JRG College of Pharmacy

JRG COLLEGE OF PHARMACY

BOARD SOLVED QUESTION

WITH ANSWER

Year : 2023

Subject : Pharmaceutics

Subject Code : ER20-11T

Subject In-Charge : Ms. Monali Padhi

ODISHA STATE BOARD OF PHARMACY

30.01.2024

D. Pharm Part - I

E. R. 2020

2023(I) Examination

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

ANSWER THE QUESTION SERIALLY AND CONTINUOUSLY

Subject: PHARMACEUTICS (Theory)

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

1. **Long type questions (Answer any six)** **(5x6)**
   i) Define Q.A. & Q.C. Write briefly about cGMP.
   ii) Discuss the advantages and disadvantages of plastic as packaging materials.
   iii) Define drying. Explain details about freeze dryer with neat and clean diagram.
   iv) Write down the principles, construction, working and application of Ball Mill with labelled diagram.
   v) Write down different methods used in formulation of parenteral preparations.
   vi) Define immunity. Write down the details about small pox vaccine.
   vii) Define suppository. Write about method of preparation of suppository.

2. **Short type questions (any ten):** **(10x3)**
   i) Classify the powders according to Indian Pharmacopoeia.
   ii) Write in brief about phagocytosis.
   iii) Write down advantages, disadvantages and applications of sterilization by ionizing radiation.
   iv) Define preservatives. Mention various types of preservatives used in pharmaceutical Preparations.
   v) Write any three polymers used for film and enteric coated tablets.
   vi) Write notes on Erythrocytes as a drug carrier.
   vii) Write & explain Darcy's law
   viii) Differentiate between calibration and validation.
   ix) Define lamination problem with its remedy.
   x) Write details about modified percolation process.
   xi) Write short note on Sustained release tablets.

3. **Answer all :**

(A) Answer the followings **(20x1)**

i) Write down one example of hydrophobic binder.
ii) One major difference between disintegration & dissolution.
iii) Write down two examples of wetting agent.
iv) What is Prodrug?
v) Write disadvantages of Glass container.

(B) Define the followings (In 20 words)

i) Capsule	ii) Co-solvent	iii) Creaming	iv) Exsiccation
v) Filter aid	vi) Impact	vii) Lyophilisation	viii) Maceration
ix) Mixing	x) Nano emulsion	xi) Poultice	xii) Paste
xiii) Sieve number	xiv) Nasal Drop	xv) Vulcanising Agent	

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ER-2020 PART-A (year-2022)
(D-pharma 1st year)

(1)(a) Define qa and qc. write briefly about cGMP.

Ans- QA (Quality Assurance)

Quality assurance (QA) refers to the systematic process of ensuring that products or services meet specified requirements, standards, and regulations.

QA focuses on:
(1) Preventing defects
(2) Ensuring Consistency
(3) Maintaing quality

QC (Quality Control)

Quality Control (QC) is the process of monitoring and testing products or services to ensures they meet specified standards and requirements. QC focuses on:
(1) Detecting defects
(2) Evaluating quality
(3) Taking Corrective actions

cGMP (Current Good manufacturing Practice)

cGMP is a set of guidelines and regulations for ensuring the quality, safety and efficacy of pharmaceutical products.

(b) cGMP principles-
(1) Ensure product quality and safety
(2) Prevent contamination and errors
(3) Maintain accurate documentation.
(4) Continuously improve processes.

CGMP compliance ensures-
(1) Regulatory approval
(2) Product reliability
(3) Patient safety
(4) Business Credibility

(b) Discuss the advantage and disadvantage of plastic as packaging material?

-Ans- Advantages-
(1) Lightweight and Flexible
(2) Low cost and economical
(3) High strength-to weight ratio
(4) Resistant to corrosion and chemicals
(5) Transparent or colored options
(6) Easy to mold and shape
(7) Waterproof and moisture-resistant
(8) Extensive shelf life
(9) Convenient for single use application.

Disadvantages-
(1) Environmental concerns: pollution, waste, and litter
(2) Non-biodegradable
(3) Health risks
(4) Limited recyclability
(5) Resource Consumption
(6) Contributes to greenhouse gas emissions
(7) Aesthetically unappealing
(8) May contain harmful additives

(9) Can damage packaging contents.

(c) Define drying. explain details about freez dryer with neat and clean diagram.

-Ans- Drying-

Drying is the process of removing moisture or solvent from a substance to preserve it, improve its texture, or enhance its shelf life.

- Freeze Dryer -

→ Freeze dryer removes moisture from a frozen product by sublimation.

- Freeze Drying process -

(I) Freezing - Product is frozen to -30°c to -50°c.

(II) Vacuum - Chamber is evacuated to create low pressure.

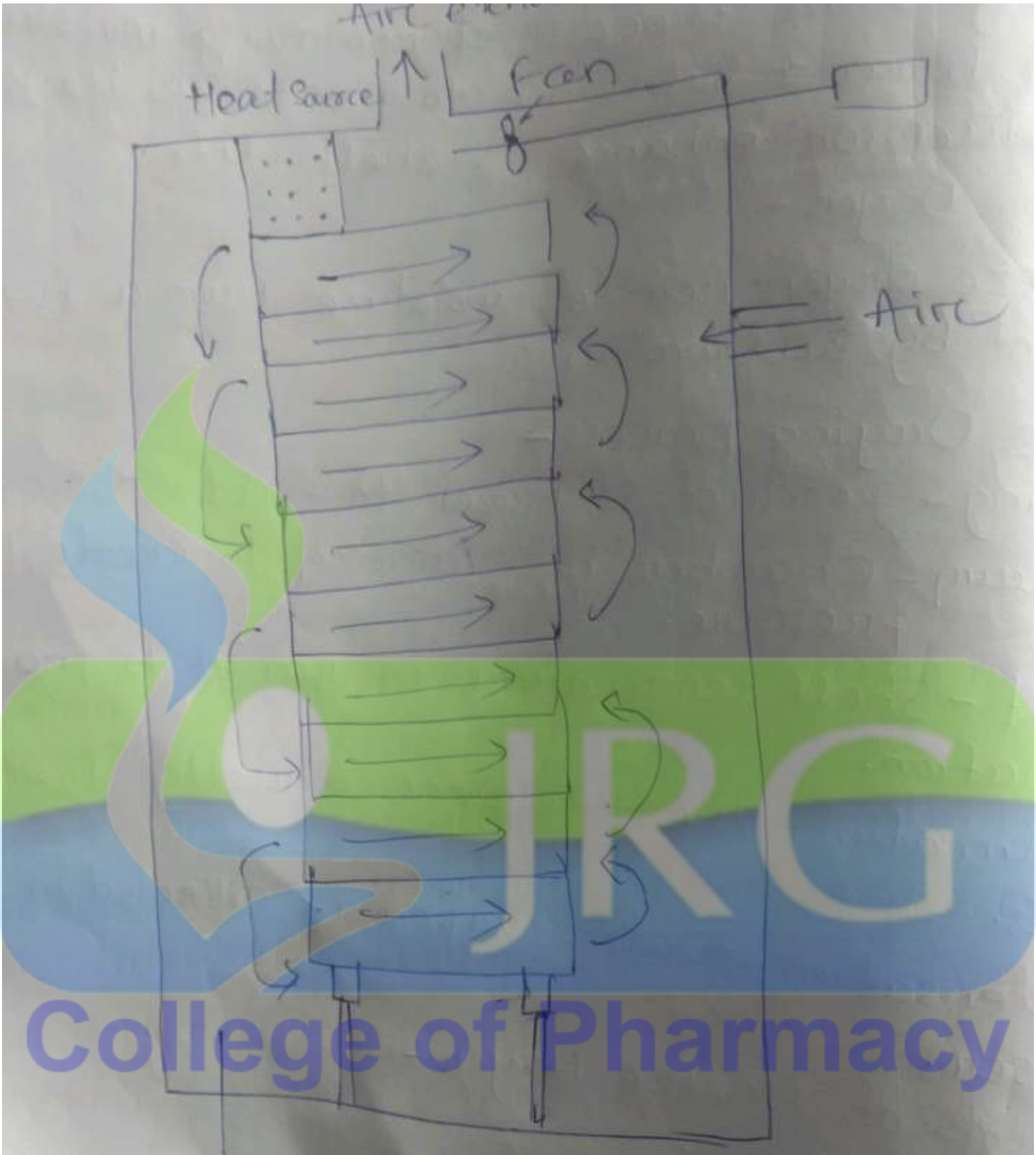
(III) Heat - Shelf temperature is raised to promote sublimation.

(IV) Sublimation - Ice vaporizes directly from solid to gas.

(V) Condensation - Water vapor is collected in a condenser.

- Components of Freeze Dryer -

(1) Chamber
(2) Shelves
(3) Condenser
(4) Vacuum pump
(5) Refrigeration System
(6) Heating System
(7) Control panel.



(d) Write down the principles, construction, working and application of ball mill with labelled diagram.

Ans- Principles of Ball mill -

(i) Impact and attrition
(ii) Grinding by tumbling action
(iii) Size reduction by collision and friction

Construction of Ball mill-

(i) Cylindrical shell
(ii) Hollow shaft
(iii) Liners
(iv) Grinding media
(v) Inlet and outlet
(vi) Drive mechanism

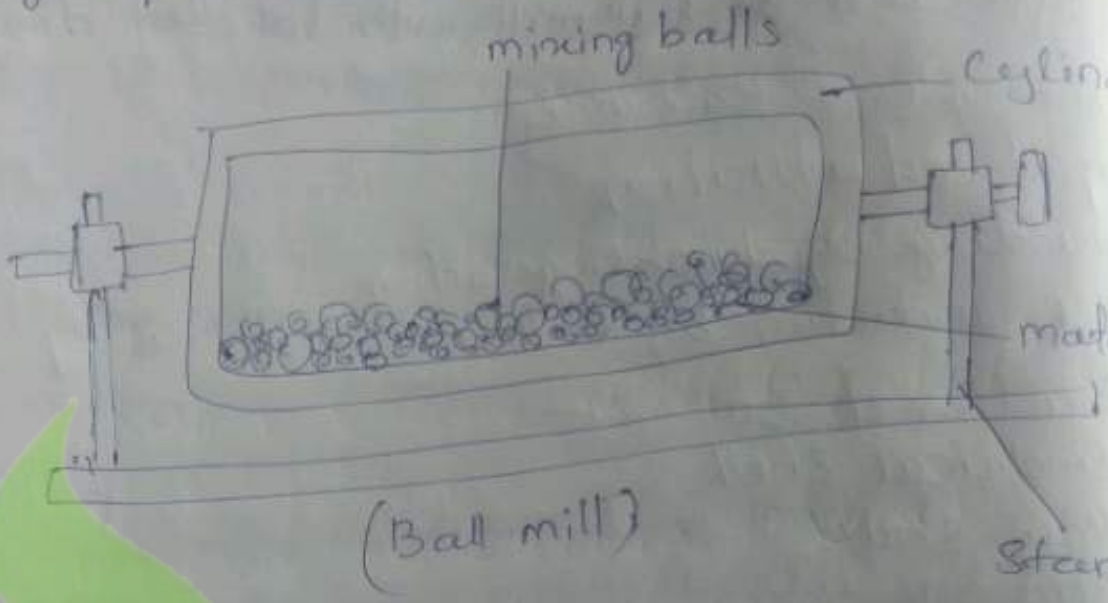
Working of Ball mill-

(1) Material feed through inlet
(2) Grinding media lifted and dropped
(3) Material crushed by impact and attrition
(4) Ground material discharged through outlet.

Application of Ball mill-

(1) Mining
(2) Cement industry
(3) Pharmaceuticals
(4) Food processing
(5) Paint and coating
(6) Ceramics and glass.
(7) Biotechnology.

diagram-



(e) Write down different methods used in Formulation of parentral preparation?

Ans- Method for Solution preparation:-

(1) Dissolution - Dissolving active ingredients.

(2) Solubilization - Using solubilizing agents.

(3) Complexation - Forming complexes with cyclodextrins or other molecules.

→ Method for Suspension preparation:-

(1) wet grinding - Grinding particles in a solvent

(2) Homogenization - Using high pressure homogenizers.

(3) Ultrasonication - Using ultrasound

- method ~~for~~ emulsion preparation-
(1) Mechanical Dispersion - using high shear mixers
(2) phase inversion - Inverting water in oil to oil in water emulsion.
(3) microemulsification - creating stable micro-emulsions.
- Method for Lyophilized preparation-
(1) Freeze Drying - Removing water content by - Sublimation.
(2) Spray Drying - Drying solutions or suspensions.
(3) Vaccum Drying - Drying under reduced pressure.
- Sterilization methods -
(1) Autoclaving - High pressure steam sterilization.
(2) Dry Heat Stercilization - using hot air or - infrared radiation.
(3) Filteration - using 0.2 µm filters.
(4) Radiation sterilization - using gamma or - electron beam radiation.

(F) Define immunity. write down the details about pox vaccin.

Ans - Immunity - Immunity is the body's ability - to resist and defend against pathogens, such as bacteria, viruses and others foreign substances. There are 2 main types - (1) Innate Immunity (2) Adaptive Immunity

pox vaccine -

Defination - A vaccine used to protect against Smallpox and other poxviruses.

Types -

(1) Smallpox vaccine - used to eradicate Smallpox globally.

(2) Monkeypox vaccine - used to protect against monkeypox.

(3) MVA (modified vaccinia Ankara) vaccine - used as a safer alternative.

Composition -

(1) Live, attenuated vaccinia virus

(2) Inactivated vaccinia virus

(3) Recombinant vaccines.

Administration -

(1) Intradermal injection.

(2) Subcutaneous injection

(3) Single dose, with booster doses as needed.

Side effects -

(I) mild - redness, swelling, pain at injection site.

(II) moderate - Fever, headache, fatigue

(III) Severe - allergic reactions, encephalitis.

(g) Define suppository. write about method of preparation of suppository.

Ans- Suppositories are a form of medication designed for insertion into the rectum, vagina or urethra where they dissolve or melt.

methods of preparation -

(1) Hand rolling method - It is the oldest and simplest method of suppository preparation and may be used when only a few suppositories are to be prepared in a cocoa butter base.

- This method is less common and is typically used for small batches or compounding pharmacies.

(2) Compression molding/ Cold compression method-

- On small scale it is prepared in mortar pestle but in large scale.
- It is prepared in compression machine.
- it is essential to maintain aseptic condition through the process to prevent contamination.
- It is a method of preparing suppositories from a mixed mass of grated suppositories base and medicaments which is forced into a special compression mold.

(3) Hot process/ Fusion process:-

- The mixture is removed from the heat & poured in a suppository mold.

- when the mixture has congealed, the suppositories are removed from the mold.
- The Fusion method can be used with all types of suppositories and must be used with most of them.

(2)

(a) Classify the powders according to Indian Pharmacopoeia.

Ans- Fine powder-
- particle size - 150 µm or less (100 mesh)
- uses - Tablets, capsules, suspensions.

- Very fine powder-
- particle size - 75 µm or less (200 mesh)
- uses - Inhalations, injections, opthalmic prep.

- Coarse powder-
- particle size - 1.18 mm to 2.36 mm (6-10 mesh)
- use - Granules, tablet coatings.

- moderately coarse powder-
- Particle size - 630 µm to 1.18 mm (12-20 mesh)
- use - capsule, tablet, granules.

- Extremely fine powder-
- particle size - 5µm or less
- use - inhalation.

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Ans- Ph
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(b) write in brief about phagocytosis.

Ans- phagocytosis is a cellular process where - cells engulf and internalize foreign particles, bacteria, dead cells, or debris.

Types-
(1) Osmotrophic phagocytosis
(2) Cellular phagocytosis
(3) pinocytosis.

importance-
(1) Immune defense
(2) Inflammation resolution
(3) Tissue repair
(4) Cellular homeostasis

phagocytic cells-
(1) Neutrophils
(2) Macrophages
(3) Monocytes
(4) Dendritic cells.
(5) Eosinophils.

(c) write down advantages and disadvantages and application of sterilization by ionizing radiation.

Ans- Advantages -
(1) High effectiveness.
(2) Penetration depth
(3) Low temperature

(4) No chemical residues
(5) Cost-effective
(6) Reliable
(7) minimal damage.

Disadvantage -
(1) Radiation exposure risks
(2) Equipment costs.
(3) Dosage control.
(4) Material alteration
(5) Public perception
(6) Regulatory Compliance
(7) Limited applicability.

Application -
(1) medical devices
(2) pharmaceuticals
(3) Food irradiation
(4) Cosmetic products
(5) Hospital supplies

(d) Define preservatives. Mention various Types of preservative used in pharmaceutical preparation.

Ans - preservatives are substances added to the pharmaceutical preparations to prevent or inhibit the growth of microorganisms and to maintain

the products quality, safety and efficacy throughout its shelf life.

Types of preservatives-

(1) Antimicrobial preservatives-
- parabens
- Phenolics
- Alcohols

(2) Antifungal preservatives-
- ~~parabens~~ - Sodium benzoate
- ~~Phenolics~~ - potassium Sorbate
- ~~Alcohols~~ - Calcium propionate

(3) Antioxidant preservative-
- Sodium metabisulfite
- Sodium Sulfite
- Ascorbic acid
- Butylated hydroxyanisole

(4) Chelating agents-
- EDTA
- Citric acid
- Tartaric acid

(5) Natural preservative-
- Essential oil
- Plant extracts
- Honey
- Vitamin E

(e) write any three polymers used for film and enteric coated tablets.

Ans- Film Coating polymers-

(1) Hydroxypropyl methylcellulose (HPMC)
- Properties- water soluble, Flexible, and transparent

- uses - Film Coating For tablets, Capsules and granules.
- advantages - Easy to apply, non-toxic, and hypoallergenic.

(2) Polyvinyl Alcohol (PVA)
- Properties - water soluble, flexible, and adhesive.
- uses - Film coating for tablets, Capsules, and granules.
- Advantages - Good barrier properties, non-toxic, biocompatible.

Enteric Coating polymers -
(1) Cellulose Acetate phthalate (CAP)
- properties - Enteric, water-insoluble, and acid-resistant.
- uses - Enteric coating for tablets and granules
- Advantages - Resistant to stomach acid, non-toxic and biocompatible.

(F) Write notes on Erythrocytes as a drug Carrier.

Ans - Erythrocytes, also known as red blood cells, have been explored as a novel drug delivery system.

Advantages -
- Biocompatibility
- Reduce toxicity
- Targeted delivery
- prolonged circulation.

Methods of Loading Drugs into Erythrocytes :-

(1) Hypotonic hemolysis -

(2) Electroporation

(3) chemical permeabilization

Application-

(1) cancer therapy

(2) Gene therapy

(3) Enzyme replacement.

(g) Write & explain Darcy's Law.

Ans- Darcy's law is a mathematical equation that describes the flow of fluids through porous media, such as sand, soil or rock. The law is named after Henry Darcy, a French engineer who first proposed it in 1856.

Equation- $Q = -K * A * (\Delta P / \Delta x)$

where -

- Q = volumetric flow rate (m^3/s)
- K = Permeability of the porous medium (m^2)
- A = Cross-Sectional area of the flow (m^2)
- ΔP = Pressure difference across the porous medium (Pa)
- Δx = Thickness of the porous medium (m)

Explanation- Darcy's law states that the flow rate of a fluid through a porous medium is directly proportional to the pressure difference across the medium, the cross sectional area of the flow.

1) Differentiate between calibration and valid

Ans- Calibration:-

(I) Definition- Calibration is the process of configuring or adjusting an instrument, system or method to ensure that its output is accurate is accurate and reliable.

(II) purpose - Calibration ensures that the instrument or system is functioning correctly and providing accurate results

(III) Process - Calibration typically involves a series of tests and evaluations to assess that instrument's or systems performance, accuracy, precision and robustness.

Validation-

(I) Definition- Validation is the proces of evaluating and verifying that an instrument, system or method is suita for its intended purpose and meets the required specifications.

(II) purpose - validation ensures that the instrument or system is fit for use and provides reliable results

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(iii) Process - Validation typically involves a series of tests and evaluations to assess the instruments or systems performance ; accuracy, precision, and robustness.

(8) Define Lamination problem with it's remedy

Ans- Lamination is a defect that occurs during the tablet manufacturing process, where a tablet splits or separates into two or more layers. This can happen due to various reasons, such as -

Causes of Lamination -

(1) Insufficient bonding
(2) Over-Lubrication
(3) Incorrect compression force
(4) moisture Content
(5) Particle size and shape

Remedy -

(1) Optimize formulation
(2) Adjust compression force
(3) Control moisture content
(4) Improve particle size and shape
(5) Use anti-Laminating agent
(6) modify tablet design.

(J) Write details about modified percolation process.

-Ans- The modified percolation process is a technique used to prepare granules or pellets with a specific size and shape.

- Modified percolation process steps-

(1) Preparation of the solution.
(2) Addition of the Binder
(3) Precipitation of the active ingredient
(4) Formation of granuales.
(5) Sizing and shaping.

~~Advantages~~-

(1) Improved Granule Strength
(2) Increased Granule uniformity
(3) Reduced Dust formation
(4) Improved Flow properties.

(K) Write ~~extend~~ short notes on Sustained release tablet.

-Ans- A sustained release tablet is a type of oral dosage form designed to release the active ingredient slowly over a prolonged period

characterestics-
(1) Matrix System
(2) Coating
(3) Multi layer tablets.

Advantages -
(1) Improved patient compliance
(2) Reduced side effects
(3) increased efficacy
(4) Convenience

Disadvantage -
(1) Higher production cost -
(ii) Limited Flexibility in dosing
(iii) potential for dose dumping.

(3) (A)
(i) polyvinylidene fluride (PVDF)
(ii) disintegration is breaking into pieces; - while dissolution is the actual solubilization of the drug.
(iii) polysorbates, Sodium Lauryl Sulfate
(iv) Prodrugs are pharmacologically inactive or less active compound that are chemically designed to undergoes biotranformation.- ~~enzymatic~~ within the body to release the active drug.
(v) Fragility, Heaviness, Cost, leaching.

(8)(i) Capsule - A capsule is a solid dosage form in which the drug or active ingredient is enclosed within a soluble container or shell.

(ii) Co-solvent - A Cosolvent is a secondary solvent added to a primary solvent to enhance the solubility of poorly soluble compounds.

(iii) Creaming - Creaming is a pheromenon in emulsions where dispersed droplets of one phase aggregate and rise to the top or settle at the bottom of the emulsion due to differences in density between the dispersed phase and the continuous phase.

(iv) Exsiccation - it refers to the process of removing moisture or water content from a substance, typically through drying.

(v) Filter aide - is a substance used during Filtration to improve the efficiency of the process by enchancing the clarity of the filtrate.

(vi) impact - impact refers to the strong effect or influence that something has on situation, system, or individual.

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(vii) Lyophilisation – it is a process used to preserve perishable materials or make them more convenient for transport.

(viii) Maceration –
Maceration is a process in which a substance usually plant material like fruit, herbs or seeds is soaked in a liquid to extract flavours, compounds or active ingredients.

(ix) Mixing – mixing is a critical process in pharmaceutical manufacturing that involves combining two or more component to produce a uniform mixture.

(x) Nano emulsion – A nanoemulsion is a type of emulsion that consists of tiny droplets of one liquid dispersed in another liquid, with a droplet size typically in the range of 10–100 nm.

(xi) Po-

(xii) paste – A paste is a semi solid dosage form that consists of a mixture of active ingredient, excipients and solvents.

(xiii) Sieve number – A sieve number also known as a mesh size, is a measure of the size of particles in a powder or granular material.

(xiv) Nasal drop - nasal drops are a type of liquid nasal dosage form that are administered directly into the nasal cavity.

(xv) Vulcanising agent -
A vulcanizing agent is a chemical substance used to cross link and harden rubber, transforming it into a more durable and resistant material.