TYBPHARM/SEM 5/ATKT SEMESTER EXAM/INDUSTRIAL PHARMACY II/QUESTION BANK WITH ANSWER KEY

MCQ

1. Which of the following can be used for aerosol moisture determination?

Cascade Impactor
Tag Open Cup Apparatus
Karl Fischer Titration
Pycnometer

2. Commonly used sealant in tablet coating is-

Shellac
Calcium carbonate
PVC
Titanium dioxide

3. Which of the following excipient shows Maillard Reaction

Acacia
Cellulose
Starch
Lactose

4. _____ part of rotary press is responsible for upward movement of lower punch

Discharge chute
Ejection cam
Feeder
Pressure roller

5. Disintegration time limit for a conventional film coated tablet as per IP is

60 min
45 min
30 min
15 min

6. which of the following is NOT an example of tamper resistant pack

Collapsible tube
Strip package

Blister package
Shrink seals

7. Advantages of Parenterals include

Painful
Difficult to reverse the physiological effect
Quick onset of action
Requires skilled personnel

8. Which is a secondary route of parenteral administration

Intrauterine
Intravenous
Subcutaneous
Intramuscular

9. Buffers used in parenterals

Sulphates
Chlorates
Acetates
Benzoates

10. _____is used as sterilization method for aqueous parenteral formulations

Moist heat sterilization
Chemical sterilization
Dry heat sterilization
Radiation sterilization

11. Animal model used for determination of ocular toxicity of ophthalmic products is

Rat
Mice
Rabbit
Dog

12. Disodium edetate is

Chelating agent
Suspending agent
Wetting agent
Lubricant

13. For softgel capsules, the gel strength of gelatin should be in the range of

0.1-0.25 gm
15-25 gm
1-2.5 gm
150-250 gm

14. Hard gelatin capsule shell moisture content ranges between_____%.

12-15%

0.1-0.5%

6-8%

1-5%

15. Which of the following is the Organoleptic property of drug

Density

Crystallinity

Colour

Dissolution

16. According to BCS Classification Class II drug have

High permeability, low solubility

Low permeability, low solubility

High permeability, High solubility

Low permeability, High solubility

17. The powder with angle of repose in the range of 25-30, the powder possess _____flow

Passable

Excellent

Poor

Good

18. Waxes is major ingredient used in

Shampoo

Lipstick

Nail polish

Toothpaste

19. Wet gum method is used for manufacturing of

Mouth washes

Suspension

Syrup

Emulsion

20. Identification test for emulsion is

Redispersibility test

Conductivity test

Particle size changes

Sedimentation volume

21. Which class of propellants shows ozone depletion as its drawback?

Chlorofluorocarbons
Hydrocarbons
Hydrofluorocarbons
Compressed gases

22. Which of the following is a commonly used enteric polymer in tablet coating?
Cellulose acetate butyrate
Cellulose acetate phthalate
Hydroxy propyl cellulose
Methyl cellulose

23. This category of excipient is essential for low dose drugs-
Disintegrant
Colourant
Lubricant
Diluent

24. The part of rotary press responsible for guiding the punches is-
Adjustment cam
Pressure roller
Feeder
Cam track

25. Disintegration time limit for a conventional sugar coated tablet as per IP is
60 min
45 min
30 min
15 min

26. _____ plastics retain their form and stay solid under heat once cured.
Thermoset plastics
Thermoplastic
Thermolabile plastic
Thermocure plastic

27. Disadvantages of Parenterals includes
First pass metabolism is avoided

Quick onset of action

Difficult to reverse the physiological effect

Useful for patients unable to swallow, nausea or unconscious

28. In sterility test of Parenetrals, fluid thioglycollate medium is used for

Staphylococcus aureus

Aspergillus niger

Candida albicans

Bacillus subtilis

29. Sterility test for parenterals is carried out under _____ conditions

Clean

Aseptic

Ambient

Cold

30. Viscosity builder used in parenterals

methyl cellulose

polycarbophil

cetyl alcohol

Carbopol

31. pH of tears is

6.4

6.8

5.8

7.4

32. Incorporation of water soluble drug in ophthalmic ointment is possible due to presence of

wool fat

liquid paraffin

soft paraffin

isopropyl myristate

33. _____ is the dependent type of capsule filling machine

Dosator type

Dosing disk and tamping finger

Rotary die machine

Auger fill type

32. The shell of soft gelatin capsules may be made flexible by the addition of

Sucrose

Mannitol

Sorbitol

Maltose

34. Which of the following is the bulk characterization property of drug

Compressibility

Taste

Common Ion effect

partition coefficient

35. According to BCS Classification Class III drug have

High permeability, low solubility

Low permeability, low solubility

High permeability, High solubility

Low permeability, High solubility

36. The powder with angle of repose more than > 40, the powder possess _____flow

Passable

Excellent

Poor

Good

37. Abrasive is used in

Shampoo

Lipstick

Nail polish

Toothpaste

38. Ostwald ripening is an instability observed in

Mouth washes

Suspension

Suspension

Syrup

39. Identification test for emulsion is

Redispersibility test

Fluorescence test

Particle size changes

Sedimentation volume

40. Which of the following is used for aerosol particle size determination?

Cascade Impactor
Tag Open Cup Apparatus
Karl Fischer Apparatus
Pycnometer

41. The function of subcoat is to-
Make the surface smooth
Increase bulk of tablet
Impart gloss
Prevent entry of moisture

42. _____ is an example of a superdisintegrant.
Polyvinyl pyrollidone
Cellulose acetate phthalate
Carboxy methyl cellulose
Sodium starch glycolate

43. The following part of the rotary press helps in filling the granules into the dies-
Discharge chute
Feed paddle
Take off blade
Pressure roller

44. Disintegration time limit for a conventional uncoated tablet as per IP is-
60 min
45 min
30 min
15 min

45. Which of the following is considered as the highly resistant glass?
Borosilicate glass
Soda Lime glass
Treated soda lime glass
NP glass

46. Benzalkonium chloride is generally used as
Antioxidant
Preservative
Surfactant
Solubilizing agent

47. Distillation is one of the methods of preparation of – ———-
WFI
Solution
Emulsion

Suspension

48. In LAL test, _____ react with LAL reagent to produce a firm gel within the incubation period

Xenobiotics

radionuclides

Endotoxins

Chemicals

49. In pyrogen test, the solution is slowly injected into marginal vein of the _____ of the rabbit

Ear

fore limb

hind limb

Tail

50. Evaluation of collapsible tubes for ophthalmic ointment includes

Pyrogenicity

Sterility

Freedom from metallic particles

Clarity test

51. Antibacterial enzyme in the tears is

Lysozyme

Liposomes

Lipoprotein

Lipase

52. Role of magnesium stearate is as

Dissolution agent

Hardness

Disintegrating agent

Lubricant

53. Bloom strength is a prime test for

Gelatin Solution

Capsule shell

Gelatin powder

Empty capsule

54. Angle of repose is used to measure

Polymorphism

Flow property

Surface area

Solubility

55. According to BCS Classification Class I drug have

High permeability, low solubility

Low permeability, low solubility

High permeability, High solubility

Low permeability, High solubility

56. The powder with angle of repose less than 20, the powder possess _____flow

Passable

Excellent

Poor

Good

57. Binder is used in

Shampoo

Lipstick

Nail polish

Toothpaste

58. Redispersibility test is done for

Mouth washes

Suspension

Syrup

Aromatic waters

59. Identification test for emulsion is

Redispersibility test

Dilution test

Particle size changes

Sedimentation volume

Set 1 Answer Key

Q.1 A) Discuss the importance of powder flow properties, partition coefficient and drug excipient compatibility in preformulation studies. 12M

POWDER FLOW PROPERTIES

- Powder flow properties can be affected by change in particle size, shape & density.

- The flow properties depends upon following-

1. Force of friction.
2. Cohesion between one particle to another.

- Fine particle posses poor flow by filling void spaces between larger particles causing packing & densification of particles.

- By using glident we can alter the flow properties.
  e.g. Talc

Determination of flow property by :
determining Angle of repose, Carrs Index and Hausners ratio

Partition Coefficient

- A measurement of drug lipophilicity i,e the ability to cross the cell membrane $p_{o/a} = \frac{c_{organic}}{c_{aqueous}}$

Distribution coefficient

- For acids: $\log_{10} D = \log_{10} P - \log_{10}(1 + 10^{(pH - pKa)})$
- For bases : $\log_{10} D = \log_{10} P - \log_{10}(1 + 10^{pKa - pH})$
- The octanol-water system is widely accepted to explain these phenomenon.
- Buccal membrane : butanol-pentanol system
- Blood-Brain barrier: chloroform-cyclohexane
- Determined by SHAKE FLASK METHOD

Shake flask method
• Chromatographic method (HPLC)
• Computation based on software
• Countercurrent/filter probe method

Drug- excipient compatibility

- Compatibility test play a very important role in the preformulation studies of oral dosage forms
- An incompatibility in the dosage form can result in any of the following changes:
  - Changes in organoleptic properties
  - Changes in dissolution performance
  - Physical form conversion
  - An decrease in potency

. Q 1 B) Elaborate on the glass containers in parenterals and discuss test to distinguish between them 12M

Classification of Glass
Glass containers are classified into Type I glass, Type II glass, Type III glass and Type IV glass based on their degree of chemical/hydrolytic resistance to water attack. The degree of attack is dependent on the degree of alkaline release under the influence of the attacking media.

i. Type I glass containers (Borosilicate glass / Neutral glass)
This is a type of glass container that contains 80% silica, 10% boric oxide, small amount of sodium oxide and aluminium oxide. It is chemically inert and possess high hydrolytic resistant due to the presence of boric oxide. It has the lowest coefficient of expansion and so has high thermal shock properties.

Uses of Type I glass containers
Type I glass is suitable as packaging material for most preparations whether parenteral or non-parenteral.
They can also be used to contain strong acids and alkalis

ii. Type II glass containers (soda-lime-silica glass/ treated soda-lime glass/ De alkalized soda lime glass)
This is a modified type of Type III glass container with a high hydrolytic resistance resulting from suitable treatment of the inner surface of a type III glass with sulfur. This is done to remove leachable oxides and thus prevents blooming/weathering from bottles. Type II glass has lower melting point when compared to Type I glass and so easier to mould.
Uses of Type II glass containers

They are suitable for most acidic and neutral aqueous preparations whether parenteral or non-parenteral.

iii. Type III glass containers (Regular soda lime glass)

This is an untreated soda lime glass with average chemical resistance. It contains 75% silica, 15% sodium oxide, 10% calcium oxide, small amounts of aluminium oxide, magnesium oxide, and potassium oxide. Aluminium oxide impacts chemical durability while magnesium oxide reduces the temperature required during moulding.

Uses of Type III glass containers

They are used as packaging material for parenteral products or powders for parenteral use ONLY WHERE there is suitable stability test data indicating that Type III glass is satisfactory.

They used in packaging non-aqueous preparations and powders for parenteral use with the exception of freeze-dried preparations

It is also used in packaging non-parenteral preparations.

Type IV glass containers (Type NP glass/General-purpose soda lime glass)

This type of glass container has low hydrolytic resistance. This type of glass containers are not used for products that need to be autoclaved as it will increase erosion reaction rate of the glass container.

Uses of type IV glass containers

It is used to store topical products and oral dosage forms

Q.2 - 1A) Enlist different methods of tablet formulation and explain wet granulation in detail.

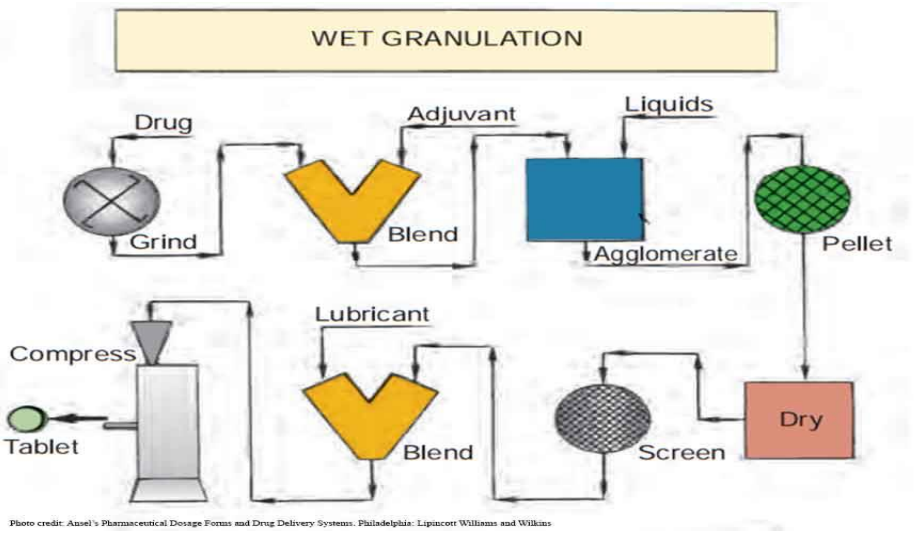
8M

wet granulation, dry granulation, direct compression

Wet granulation method is a process of size enlargement in which fine powder particles are agglomerated or brought together into larger, strong and relatively permanent structure called granules using a suitable non-toxic granulating fluid such as water, isopropanol or ethanol (or mixtures thereof). The granulating fluid can be used alone or as a solvent containing binder or granulating agent. The choice of the granulating fluid depends greatly on the properties of the materials to be granulated. Powder mixing, in conjunction with the cohesive properties of the granulating agent, enables the formation of granules. The characteristics and performance of the final product, greatly depends on the extent to which the powder particles interact with each other to form aggregates (granules).

The four key mechanisms of granule formation

- Wetting and nucleation
- Coalescence or ball growth
- Consolidation
- Attrition or breakage



Q2 1 B) Write a note on form-fill-seal(FFS)
4M

Form Fill Seal (FFS) machines are packaging machines in which filling and sealing of a package take place on the same machine.

Form Fill Seal machines are highly sophisticated that features computer interfaces and control networks. Many companies prefer to use FFS systems as they are included with greater benefits such as speed and versatility.

The form-fill-seal process involves the use of a single piece of equipment to form a plastic container, fill the container with the parenteral drug product and then hermetically seal the container. All of the steps are completed within a few seconds and take place without any operator involvement.

In addition to the pharmaceutical industry, FFS technology is used in food processing and other applications. It is ideally suited for the production of parenteral products; however, because the filling and packaging of the formulated drug product takes place under specific clean room conditions, it is key to minimizing direct human intervention, eliminating contamination risks and thus the possibility of error and maximizing quality assurance and safety.

In general, drug manufacturers want to achieve several fundamental goals, which can include optimizing the cost of drug manufacturing, reducing the lead time for products and ensuring patient safety through the production of the highest quality products — FFS technologies help manufacturers achieve all of these goals for parenteral drug production. With FFS, the container production, filling and sealing processes are all optimized through automation. Lead time is reduced because three discrete steps are combined into one process. In addition,

fewer starting materials must be retained in stock, reducing the complexity of managing materials and requiring less storage space.

The products manufactured using FFS technology are inherently safer owing to the automated nature of the process. Elimination of human interaction in the container-forming, filling and sealing processes reduces the risk of contamination or error. In addition, one of the key opportunities for particle generation occurs during the bag molding process. With FFS technology, control over this critical aspect of injectable solution manufacturing is now in the hands of the drug manufacturer.

There are environmental benefits to the process as well: lower energy consumption, reduced waste generation and a lower carbon footprint. Furthermore, the plastic containers do not shatter, like glass bottles and vials, and the resins used to form the plastic containers are recyclable.

Managing a Complex Process

FFS is a complex process that combines three steps into one. Establishing an effective manufacturing solution requires extensive understanding of the materials involved and the behavior of plastics. Specialists with knowledge of welding, injection molding, plastic transformation and the incorporation of ports, connectors and other features are needed to design an effective FFS system. Process engineers and machine designers must also be consulted throughout. Completion of a thorough risk analysis is important, and a robust system design based on experience, process data and risk analysis is essential for achieving an efficient, reliable process outcome that generates robust containers and connections that meet all quality requirements.

Q.2- 2 A) Coating defects and remedies 8M

- Blistering - optimizing drying temperature
- Blooming/Dull film - optimizing plasticizer concentration
- Blushing- decrease drying, avoid sorbitol
- Chipping/ Edge Erosion- use appropriate baffles
- Cratering- decreasing spray rate
- Cracking/Splitting- adjusting plasticizer
- Color variation- control drying, use geometric mixing
- Core Erosion/ Surface Erosion- control drying
- Discoloration- protection from moisture
- Logo Bridging- optimal plasticizer
- Logo In-filling /Break Lines In-filling- optimal plasticizer
- Orange Peel (Roughness)-reduce viscosity, mild drying
- Peeling- high adhesion
- Sticking and Picking- optimum viscosity and drying conditions
- Twinning- adjust stickiness, reduce spray rate
- Tablet Breakage-optimize binder, adjust machine compression parameters

Q.2 B) ingredients used in formulation of Shampoo 4M

Surfactant
foam booster
pH adjuster
Viscosity modifier
sequestering agent
opacifier
conditioning agent
perfume
colour
preservative
water
write role of each ingredients with examples

Q. 3 A) Classify propellants with examples. Elaborate on the merits and demerits of each class of propellants used in aerosols. 8M

- Chloro Fluoro Carbons (CFCs) eg Propellant 11, 12, 114
  best propellant as it maintains constant pressure, non explosive but problem of ozone depletion

- Hydro Fluoro Carbons (HFCs) Propellant 153
  green house effect poor solvent for MDIs
- Hydrocarbons (HC) eg Propane, Butane
  economic alternative but combustible
- Compressed gases eg CO2, Nitrous oxide
  useful for topical products but does not maintain constant pressure.

Q 3 B) Write quality control of ophthalmic suspensions. 4M

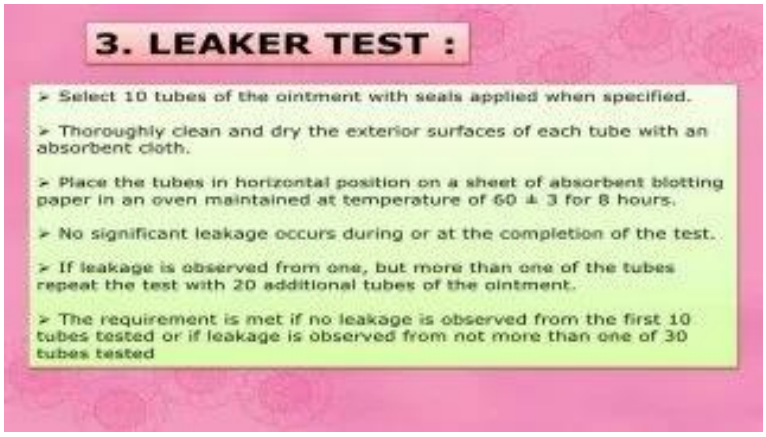
Redispersibility

Particle size analysis

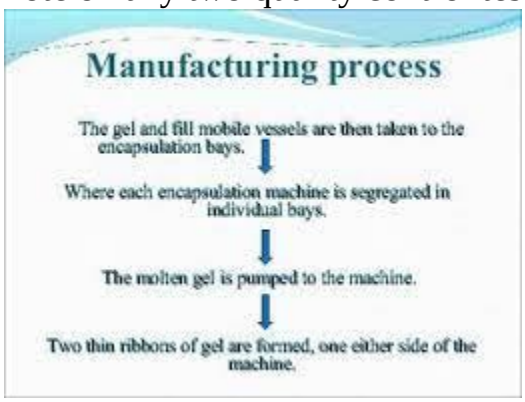
Ph

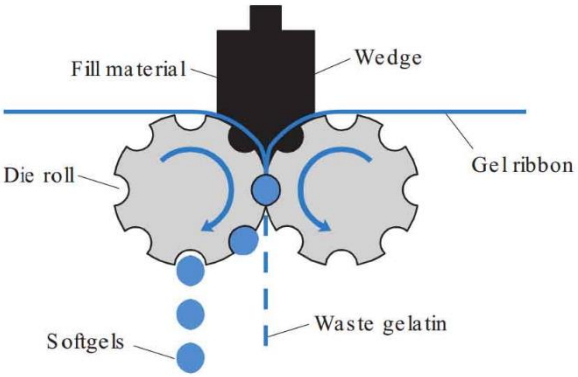
Viscosity

Pyrogen test



Q 4 A) Discuss large scale manufacturing of soft gelatin capsule and write a note on any two quality control tests 8M





Discuss about any 2 test of the above

Q.4 B) What is the importance of preformulation studies . Give 2 examples 4M

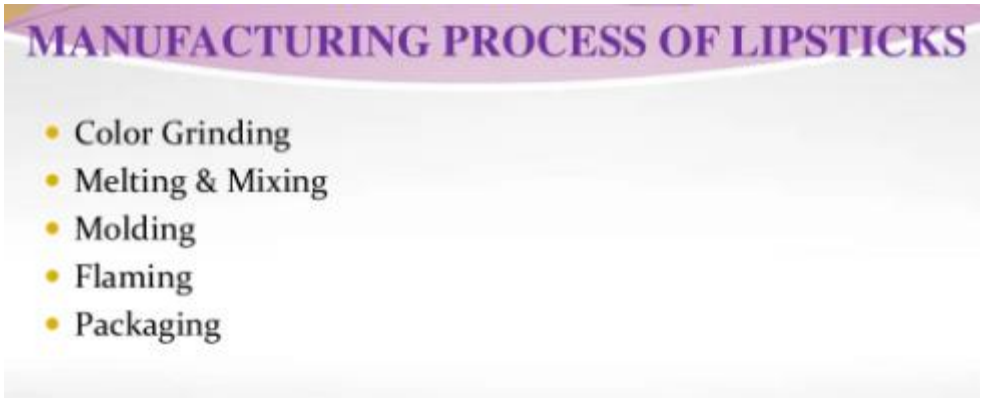
1. **To establish the physicochemical parameters of a candidate drug molecule.**

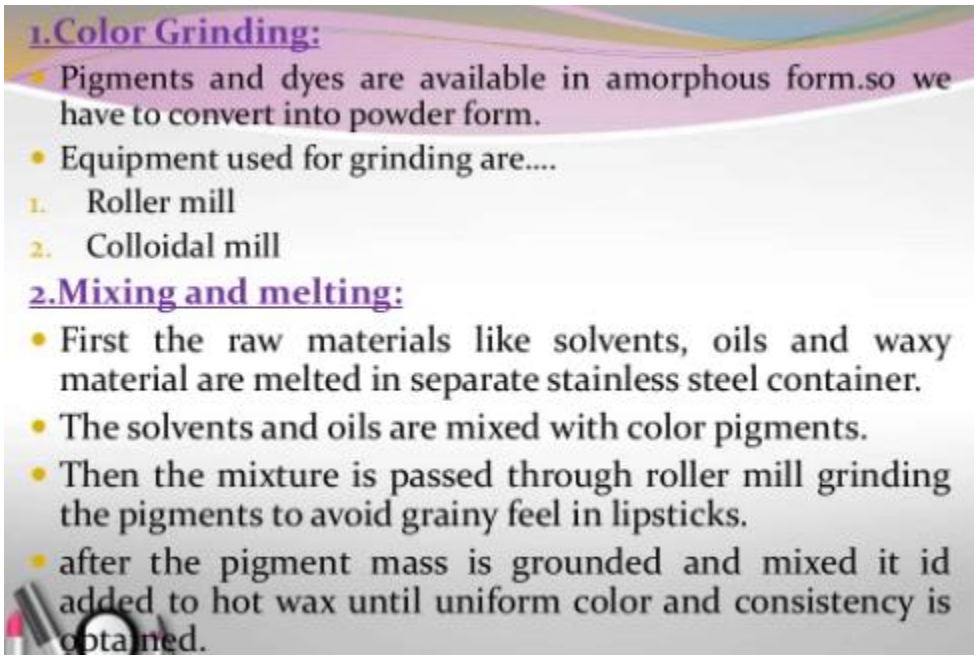
2. To determine the kinetic rate profile of drug substances.

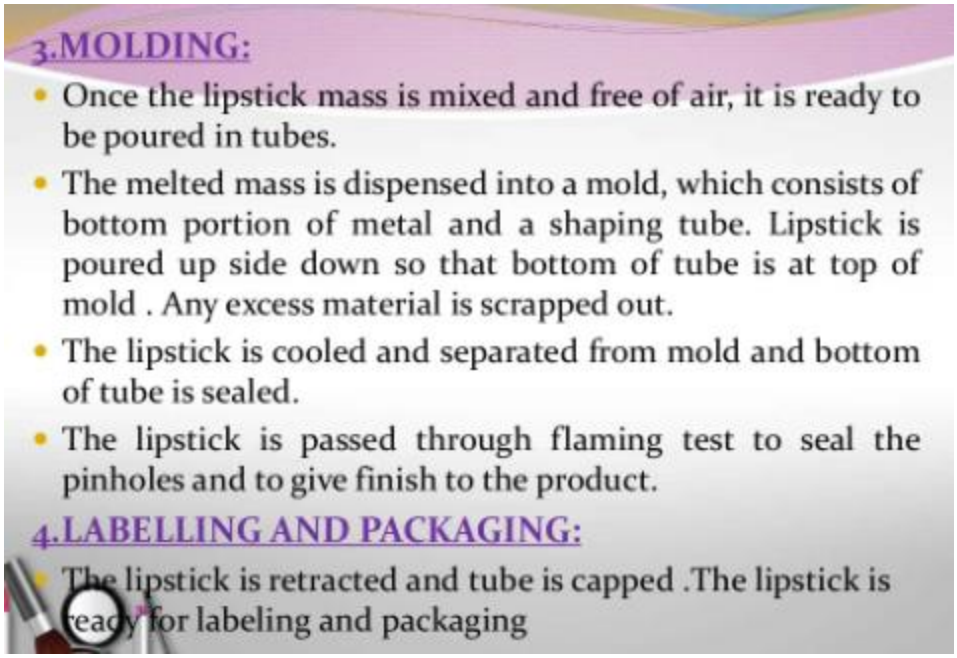
3. To establish the compatibility of a candidate drug molecule with common excipients.

any two example can be written of students choice eg to increase solubility , compatibility issue, most bioavailable polymorph etc

Q.5 a) Manufacturing of Lipstick 5M



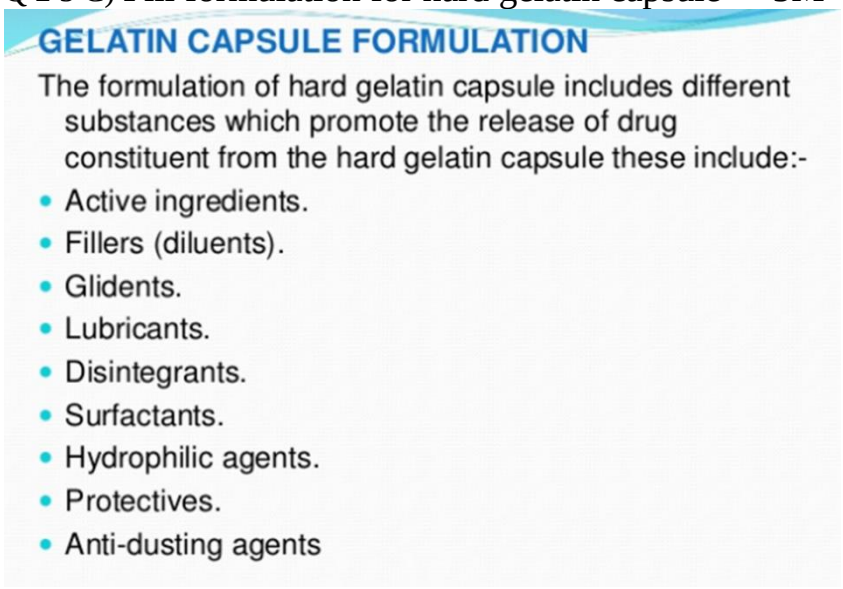




Q.2 5 B) factors influencing packaging 5M

- Compatibility and safety concerns
- The degree of protection required - protection from light, moisture, oxygen
- Cost
- Convenience- Patient use
- Legibility- for labelling
- Ease of transportation
- Presentation for over-the-counter (OTC) drugs.
- Approved by regulatory agencies- material should be approved- GRAS

Q 2 5 C) Fill formulation for hard gelatin capsule 5M



write the role of each ingredient with examples

Set II Answer Key

Q.1 A) Discuss the preformulation aspects to be considered in formulation development of oral solid dosage forms 12M

Major Area of Preformulation Research

- **ORGANOLEPTIC CHARACTERS**
- **BULK CHARACTERS**
  - Crystallinty and polymorphism
  - Hygroscopicity
  - Fine particle characterization
  - Powder flow properties
- **SOLUBILITY ANALYSIS**
  - ionization constant-PKa
  - pH solubility profile
  - Common ion effect-Ksp
  - Thermal effects
  - Solubilization
  - Partition co-efficient
  - Dissolution
- **STABILITY ANALYSIS**
  - Stability in toxicology formulations
  - Solution stability
  - pH rate profile
  - Solid state stability
  - Bulk stability
  - Compatibility

Discuss each point giving examples

. Q1 B) Explain methods of preparation of water for injection and discuss storage of water for injection. 12M

Vapor Compression Distillation

VC distillation system is also known as thermocompression / vapor recompression or thermal / mechanical vapor compression. It is a technology similar to the evaporation systems used for the water desalination (vapor compression is also a common term in the refrigeration industry).

Furthermore, the VC distillation system can be powered by either steam or electric heating, and have a minimal feedwater quality requirement due to lower operating temperature. VCD units are driven by a more mechanical process than MED, involving a compressor and other moving parts to compress steam and increase its pressure/temperature for evaporation.

Multiple Effect Distillation

ME System is a well-know method. Multiple-effect stills are mainly noted for their multiple column design which re-uses steam energy through the process, requiring minimal moving parts, but requiring cooling water for final distillation of product.

In case of low required capacities (since MED systems absorbing much energy and cooling water) you can also get WFI from Single Effect Distiller (BRAM-COR Mod. DPSG), that is both a Still and a Pure Steam Generator.

Reverse Osmosis + Ultrafiltration (UF)

As we have already observed, we do not think that RO Reverse Osmosis system is the safest method to produce Water for Injection (WFI), unless the feed water is really excellent. Above all, theoretically, with the availability of more technologically advanced membranes, we can produce "cold" WFI with the addition of an Ultrafiltration unit in downstream position (pre-treatment techniques, such as water softening, descaling, pre filtration, degasification, nanofiltration, electro-deionisation, ozonation, UV treatment and micro-filtration, should all be considered, in relation to the feed water quality). So, we can produce cold WFI that meets all the parameters required (USP, Ph. Eur., JP, …).

Storage and Distribution:

WFI should be stored at 80°C for prevention of any contamination

Heat exchangers must be installed to reduce the temperature at the point of use

WFI to be stored at room temperature but for a maximum of 24 hrs requires frequent sanitization to minimize the risk of viable microorganisms. (Permitted by USP)

Storage Tank: stainless-steel connected to a distribution loop

Hydrophobic membrane vent filter capable of excluding bacteria and non-viable particulate matter

Q.2 1A) Elaborate various in-process and finished product quality control tests for tablets.
8M

IPQC and FPQC tests for tablets

IPQC- weight variation, diameter, thickness, hardness, DT

FPQC- Pharmacopeial tests

- Content of Active Ingredient
- Uniformity of Weight
- Uniformity of Content
- Disintegration time test
- Dissolution test

Non pharmacopoeial

- Organoleptic characterization
- Dimension measurement
- Microbial count
- Stability Assessment

1 B) Enlist advantages and limitations of Parenterals as dosage form 4M

Advantages:

Quick onset of action

Maximum bioavailability

Suitable for the drugs which are not administered by oral route

Useful for unconscious/vomiting/ Non-cooperative patients.

Duration of action can be prolonged by modifying formulation.

Suitable for nutritive like glucose & electrolyte. Suitable for the drugs which are inactivated in GIT or HCl (GI fluid)

Disadvantages:

Only trained person is required

If given by wrong route, difficult to control adverse effect

Difficult to save patient if overdose

Sensitivity or allergic reaction at the site of injection

Requires strict control of sterility & non pyrogenicity than other formulation. Once injected cannot be controlled (retreat)

Injections may cause pain at the site of administration

2A) Write a note on QC of shampoo 4M

Enlist and write about any 2 or write in short on each

1. Physical appearance/visual inspection
2. Determination of pH
3. Rheological evaluation (Viscosity)
4. Dirt dispersion
5. Foaming ability and foam stability
6. Percentage of solid content
7. Surface tension
8. Wetting time

Q.2 B Write in detail any one method of manufacturing a tablet . 8M

Wet granulation, dry granulation, direct compression

Wet granulation method is a process of size enlargement in which fine powder particles are agglomerated or brought together into larger, strong and relatively permanent structure called granules using a suitable non-toxic granulating fluid such as water, isopropanol or ethanol (or mixtures thereof). The granulating fluid can be used alone or as a solvent containing binder or granulating agent. The choice of the granulating fluid depends greatly on the properties of the materials to be granulated. Powder mixing, in conjunction with the cohesive properties of the granulating agent, enables the formation of granules. The characteristics and performance of the final product, greatly depends on the extent to which the powder particles interact with each other to form aggregates (granules).

Dry Granulation- useful for moisture sensitive drugs- involves formation of slugs

Direct compression- fastest method- involves mixing of API and directly compressible excipient and punching the tablet

Layouts and diagrams required

Q.3A) Explain two phase and three phase system of aerosols 8M

1.**Two-phase system aerosol**: This is applicable when the drug is soluble in the propellant and no separate solvent is needed. It consists of the liquid phase containing the liquefied propellant and product concentrate and the vapor phase.

2.**Three-phase system**: This is applicable when the drug is insoluble in the propellant and water/ aqueous solvent is used to solubilize the drug/ product concentrate. It consists of a layer of water immiscible liquid propellant, a layer of highly aqueous product concentrate and the vapor phase. Because the liquefied propellant usually has a greater density than the aqueous layer , it generally resides at the bottom of the container with the aqueous phase floating above it. To avoid expulsion of the reservoir of liquefied propellant, the dip tube must extend only with in the aqueous phase (product concentrate) and not down into the layer of liquefied propellant.

elaborate with diagram

B) Justify the need for preservative and tonicity adjustment in ophthalmic solutions. 4M

Multiple-dose eye solution requires product sterility: solved by using preservatives in the formulation

Unit-dose package : Not required

Surgical application products: preservatives is prohibited (clouding of the cornea and possible loss of vision)

Q.4A) Explain different coating pans with merits, demerits and applications of each.
8M

Pellegrini Pan

This type of pan is available in different sizes ranging from 10- 1000 kg. Pellegrini Pan has the provision for baffled pan as well as a diffuser. The combination of this type of fan and diffuser helps to distribute the uniform heat. This pan has a limitation that it can only be maneuvered with sugar coating but not with a film coating. The reason behind this limitation lies in the pan's incapability to evenly heat the solution and thus it doesn't get uniformly dried in the film coating pattern.

Immersion Sword Coating Pan

They are further categorized into PLG and GS system. They differ because of the process of the entry and exit of hot air into the system. PLG system has the inlet through a sword structure. Exhaust air is removed through the plenum. In the GS system, the inlet is via plenum and the exhaust air leaves the system through two perforated systems.

Conventional Coating Pan Industrial Use

The *Coating Pan* finds its immense use with Pharma Industry, Food industry. It provided automation with its highly equipped machine which can avoid chances of error. So for a solid dose, there is a need for such machines.

Q.4 B) Write a note on methods to determine particle size . 4M

Methods to Determine Particle Size

- Sieving (5µ-150µ)
- Microscopy(0.2µ-100µ)
- Sedimentation rate method(1µ-200µ)
- Light energy diffraction(0.5µ-500µ)
- Laser holography(1.4µ-100µ)

write in short about each

Q.5 a Formulation of toothpaste 4M

TABLE 6-2 Toothpaste Constituents

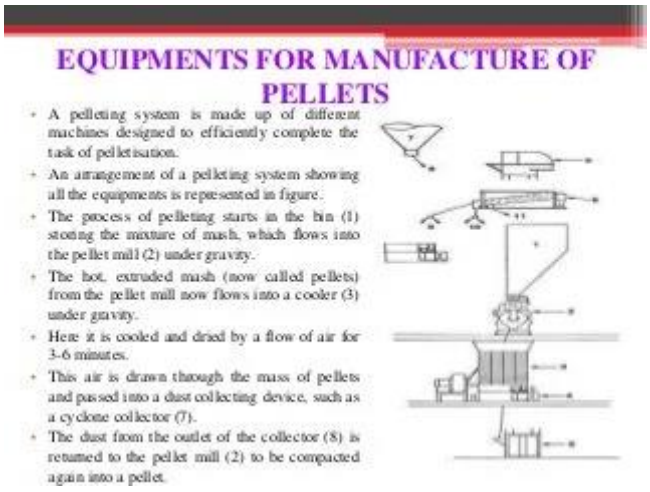
Ingredient	Percentage
Abrasives	20–40
Water	20–40
Humectants	20–40
Foaming agent (soap or detergent)	1–2
Binding agent, up to	2
Flavoring agent, up to	2
Sweetening agent, up to	2
Therapeutic agent, up to	5
Coloring or preservative, less than	1

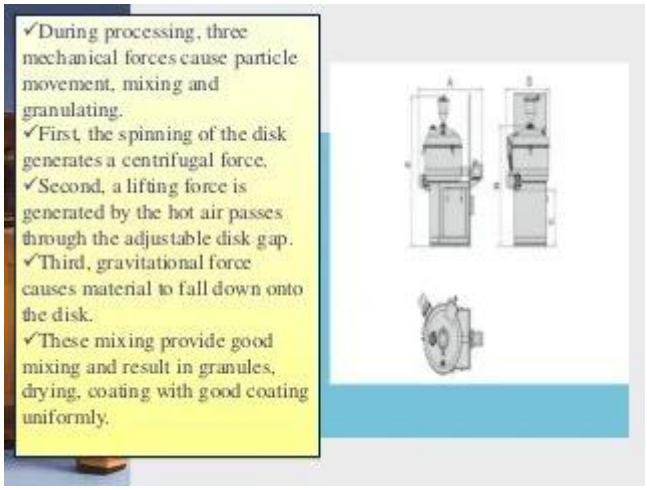
write role of each ingredient with examples

. Q.5 B Quality control tests of glass as packaging material 4M

- Powdered glass test: Done to estimate the amount of alkali leached from the powdered glass, which usually happens at elevated temperatures. ...
- Hydrolytic resistance of glass containers: ...
- Arsenic test: ...
- Leakage test: ...
- Collapsibility test: ...
- Clarity of aqueous extract: ...
- Residue on evaporation: ...
- Sterilisation test:

C) Explain equipment for the manufacture of pellets 4M





Set III- Answer Key

Q.1 A)

. Discuss sugar coating of tablets. Write a note on the sugar coating defects and their remedies. 12M

Sugar coating of tablets- defects and their remedies

Steps involved in sugar coating

Sugar-coating process consists of various steps, each designed to achieve a particular function. A typical sugar-coating process encompasses six stages:

1. **Sealing of the tablet core**
2. **Subcoating**
3. **Smoothing**
4. **Colour coating`**

5. **Polishing**
6. **Printing**

Sugar coating defects

1. **Chipping of coatings**
2. **Cracking of the coatings**
3. **Non-drying of the coating**
4. **Twinning (buildup of multiples)**
5. **Uneven coloring**
6. **Blooming and Sweating**
7. **Marbling**

Remedies

optimizing plasticizer, spray rate, drying rate, solid content etc

. **B)** Elaborate on quality control testing for injectables 12M

Injectability and Syringeability

Freeze-thaw cycles

Resuspendability

Sedimentation volume

Crystal growth

Particle size measurements

Zeta potential determinations

Viscosity

Q.2- 1A) Classify excipients used in tablet formulation and elaborate on disintegrants with their mechanisms.
8M

Tablet excipients- Diluents, Binders, Disintegrants, Lubricants, anti-adherants, glidants, colours, flavors, sweeteners, preservatives, antoxidants and other miscellaneous excipients as per the requirements.

Disintegrants mechanisms-

- swelling
- wicking (capillary action)
- Deformation
- Repulsive forces

B) Write a note on pyrogen
4M

Pyrogens are the metabolic products of microorganisms

Endotoxin :

complex of pyrogenic lipopolysaccharide

heat-stable,

resistant to proteolytic enzymes,

immunogenic,

cannot be converted to toxoids and

produced by Gram-negative bacteria

Monomer unit of LPS is less than 10,000 daltons, enabling endotoxin to easily pass through sterilizing 0.2-micron filters

Sources:

• Solvent

• The medicament

• The apparatus

The method of storage between preparation and sterilization

Elimination:

Pyrogens can be destroyed by heating at high temperatures

Solvent extraction methods are useful in the production of antibiotics

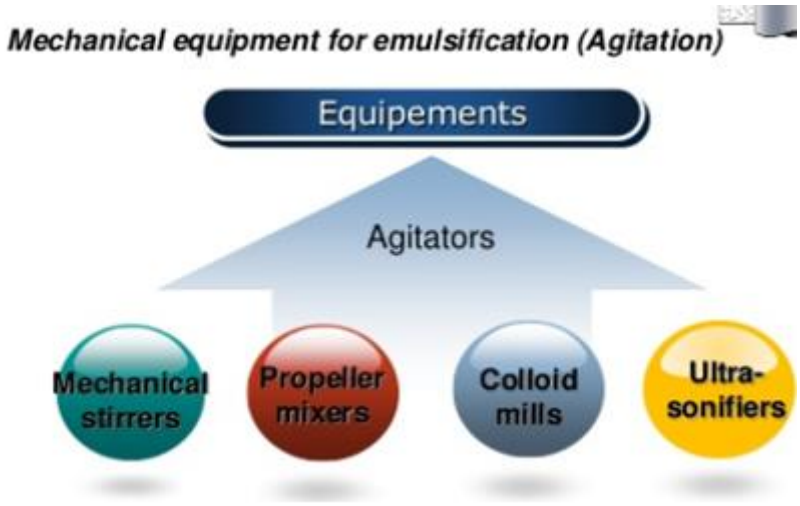
Adsorption on the surface of selective adsorbents

Other in-process methods for their destruction or elimination include

selective extraction procedures and careful heating with dilute alkali, dilute acid, or mild oxidizing agents.

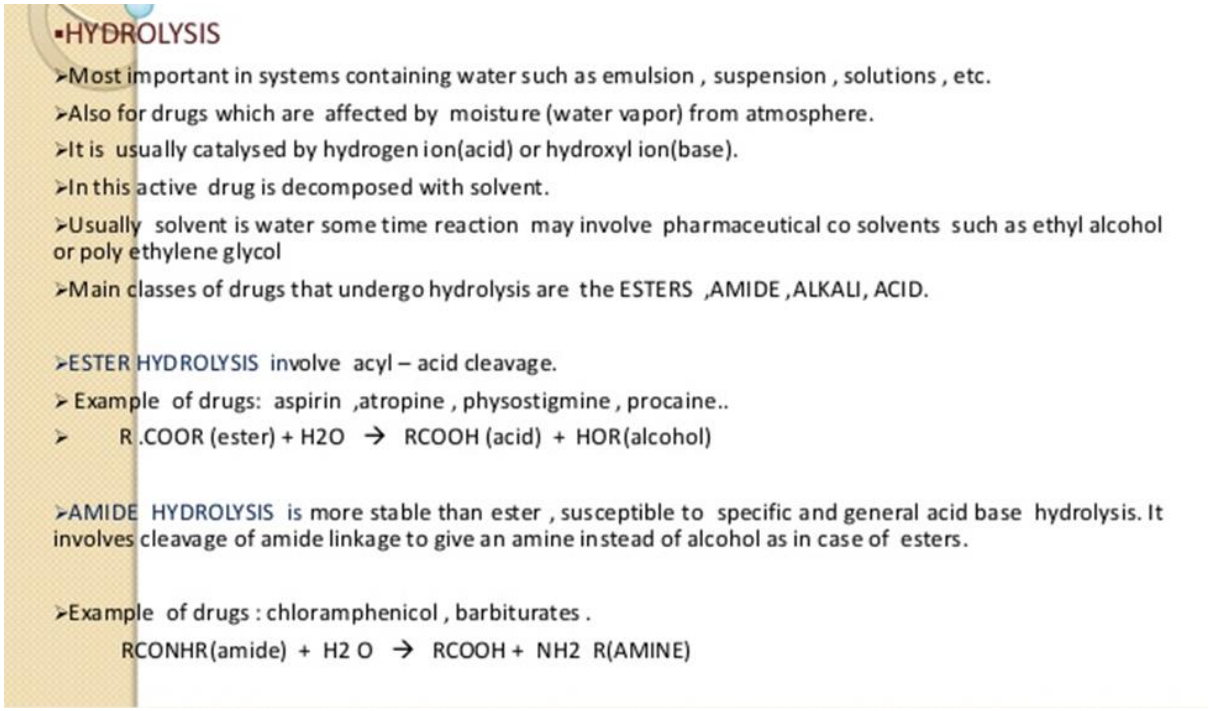
Ultrafiltration is also sometimes used to eliminate pyrogens.

Q.2A) Write a note on the equipment used in the manufacturing of emulsion. 4M



write in short with purpose of using each manufacturing vessel : for oil phase, oil phase and to mix both phases Manufacturing vessel with heating facility and piping system and pump for transfering

Q.2B) Explain hydrolytic degradation in pharmaceutical products and the methods of prevention. 8M



Protection against hydrolysis:

- By avoiding contact with water vapour control of atmospheric humidity during preparation & packing
- Adjusting ph to an optimum level
- Hydrolytic reactions generally minimized by partial (or) full replacement of water with lower dielectric constant sol such as glycol, glucose, mannitol
- By modification of chemical structure by increasing the length of branching the alkyl groups, hydrolysis of ester may be decreased by owing to steric hindrance.

Q.3 A) Write in detail about quality control tests for aerosols. 8M

Quality control test for aerosols-

It involves testing of container, valve assembly, propellant and product concentrate.

FPQC tests-

Quality Control Tests for Pharmaceutical AEROSOLS

A Flammability and combustibility
1. Flame extension .
2. Flash point test.

B.Physicochemical characteristics
1. Vapor pressure
2. Density
3. Moisture content
4. Identification of propellants

C. Performance
1. Aerosol valve discharge rate
2. Spray pattern
3. Net contents
4. Uniformity of delivered dose
5. Particle size determination
6. Leakage

D.Stability testing

B) Write a short note on ophthalmic ointment bases
4M

Ointment bases

There are five (5) classes or types of ointment bases which are differentiated on the basis of their physical composition.

These are: 1. Oleaginous bases.

2. Absorption

3. Water in oil emulsion

4. Oil in water emulsion bases.

5. Water soluble or water miscible bases.

These bases are fats, fixed oils, hydrocarbon or silicones. They are anhydrous, greasy, non-washable does not absorb water and occlusive (form a film on skin so it increases the skin hydration by reducing the rate of loss of surface water. They should not be applied to infected skin. they are used as protectants, emollients , vehicles for hydrolysable drugs. Example: White Petrolatum, White Ointment Oleaginous O.B.Oleaginous O.B.

Oleaginous base + w/o surfactant. Anhydrous but hydrophilic ointment bases, they can absorb several times their weight of water to form water-in-oil emulsion. They are non-washable, not water soluble They used as protectants, emollients (+/-), vehicles for aqueous solutions, solids, and non-hydrolyzable drugs. Example: Hydrophilic Petrolatum, Anhydrous Lanolin, Aquabase™, Aquaphor®, Polysorb® Absorption O.B.Absorption O.B.

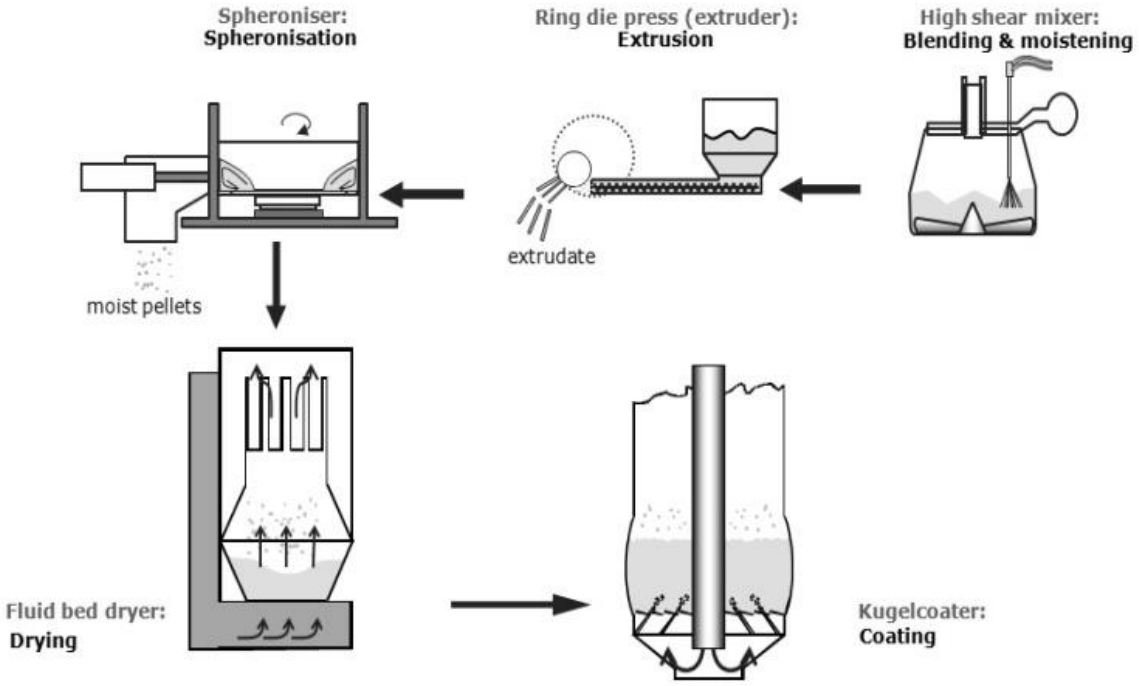
These are anhydrous, hydrophilic, absorbs water and non water removable, with low thermal conductivity and occlusive. They have the same properties as the absorption bases. They are used as emollients, cleansing creams, vehicles for solid, liquid, or non-hydrolysable drugs . Examples: Cold Cream type, Hydrous Lanolin, Rose Water Ointment, Hydrocream™, Eucerin®, Nivea® . W/O emulsion O.B.W/O emulsion O.B.

These bases are anhydrous, water soluble, absorb water and water washable. They are either carbowaxes Polyethylene Glycols (PEGs) or hydrated gums (bentonite, gelatin, cellulose derivatives). They are used as drug vehicles. Examples: PEG Ointment, Polybase™ O/W emulsion O.B.O/W emulsion O.B.

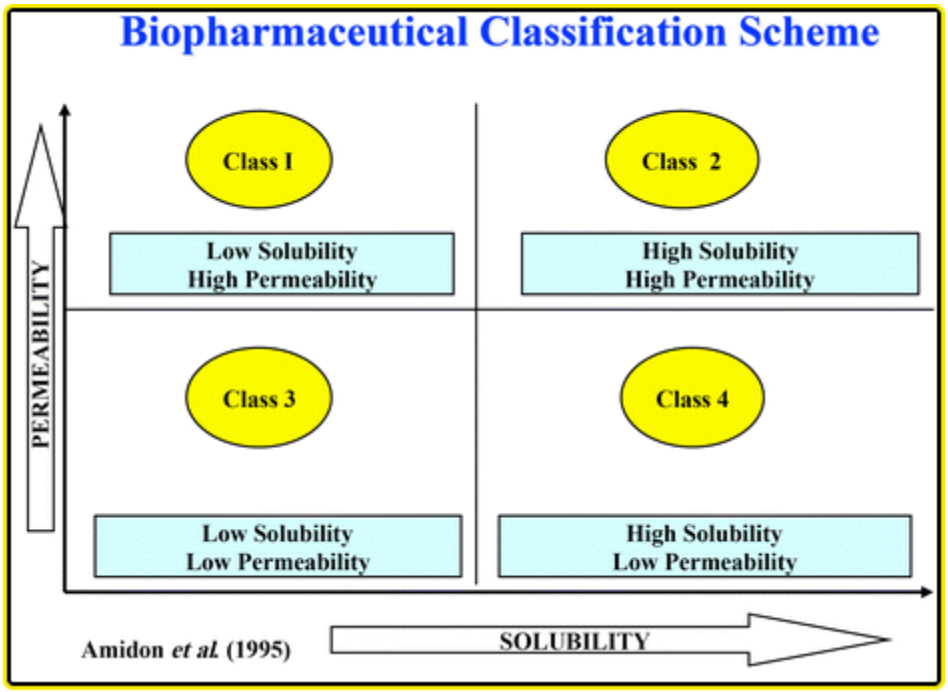
These bases are anhydrous, water soluble, absorb water and water washable. They are either carbowaxes Polyethylene Glycols (PEGs) or hydrated gums (bentonite, gelatin, cellulose derivatives). They are used as drug vehicles. Examples: PEG Ointment, Polybase™ Water miscible O.B.Water miscible O.B.

Q 4 A Elaborate on Extrusion-spheronization method for manufacturing pellets. 8M

In extrusion–spheronization, first the dry powder mix is agglomerated with the help of a binding liquid. Then it is processed in the extruder to produce high-density extrudates. These extrudates are finally converted to pellets on spheronizer.



Q.4 B) Write a note on BCS Classification of drugs 4M



Q.5 a) Formulation of Lipstick 4M

Formulation of Lipstick

Ingredients	Examples
1. The solid components waxes: (a) Hydrocarbon waxes (b) The mineral waxes (c) Hard waxes (d) Microcrystalline waxes	 White bees waxes Ozokerite wax, ceresin wax Carnauba wax, candellila wax
2. The liquid component	Mineral oil, vegetable oil, castor oil
3. The softening agent	Anhydrous lanolin, lecithin
4. The colouring agent	Carmine, pigmented stain
5. Pearlescent pigment	Guanine crystal
6. Opacifying agent	Titanium dioxide
7. Perfumes	Rose oil, cinnamon oil
8. Miscellaneous agents: (a) Preservative (b) Antioxidant (c) Flavouring agent	 Prabeans BHA, BHT Cinnamon oil, spearmint oil etc.

write the role of each ingredient in the formulation of Lipstick

Q.5 B Write a short note on 'types of glass' used in pharmaceuticals. 4M
'types of glass' used in pharmaceuticals.
Type I, II, III, IV

- Type I- Borosilicate-This is a type of glass container that contains 80% silica, 10% boric oxide, small amount of sodium oxide and aluminium oxide. It is chemically inert and possess high hydrolytic resistant due to the presence of boric oxide. It has the lowest coefficient of expansion and so has high thermal shock properties.

Uses of Type I glass containers

- Type I glass is suitable as packaging material for most preparations whether parenteral or non-parenteral.
- They can also be used to contain strong acids and alkalis

Similarly elaborate each class with its applications

- Type II- Treated Soda Lime,
- Type III- Untreated Soda Lime,
- Type IV- General purpose (NP glass)

Q.5 c) Explain storage and stability testing of soft gelatin capsules 4M

Normally, the recommended storage conditions for empty capsule shells are **15 to 25°C and a relative humidity of between 35% and 65%**. This condition is designed to minimize moisture absorption or loss, and the resultant changes in physical dimensions, during the encapsulation operation

While there is no strict guidances for stability testing of soft gelatin capsules, there are a couple of guidelines available that will help evaluate the storage conditions and length of study required for specific formulations, including soft gelatin capsules.