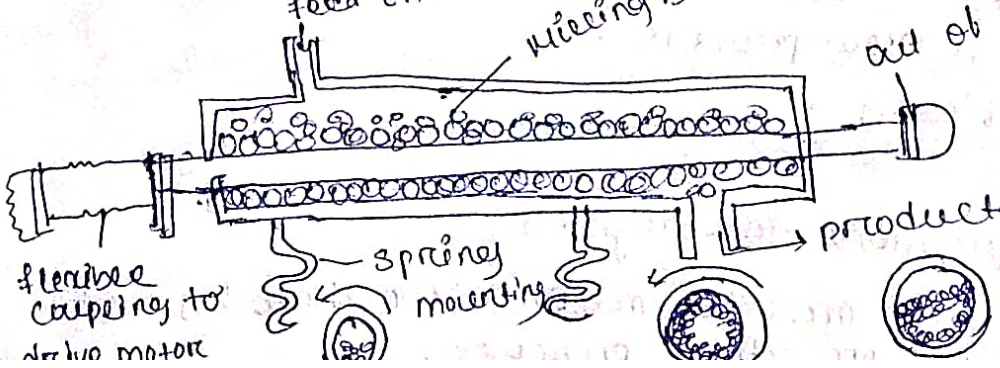
③ End Caps :-
Attached to both ends of the cylinder to retain the grinding materials inside the mill. These may include manholes for charging and inspection

④ Girth Gear :-
A large gear that rotates the mill shell & is driven by a motor.

⑤ Pinion Gear :-
Meshes with the gear, transferring power from the motor the mill shell.

⑥ Trunnions :-
Horizontal projections from the ends of the cylinder allowing it to rotate on bearings.

⑦ Drive Mechanism :-
Includes Motor, gear box or belt drive system providing the rotational force necessary for milling



Working :-

→ The drug to be ground to put into the cylinder of the mill
→ And it noticed the speed of rotation is very important as a low mass of ball will slide and rollover each other.
→ Only a negligible amount of size reduction at a high speed the ball mill will be thrown out of the walls by centrifugal force. ✗ grinding.
→ But at about to 2/3rd of the speed centrifugal force just occure with the result that the balls are carried out most to the top of the mill.
→ And then fallen by this way the mix size reduction is effect by attrition after a suitable time the material is taken out & pass through a sieve to get powder of required size.

Advantage :-

- It can produce very fine powder
- It can be used for continous operation
- This is suitable for both wet & dry grinding process.

Disadvantage :-

- It has a large size
- During the process of size reduction, strong vibration & sounds are produced.
- Ball milling is a slow process.
- It has low efficacy.

Application :-

- It is the key equipment for regrinding
- It can grind ores or other materials either by wet process or dry process.

(11) write down different quality control tests for tablets

A→ Tablets are a solid dosage form of medicaments with or without excipients which are prepared by compression or moulding method & intended for oral administration for local & systemic effect.

Quality control :-

→ quality control is a small part of QA it is concerned with sampling, testing & documentation during manufacturing and also completion of manufacturing

→ In general form quality control refers to a procedure a set of steps taken during the manufacturing of a product to ensure that it meets requirements & that the product is reproducible.

Types of QA test :-

① Official Tests
- weight variation test
- Drug content
- Disintegration time test
- Dissolution test

② Unofficial Tests :-
- Thickness
- Hardness
- friability
- Organoleptic characters

1) Organoleptic characters :-

Colour :- Many pharmaceutical tablets use colors as a vita means of rapid identification & consumer acceptance

Odour :- The presence of odour in a batch of tablets could indicate stability problems, such as the odour of acetic acid in degrading aspirin tabl

Taste :- Taste is important in consumer accepteance of, especialy, chewable tablets.

2) Weight variation Test :-

According to USP, weight variation test is run by weighing 20 tablets individually calculating average weights & comparing the individual tablet weights to the average. The value of weight variation test is expressed in percentage.

$$\text{weight variation} = (IW - AW)\ AW \times 100\%$$

where, IW - Individual weight

AW - Average weight

3) Thickness Test :-

- Tablet thickness is determine by the dicmeter of the tablet.
- Micrometer & vernier Calipers are used for tablet thickness.
- Thickness should be controlled within ± 5% variation of a standard value.

4) Hardness Test :-

- This test is also knowmas crushing strength test.
- Tablets require a certain amount of strength, or hardness to withstand mechanical shocks of handling

in manufacture packaging.

→ Monsanto hardness tester, Pfizer, strong Cobb, Erweka hardness tester used in in this test.

5) Friability Test :-

Friability is the phenomenon where the surface of the tablet is damage due to mechanical shock.

Friability can be calculated by following formula

$$\% \text{ friability} = W1 - W2/W1 \times 100$$

where
W_1 = weight of tablet before testing
W_2 = weight of tablets after testing

6) Disintegration Test :-

→ It is a process in which tablets are break up into small particles.

→ This test is essential for tablets intended for administration by mouth, except those intended to be chewed before being swallowed that should slowly dissolved in mouth.

e.g:- lozenges, sublingual tablets

7) Dissolution test :-

When a dosage form is swallowed, the rate at which it release the active ingredient is critical to ensure that the drug is delivered properly. The rate at which the drug is release called the dissolution rate.

(8) Content uniformity Test :-

- Content uniformity test was developed to ensure content consistency of active drug substance.
- By the USP method, 30 tablets are randomly selected, 10 of these tablets are assayed individually according to the method described in the individual monograph.

(vii) Write down different method used in formulation of parenteral preparation.

→ parenteral administered via injection, infusion, by passing the gastrointestinal tract to deliver the active ingredient directly into the body.

① Sterile solution Method :

- conduct the preparation in a controlled environment, such as laminar flow hood, to minimize contamination risks.
- ensure all ingredients are sterilize before use.
- combine the sterilized ingredient using aseptic technique to prevent contamination.
- filter the prepared solution through a sterile filter to remove any potential contaminants.

② Sterile Suspension Method :-

→ In this method parenteral preparation involves creating a uniform mixture of sterile solid particle

→ This process controlled the aseptic environment, filtering the suspension to remove contaminants & filling it into sterile containers.

③ Sterile Emulsion Method :-

This method involves creating a stable mixture of oil & water phases, using emulsifiers to maintain uniformity.

This process is carried out under aseptic conditions to ensure sterility, often involving techniques like high shear mixing.

→ The final product is filtered to remove any particulate matter, ensuring it meets the required standards for intravenous administration.

④ Lyophilization Methods :-

→ It is a freeze-drying method used in parental preparation to enhance the stability of heat-sensitive drugs.

→ It involves freezing the product, followed by sublimation of the ice under vacuum, which removes water without passing through a liquid phase.

→ This process results in a dry, stable powder that can be reconstituted before administration.

⑤ Sterilization Method :-

- It include steam sterilization, which use high-pressure steam to eliminate microorganism. & filtration which remove pathogens through micro-filtration membranes.
- Other methods include dry heat & gas sterilization each method is selected based on the stability of the product.

⑥ Additive Method :-

- It involves incorporating excipients, such as stabilizers preservatives into the formulation to enhance the drugs stability.
- This method ensure the API remain effective & safe during storage.
- proper selection & compatibility of additives are crucial to avoid adverse reaction.

(1) Quality control method :-

> It involves a series of tests to ensure the product's safety & sterility.

- common techniques include sterility testing, potency assay & particulate matter. Analysis, along with pH, osmolarity & stability.
- these methods help ensure that the final product meets regulatory standards & is suitable for patient use.

12i) Write the ideal properties of filter aids. Give two examples of filter aid.

Ideal properties of filter aid :-

- It should be chemically inert & light in weight.
- It should form a porous cake.
- It should be free from impurities.
- It should be insoluble in liquids.
- It should be free from moisture.
- It should provide a thin layer of solids having high porosity.
- It should give the desired flow rate & clarity.
- It consist of rigid, compact shaped, discrete particles.
- Remove fine solids at high flow rates.

e.g :- Diatomite,

① Diatomite :-

- Diatomite is also known as Diatomaceous earth
- Chemical composition :-
  86% silicon, 5% sodium, 3% magnesium & 2% iron.
- It forms a rigid & highly porous structure.
- It forms a non-compressible cake & acts as a sieve to remove fine solides.
- It may contaminate process liquids.

② perlite :-

- It formed from glass like volcanic rock that consists of small particle with cracks that retain water & gas.
- Chemical composition :- silicon dioxide, sodium oxide, Iron oxide.
- Low specific weight than DE, which allow less filter aid to be used.
- Relative pure than diatomite.
- It is more soluble.

ii) write a short note on Homogenisation :-

Defination :-

Homogenization is a process that ensures uniformity in the size & distribution of fat molecules in milk & other liquids.

purpose :-

- Prevents cream seperation
- Enhances shelf life
- Improves texture & appearance
- Increase nutritional value

Types of Homogenization :-

Homogenization methods can be divided into 3 categori

(1) Ultrasonic Homogenising :-

- Ultrasound waves are used to breakdown the particles into a smaller piece.
- These devices operate by producing a very-intensi of sonic pressure waves in liquid medium.

(2) Pressure Homogenising :-

- It has been found to be usually acceptable for a various type of bacteria, yeast & mycelia with the exception of very filamentous microorganism.
- The rate of cell rupture is proportional to the turbulent velocity of a product passing through a homogenizer channel.

(3) Mechanical Homogenizers :-

- Mechanical homogenization is the most basic method of homogenization.
- This entails physically breaking up the particles into tiny pieces with a machine.
- This is the most frequent type of homogenization, which is utilised in variety of industries such as food, medicines & cosmetics -

(iii) Write a short note on soxhlet extraction :

Principle :-

Soxhlet extraction is based on the principle of continuous solvent circulation & percolation through a sample, allowing for efficient extraction of desired compounds.

Construction :- (Soxhlet apparatus)

i) It is a small scale extraction apparatus consit of three main part -

(a) The flask, holding the maceration.

(b) The extraction or a cylinder percolation provided with an attached siphon called the soxhlet extraction.

(c) And a reflux condenser fitted at the top of soxhlet.

(ii) Heat is applied to the bottom of the flask work as a still.

(iii) When the maceration is boils & evaporate through tube of the soxhlet.

(iv) At right hand sid, this is siphon tube.

Procedure :-

- place the solid sample in the extraction chamber
- fill the round bottom flask with the solvent
- Heat the flask to vaporize the solvent, which rises into the condensor.
- The vapors condenses & drops back into the extraction chamber, dissolving the solute
- The cycle repeats until the extraction is complete, indicated by the solvent level in the siphon

Advantage :-

(i) Faster method.
(ii) complete extraction of drug
(iii) concentrated extract can be obtain.
(iv) Minimum requirement of monstruem.
(v) fireproof assembly

Disadvantage :-

(i) Method is not suitable for drug which are sensitive to high temp
(ii) Only pure solvent can be used gummy substance, cannot be extracted by this method.

(iv) Write a short note on sterilization.

The process that eliminates or removes all forms of life and other infectious micro-organisms are called sterilisation.

Types of sterilisation

Physical Method :-

(i) Dry heat sterilisation
(ii) Moist heat sterilisation

(iv) Sterilisation by radiation

Mechanical Method :-

(i) Sterilisation by filtration membrane
(ii) Sterilisation by chemical method

① Dry heat sterilisation :-

- This process is done by conduction the heat is observed by outside surface of objects, then passes towards the center of object.
- sterilisation by heat is primarily a process of congulation of proteins.
- Dry heat removes water from micro organism cell while moist heat adds water to them.

② Moist Heat sterilisation :-

- It is based on the use of saturated steam and pressure. The pressure increases the Boiling point of water, these by increasing the temperature to which water can be heated.
- cells are destroyed by the highes temp not by pressure.
- Most of the organism are killed at 121°c in 15 min.

③ sterilisation by raddiation :-

→ It is a gamma rays or electron beam is used to ensure the sterility of pharmaceutical product.
→ This method effectively inactivates pathogenes & spores by damaging their DNA, allowing for the safe use of heat-sensitive.

(4) Sterilisation by filtration membrane :-

→ It involves passing the solution through a filter with specific pore sizes, typically 0.2 micrometers to remove microorganism.

→ This technique is crucial for sterilizing heat-sensitive liquid. e.g :- vaccines.

(5) Sterilization by Chemical method :-

- chemicals like ethylene oxide, hydrogen peroxide, & isopropyl alcohol are frequently used.
- These agents disrupt cellular structures & functions.
- This method is vital for sterilizing injectable drugs, surgical instruments & other medical devices.

(v) Differentiate between flocculated & deflocculated suspension.

Flocculated	Deflocculated
- A suspension in which particle of suspension settle down & form floc	A suspension in which no flocculation take place takes place.
- particle exists as loose aggregates.	- particle exists as separate entity
- Rate of sedimentation fast	- Rate of sedimentation slow.
- No hard cake	- Hard cake
- Redispersion easily	- Redispersion not easily

- Bioavailability low	- Bioavailability high
- particles experience attractive forces between them.	- particles experiences repulsive forces between them
- Supernatant clear	- supernatant not clear
- Not pleasing in appearance	- pleasing in appearance

(vi) write notes on factors affecting size reduction.

→ size reduction refers to the breaking of large particles of solid into smaller or fine particles.

→ variety of factor affect the size reduction some of them includes.

① Hardness :-

- surface property of the material
- It is measured by Mohr's scale which is from 1 to 10 Materials.

1 to 3 - soft e.g:- talc
4 to 7 - intermediate e.g:- limestone
8 to 10 - Hard eg:- diamond.

② Toughness :-

A soft but tough materials create more problem in reducing size than hard but brittle substances.

e.g:- difficult to break rubber than a blackbord chalk stick

③ Abrasiveness :-

- property of hard materials during the grinding of abrasive substances, the final powder may be contamin. with more than 0·1 percent of the grinding mill's ~~material~~ ~~metal~~.

④ stickiness :-

It causes considerable difficulty in reducing the size because materials get adhere to the grinding substance.

⑤ slipperiness

lead to size reduction difficult as the material act as lubricant & decrease the efficiency of grinding surfaces.

(6) softening temperature :-

During size reduction, heat is generated which may causes some substances such as waxy substances. drug containing oil, fats to soften.

⑦ Moisture content :-

presence of moisture in this material influences a no. of its properties such as hardness, ~~softness~~ toughness, stickness which in turn affects the size reduction.

⑧ Ratio of fed size to product size :-

To get a fine powder in a mill, it is required that a fairly small fed size should be used. Hence, it is necessary to carry out the size reduction process in equal stages.

(VII) Define Dittusible solid & Indittusible solid.

~~Suspension~~ ~~and~~ Dittisuble solid :-

> It is insoluble in water but easily wettable.

> On shaking with water solid particles dittuse readily through out the liquid & remain suspended for a long time.

> The suspensions containing dittusible solids are prepared by trituerating the solid in a morter & with sutticient quantity of vehicle to form a smooth cream.

> More vehicles are then added & any foreign particles is strained through a muslin cloth.

> Any volatile component is added at this steage & adding the required quantity of vehicle. make up the final volume.

e.g:- Magnesium Trisilicate Mixture.

Indittusible solid :-

- It consist of substances, which do not remain distributed in dispersion medum when sheaken for long time to ensure uniformity of dosage.

- They are prepared by adding a suitable thickening agent to the vehicle, which increases the viscosity of the vehicle & delays the

sepercation.

e.g:- calamine lotion.

(viii) write down the difference between liniments & lotions.

Liniment	Lotion
- Liniment are liquid or semiliquid dosage form - They are applied on the skin with the friction - Rubbing action is involved - On the basic they are greasy & more viscos - Mainly used for analgesic soothing rube facient, counter stimulating property rubifecation cause irritation & redness of the skin due to increase blood flow they are used in the treatment of pain in various muco skeletal condition. - Alcohol used to provide easy penetration & it is used to increase rubification action e.g:- Turpentine liniment	- Lotions are liquid preparation - They are meant to be applied to the skin without friction. - They can be applied with the help of absorbed material. - They are soft & greasy - Mainly used for antiseptic action - They can be applied on broken skin - Alcohol used to provide soothing effect - e.g:- calamine lotion

x) Write short note on fusion method of preparation of suppositories.

The method of preparation for suppositories depends on the type & intended use, but the most common method, & the fusion method

- > Hand rolling
- > Compression molding
- > Hot process / fusion method

Fusion Method :-

- Involves first melting the suppository base, & then dispering or dissloving the drugs in the melted base.
- The mixture is removed from the heat & poured into a suppository mold.
- when the mixture has congealed, the suppositories must be used with most of them.
- Suppositories are generally made from solid ingredients ~~are generally made~~ & drugs which are measured by weight.
- when they are mixed, melted, & poured into suppository mold cavities

the occupy the volume of the mold cavity.

- since the componets are measured by weight but compounded by volume, density calculations & mold calibration required to provide accurate doses.

(X) Differentiate between calibration & validation.

Calibration :-

- calibration ensure that instrument or measuring device gives accurate result.
- In calibration, performance of an instrument or device is compared against refrence standard.
- use periodically to eliminate drift from the instrument.
- It is performed for calibration SOP (provide document ~~evidence~~)
- Benifits :- To ensure specificity, accuracy, sensitivity of system.

Validation :-

- validation provide documented evidence that process equipment provide consistent result.
- In validation no such refrence standards are used.
- performed only once to change SOP.

· It is performed as per validation protocol

Benefits :- · To minimize rejection loss.
· Help timely corrective action.
· Ensure achievment of quality goals.

(xi) Write a short note on effervescent granules.

· These are specially prepared solid dosage form for internal use.
· It contains medicaments mixed with citric acid & sodium bicarbonate.
· Before administration desired quantity is dissloved in water.
· Acid & bicarbonates react together producing effervescences.
· Carbon dioxide stimulates flow of gastric juice help in absorption of medicaments.

Method of preparation :-

① Heat Method ② wet method.

① Heat Method :-

· A large stainless steel evaporating dish places on boiling water bath.
· The dish must be sufficiently hot before transferring powder into it.

→ Heating stage takes 1 to 5 minutes.

→ Damp mass then pass to sieve to prepare granules of suitable size.

→ Then packed in a air tight containers.

Wet Method :-

→ Mixed ingredient are moisten with no aqueous liquid such as alcohol.

→ prepared mass passes through 8 no sieve & dried in oven below 60°c.

→ dried granules packed in Air tight Container.

→ It is meant of internal use only.

→ Used as a Antacid.

(iii) Impact

Impact refers to the effect that a drug formulation or delivery system has on the efficacy, safty & overall therapeutic outcomes for patients.

(ii) Co-solvent :-

Vehicle used in combination to increase the solubility of drugs. frequently, the solubility of a drug in a mixed solvent systems greater than can be predicated from its solubility in each solvent component separately.

(iii) Colloidal suspension :-

A colloidal suspension is basically a stable phase showing little tendency to aggregate & separate from aqueous phase for separation of chemical precipitates effectively from water phase.

(iv) Enteric coated Tablet :-

This tablets are designe in such a way that it by pass the stomach & get disintegrated in intestine.

(v) Microencapsulation :-

It is a process where small discrete of solid particles are surrounded & enclosed an intact cell it comprise of following.

(vi) Clarification :-

Clarification is a process that involve the removal of a solid form a liquid or a fluid from another fluid.

(vii) Lyophilisation :-

Lyophilisation is the process in which coater is removed from liquid product by sublimation. The material is first frozen in to ice then reduces the surrounding pressure to allow the frozen coater in the material to sublimate directly from solid to gas phase.

(viii) Sieve number :-

Sieve number refer to the mesh size of a sieve used to classify particles based on their size indicating the maximum particle diameter that can pass through the sieve.

(ix) Mottling :-

Mottling refers to the uneven coloration on a tablet's surface, often resulting from improper coating or blending of materials.

(x) Opsonin :-

Opsonin ~~refer~~ is define as an antibodies or complement protein that enhance the phagocytosis of pathogens by marking them for destruction by immune cells.

(xi) Pharmacopeia :-

The ~~pharm~~ terms comes from greek word pharmacon (drug) & poeia (to make). It is a book containing collection of monographs & published by an authorities body type goverment of pharmacy society.

(xii) Elixir :-

Elixir are defined as clear sweetened, aromatic, hydroalcoholic liquids intended for oral use.

(xiii) Tablets :-

Tablets are unit solid dosage form of medicament which are prepared by moulding, compression it is a mixture of API & excipeant in drug powder from & make a tablet by compression.

(xiv) Poultice :-

Poultice consist of moistened mass of vegetable material on clay that were ~~some~~ ~~some~~ sometimes heated before application

(xv) Extraction :-

Extraction is a process used to separate a desired substance from a mixture. It is the initial step in obtaining the desired natural products from crude materials.

(Bi) Give two major differences between emulsion & suspension.

Emulsion

→ These are biphasic liquid preparation containing two immiscible liquids one of which is dispersed as min. globules into the other.

→ During storage freezing should be avoided as it may lead to cracking.

Suspension :-

- These are biphasic liquid dosage from of medicament in which finely divided solid particles are dispersed.
- During storage freezing should be avoided as it leads to aggregation

ii) Different between 'purified water' & 'water for injection'.

purified water	water for injection
- It is prepared by distillation ion-exchange treatment, reverse osmosis or any suitable process	- It is prepared by distillation or by riverse osmosis
- Used in excipient in nonparenteral preparation & other pharmaceutical application such as cleaning of certain equipments	- free form volatile & non-volatile impurities, micro-organism & pyrogens is water for injection.

iii) Write advantages of evaporating pan.

→ simple in construction
→ Easy to operate, clean & maintain
→ its cost of installation & maintenance is low.

iv) Give two examples of wetting agent.

→ Methylcellulose, acacia

(v) What is prodrug.

prodrug is a chemically modified inert precursor of the drug that on biotransformation liberates the pharmacologically active parent compound.