

UNIVERSITY SOLVED QUESTION WITH ANSWER

Year : 2024-25

Subject : Pharmaceutics

Subject Code : BP103T

Subject In-Charge : MS.Monali padhi & Mrs. Adyasha Senapati



Registration No.:

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Total Number of Pages:02
SUBJECT: Pharmaceutics - I

Course: B. Pharm
Sub Code: BPT103T

1st Semester Regular/Back Examination: 2024-25

BRANCH(S): B. Pharm
Time: 3 Hours

Q. Code: A220
Max Marks: 75

Answer Question No.1 (Part-I) which is compulsory, any seven from Part-II, and any two from Part-III.

The figures in the right-hand margin indicate marks.

Part-I

| QI | Answer the following questions mentioning the answer with correct option (MCQs) | | | | (20 x1) |
|-----|---|-------------------|------------------|--------------------|---------|
| 1) | Advantage of liquid dosage form over the powders: | | | | |
| | a | b | c | d | |
| | Bioavailability is less |) More bulky | Easy to swallow | Easy to handle | |
| 2) | In heat method of preparing effervescent granules to make damp mass _____ releases 1 molecules of water of crystallization. | | | | |
| | a | b | c | d | |
| | Citric acid | Tartaric acid | Sucrose | Sodium bicarbonate | |
| 3) | _____ increases viscosity of suspension and delays sedimentation of particles. | | | | |
| | a | b | c | d | |
| | Preservatives | Co-solvents | Thickening agent | Sweetening agent | |
| 4) | Cocoa butter also known as: | | | | |
| | a | b | c | d | |
| | Theobroma oil | Olive oil | Glycerin | Coconut oil | |
| 5) | The chairman of the first edition of IP was _____. | | | | |
| | a | b | c | d | |
| | Dr. B.N. Ghosh | Mr. Prasana Totta | Dr. Nityanand | Dr. B. Mukherjee | |
| 6) | As per Young's formula, what is the dose of the drug for a 6 years child if adult dose is 1000 mg | | | | |
| | a | b | c | d | |
| | 333.3 mg | 33.3 mg | 666.6 mg | 66.6 mg | |
| 7) | Nasal drops are _____. | | | | |
| | a | b | c | d | |
| | Isotonic | Hypertonic | Hypotonic | None | |
| 8) | Which base should be selected when water wash ability is the key requirement? | | | | |
| | a | B | C | D | |
| | Hydrocarbon | Absorption | Emulsion Base | Water Soluble | |
| 9) | Which base is likely to be the most occlusive on the skin? | | | | |
| | a | b | c | d | |
| | Hydrocarbon | Absorption | Emulsion | Water Soluble | |
| 10) | In the preparation of cold creams, which types of bases are used generally? | | | | |
| | a | b | c | d | |
| | Hydrocarbon | Absorption | Emulsion | Water removable | |
| 11) | The sizes of the dispersed particles in a colloidal dispersion are _____. | | | | |
| | a | b | c | d | |
| | Less than 1 nm | More than 0.5 μm | 0.5 to 1μm | 1 to 500nm | |
| 12) | In liquid dosage form which of the following dosages forms is used for oral administration? | | | | |
| | a | b | c | d | |
| | Elixirs | Liniments | Lotion | Enema | |
| 13) | _____ is a branch of medicine which deals with doses of drug. | | | | |
| | a | b | c | d | |
| | Pharmacology | Pharcotherapeutic | Posology | None | |
| 14) | Bougies are meant for: | | | | |
| | a | b | c | d | |
| | Vagina | Urethra | Rectum | Nasal cavity | |
| 15) | Disodium EDTA is an example of _____ agent. | | | | |
| | a | b | c | d | |
| | Sweetening | Flavoring | Chelating | None | |
| 16) | Which of these is an example of inorganic emulsifying agent? | | | | |
| | a | b | c | d | |
| | Methyl cellulose | Gelatin | Bentonite | Tragacanth | |

| | | | | | |
|-----|--|----------------------------------|---|-------------------------|--|
| 17) | Massuppol consist | | | | |
| | a | b | c | d | |
| | Triglycerides of saturated vegetable oil | Glyceryl esters | Monoglycerides of saturated fatty acids | All of the above | |
| 18) | The monophasic liquid dosage form is a form of _____ solution. | | | | |
| | a | b | c | d | |
| | True | Course | Fine | Micro | |
| 19) | Suppositories are generally evaluated by; | | | | |
| | a | b | c | d | |
| | Melting range test | Liquefaction | Breaking test | All of the above | |
| 20) | Which statement is false for flocculated suspension | | | | |
| | a | b | c | d | |
| | High rate of sedimentation | Stick to the sides of the bottle | Particles exhibit loose aggregates | Difficult to redisperse | |

Part-II

QII Focused-Short Answer Type Questions- (Answer Any Seven)

(7 x 5)

- Write a short note on parts of a prescription.
- Discuss with proper examples effervescent, efflorescent and hygroscopic powders.
- Write a short note on solubility enhancement techniques.
- What are the contents of current edition of Indian Pharmacopoeia?
- Calculate the volume of 95% alcohol required to prepare 300ml of 70% Alcohol by alligation method.
- Write a short note on dusting powder.
- Differentiate between flocculated and deflocculated suspension.
- What is therapeutic incompatibility, discuss with its remedy.
- What are the various methods of preparation of creams, discuss in detail.

Part-III

QIII Long Answer Type Questions (Answer Any Two)

(2 x10)

- Define emulsions. Discuss their methods of preparations and stability problems in detail.
- Define and classify incompatibility. Discuss physical incompatibility with examples
- What are the various factors affecting dermal penetration? Discuss method of preparation of ointments.

(Q₁)

(1) Easy to swallow

(2) Citric acid.

(3) Thickening agent

(4) Theobroma oil

(5) Dr. B.N. Ghosh

(6) 333.3 mg

(7) Isotonic

(8) Emulsion base

(9) Emulsion

(10) emulsion

(11) 1 to 500 nm

(12) Elixens

(13) Posology

(14) urethra.

(15) Chelating

(16) Bentonite

(17) All of the above

(18) True

(19) All of the above.

(20) Difficult to redispens.



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Part-11

Q11)

(1) Prescription is a legal document or order written by a qualified health care professional on diagnosis, prevention or treatment of a specific patient disease is retained by a licensed practitioner.

→ The prescriptions are generally written in the English language but Latin words or abbreviations are frequently used to save time.

Parts of Prescription

- Date
- Name, Age, sex and address of the patient.
- Superscription
- Inscription.
- Subscription.
- Signatura / Transcription.
- Renewal instruction.
- Signature, address and registration number of prescriber.

Date

→ It is very important part of a prescription as it helps a pharmacist to find out the date of prescribing and date of prescription.

- In case of narcotic and habit forming drug, the date prevents the misuse of drug by the patient.

Name, Age, sex & address of the patient

- Name and address of the patient helps in the identification of patient while age & sex helps to decide the dose for that particular patient.

Superscription

→ It is represented by 'Rx' symbol.

→ It is a Latin word which means 'You Take'

- In olden days ; the symbol was considered to be on the symbol of Jupiter, which is considered as God of healing. The symbol was employed by the ancient in requesting god for the quick recovery of the patient.

Inscription

→ It is the main part of the prescription containing name and quantities of prescribed medicaments.

- The name of each ingredient is written on a separate line along with its quantity.

Subscription

- In this part prescriber gives direction to the pharmacist regarding to dosage form and number of dosage to be dispensed.

Signatura

- In this part prescriber gives direction to the patient regarding to dosage form administration of drug.

It contains

- Quantity / Amount to be taken.
- Frequency / Timing of administration
- Special instruction such as dilutions.

Renewal Instruction

- In this part prescriber indicates whether the prescription may be renewed or not and if so then how many times.

→ It is very important specially in the prescription containing narcotic and habit forming drug to avoid its misuse.

Signature, Address and Registration No. of Prescriber.

→ It is very important and how much needed part of presentation to verify that the prescription is official & issued by the doctor.

(2)

Effervescent powder

→ These are those powder which produce Effervescent i.e. release of CO_2 . If contain medicaments (API) mixed with acid and base which react together and it produce CO_2
ex - ENO

Method

→ After citric acid mixed with sodium bicarbonate then the powder passed through granulator to obtain granules.

Efflorescent powder

→ These are those substance which loses water to form a lower hydrate or become anhydrous is termed as efflorescent powder.

→ Present in the form of crystal granules.

Hygroscopic powder

powders absorb moisture from air leading to clumping & caking or changes in properties like dissolution, rate & bio-availability

ex - NaCl

(3) Solubility enhancement techniques

(i) pH change.

(ii) Co-solvent.

(iii) Particle size reduction.

(iv) Solid dispersion.

(v) Hydrophobic method.

(vi) complexation.

(i) pH change

→ A solubility of poorly soluble drug i.e. either weak base or ~~weak~~ weak acid may be altered by adjusting the pH of the solution.

ex → Addition of buffer to the formulation.

(ii) Co-solvent

→ It is a technique to increase the solubility of poorly soluble drug in a liquid.

→ By using co-solvent we can increase the solubility of poorly soluble drug.

ex → Procaine glycol.

(iii) Particle size reduction

→ The solubility of a product is also dependent on a particle size, so by decreasing the particle size we can increase the solubility of product.

(iv) Solid dispersion

→ In solid dispersion a poorly soluble drug dispersed in a highly soluble solid hydrophilic matrix which enhance the solubility.

(v) Hydrotropy method

→ In this method by adding large amount of secondary solute increase the aqueous solubility of water insoluble drug.

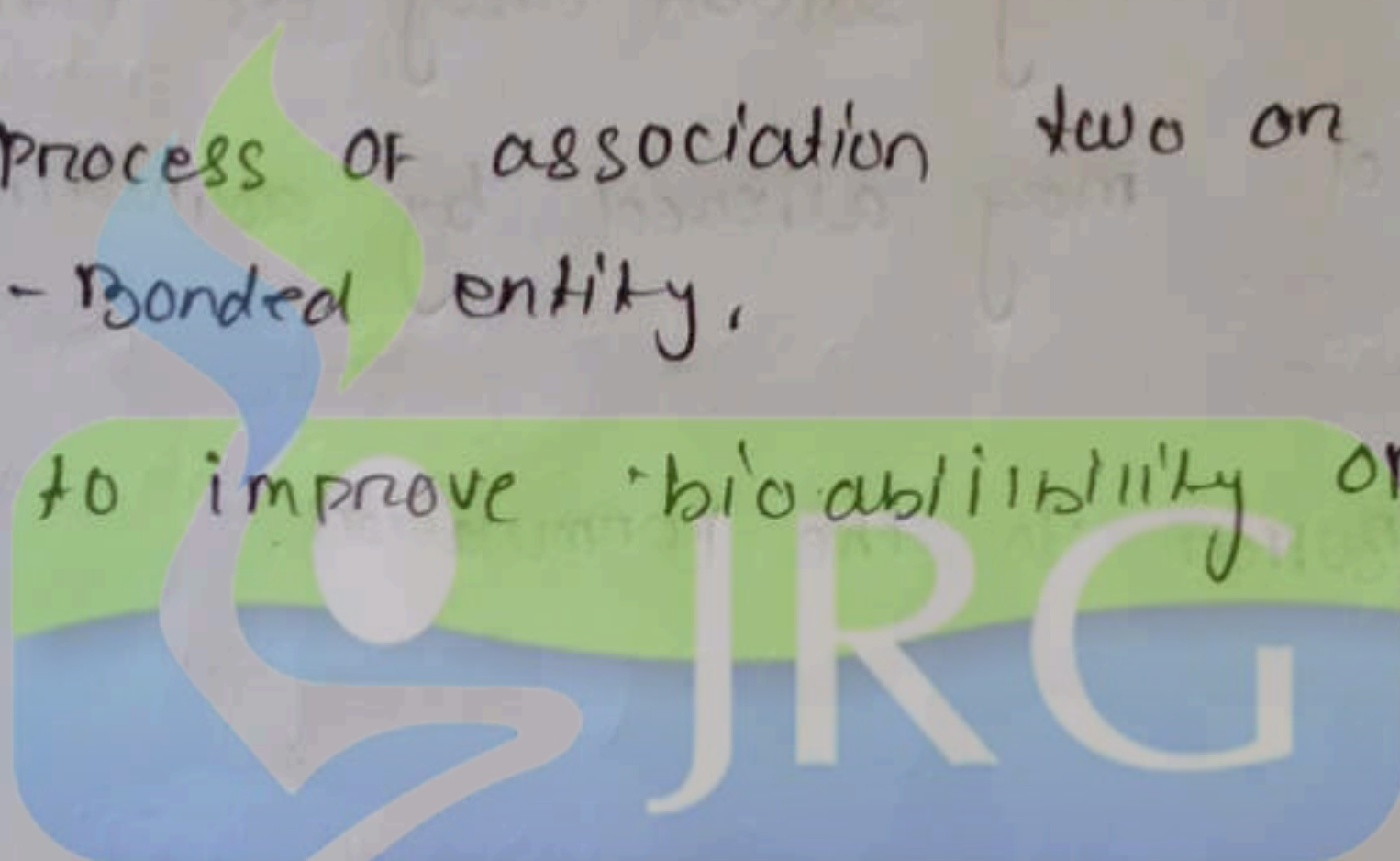
Ex - solubility of the opiltne with Sodium benzoate.

(vi) Complexation

→ It is a process of association two or more molecules to form a non-bonded entity.

→ It is used to improve bioavailability of poorly soluble drug

Ex → Chelates,



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(A) Contents of Indian Pharmacopoeia

- contents of Indian Pharmacopoeia is 2022 (9th edition)

→ It is published by Indian Pharmacopoeia Commission (IPC) Ministry of Health & Family Welfare Govt. of India.

→ It is effective from 1st december 2022.

→ Comprises - 4 volumes containing 3,152 monographs and 12 new general chapters.

Major contents includes:-

→ - General Notices and general chapters (testing method)

reagents, reference, standards.

- Monographs on drug substance, dosage forms and pharmaceutical Aids (A to Z)

→ Monographs on:

- vitamins, minerals, amino acid & fatty acids
- Phytopharmaceuticals and herbal products.
- Vaccines and immunosera.
- Blood & blood-related products.
- Allergen and radiopharmaceutical preparation.

→ Veg. veterinary monographs and diagnostic biologicals.

Special features:-

- Harmonised with USP, BP & EP.
- Promotes in vitro testing and updated analytical methods.
- Legally enforceable under the drugs and cosmetic Act (1940)

(5) Given,

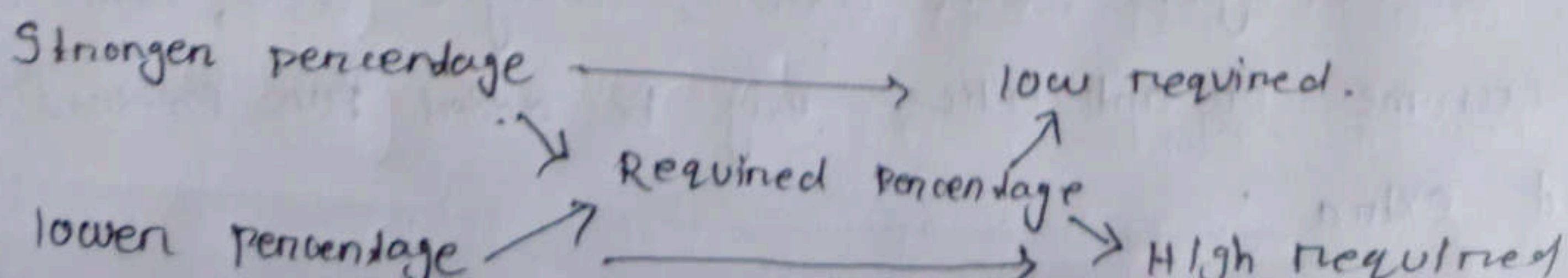
Volume required = 300ml

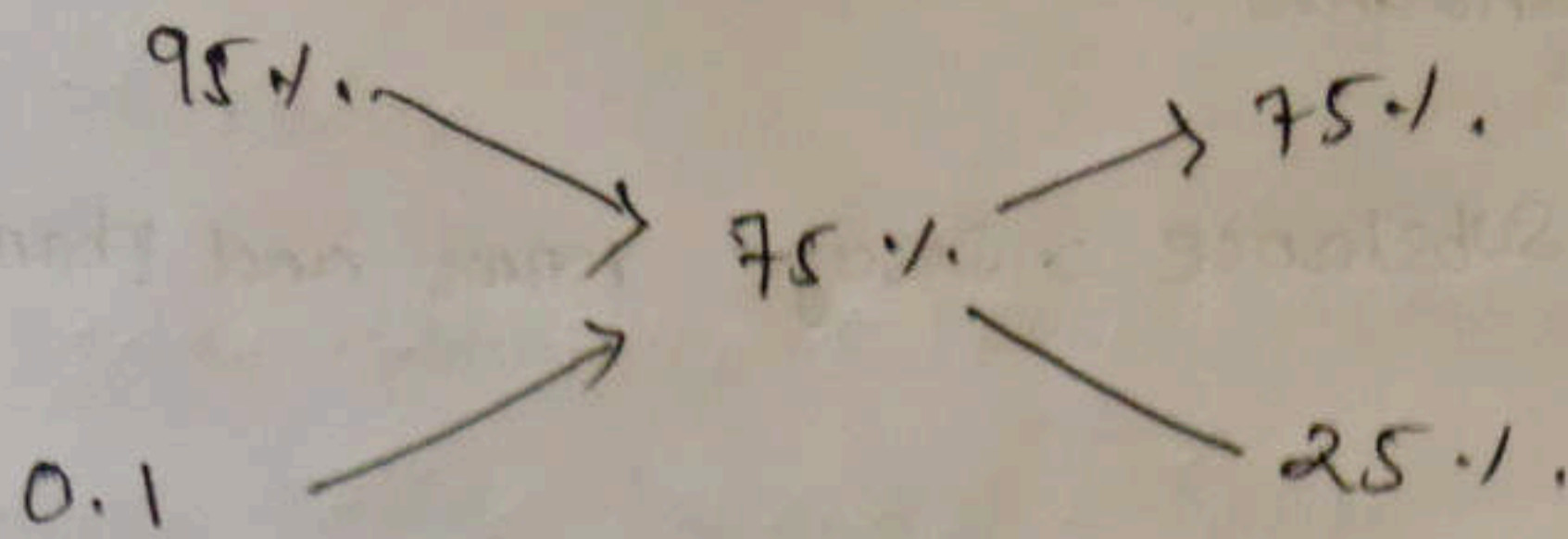
Volume of 1% required = 70%.

High percentage = 95%.

Low percentage = 0%.

According to alligation method.





$$\text{Volume of alcohol} = \frac{\text{Volume required} \times \% \text{ required}}{\text{Percentage used}}$$

$$= \frac{300 \text{ ml} \times 75}{95}$$

$$= 236.84 \text{ ml}$$

Hence the volume of alcohol is 236.84 ml.

(6) Dusting Powder

→ Dusting Powders are finely divided; free-flowing powders used for external application on the skin to provide a cooling, soothing & protective effect. They are generally applied to absorb moisture, reduce friction and prevent skin infection.

Characteristics

- Should be free from grittiness and irritant substances.
- must have good covering and adhesive properties.
- Should be non-toxic and chemically stable.

Common ingredients

- Base: Talc, kaolin, starch
- medicinal agents: zinc oxide, salicylic acid, boric acid.
- perfume or antiseptics may be added for pleasant odour and extra.

Examples:

- Talcum powder
- Antifungal dusting powder containing clotrimazole or miconazole.

Uses

- To keep skin dry and smooth
- To prevent rashes, infections and irritation.

(7) Flocculated

→ In this type of suspension the particles form a network like structure on flocculation.

→ Due to smaller particles (higher size) the sedimentation rate is high.

→ Re-dispersion is easily done by agitation

→ Bio-availability is low

→ Supernatant liquid is clear.

→ Suspension is not pleasing in appearance.

→ It is stable.

Deflocculated

→ In this type of suspension the particle exists as separate entity

→ Due to small particles the sedimentation rate is slow.

→ Re-dispersion is difficult by agitation (hard cake)

→ Bio-availability is high

→ Supernatant liquid is not clear.

→ Suspension is pleasing in appearance.

→ It is very less stable.

(8) Therapeutic Incompatibilities

→ Therapeutic incompatibility may be the result of prescribing certain drugs to the patient with the intention to produce a specific degree of action but the nature or intensity of the action produced is different from that intended by the prescriber.

Causes of Therapeutic Incompatibilities

It may be occur due to

- overdose / improper dose of a single drug.
- improper dosage form
- contraindicated drug.
- synergistic and antagonistic drug.

Example of overdose.

Codeine Phosphate 500 mg

Direction for Pharmacist

- ~~make for Pharmacist.~~
- make powders.
- Send much to powders.
- 1 dose to be taken at bed time.

In the above prescription; physician write 500 mg (0.5 gm) instead of 5 mg of codeine phosphate.

Example of drug interaction

Tetracycline Hydrochloride - - - - - 250gms.

Direction for Pharmacist

- make capsule send such 10 capsules.
- Take 1 capsules every 6 hrs with milk

→ Now in the above prescription dose is alright but the direction is wrong tetracycline should not be given with milk because the calcium that present in milk inactivates the action of tetracycline.

(9)

Creams

→ These are semi-solid preparation in which one or more medicines are dissolved in emulsion base (w/o, o/w) or in water soluble bases.

Eg - Vanishing cream (o/w emulsion) / aqueous cream
Cold cream (w/o emulsion) (oil in cream)

→ These are prepared using fusion method.

Fusion method

→ This method involve heat and sweatable for waxy material and hard bodies and for these ointments bases which contain solid ingredient having different melting point melt substances by using decreasing order of their melting point.

Step

Takes the waxy base



Melt using water bath



High melting point base first ; mix low melting

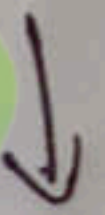
point bases it .



Dissolve .



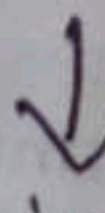
Add small volume phase in large vol . phase .



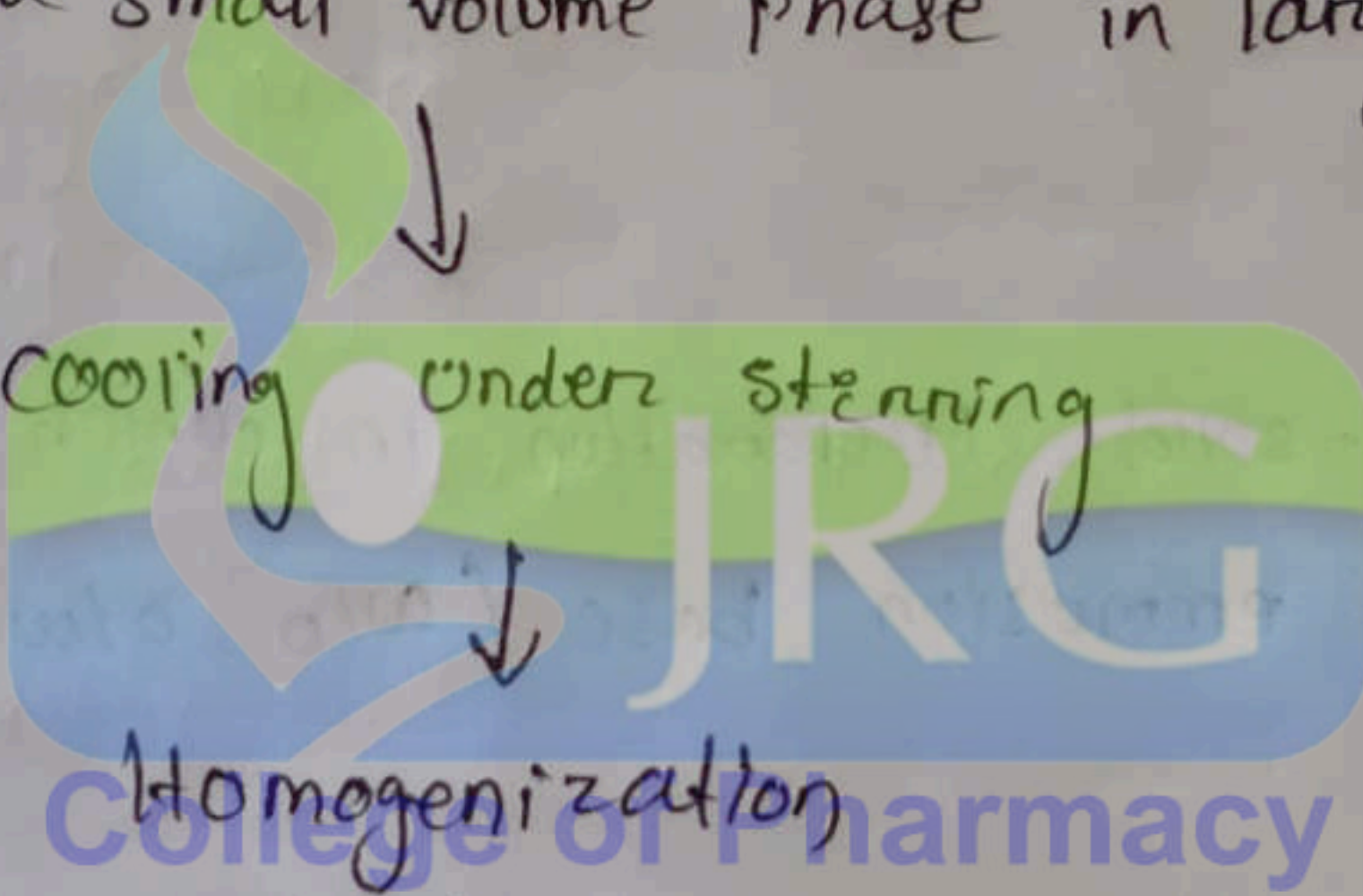
Cooling under stirring



Homogenization



Filling .



(Q III) EMULSION

Part - III

An emulsion is a biphasic liquid dosage form in which two immiscible liquid are mixed together to form a stable emulsion with the help of emulsifying agent.

E.g. : Vanishing, Cream, Gel, Lotion.

Advantages

- > More rapid absorbed.
- > Sustained release medication.
- > Mask unpleasant taste.
- > Improved bio-availability.
- > Easy to produce and scale up.
- > High encapsulation efficiency.
- > More Economic.

Disadvantages

- > Chances of cracking emulsion.
- > Dose accuracy decrease.
- > Unstable emulsion.

Types

(i) Oil in Water (O/W)

These are those types of emulsion in which oil is a dispersed phase and water is continuous phase.

Ex: Milk, Cream, Lotions.

(ii) Water in oil (W/O)

These are those type of emulsion in which water is mixed in oil or water is dispersed phase and oil is continuous phase.

Ex: Butter, Cold cream.

Preparation of Emulsion

- 1) Dry gum method.
- 2) Wet gum method.
- 3) Bottle method.

1) Dry gum method

→ In this method the oil is first triturated with gum with a little amount of water to form the primary emulsion.

↓
The trituration is continued till a 'creaking' sound is heard and a thick white cream is formed.

↓
Once the primary emulsion is formed the remaining quantity of water is slowly added to form the final emulsion.

∴ Ratio used [4:2:1] [oil : water : gum]

(2) Wet gum method

In this method firstly gum and water are triturated together to form a mucilage.

↓
The required quantity of oil is then added gradually in small portions through trituration to form the primary emulsion.

↓
Remaining quantity of water is added to make the final emulsion.

∴ Ratio used [4:2:1] [oil : water : Gum]

(3) Bottle Method :-

→ used to prepare emulsion of volatile oils or substance having very low viscosities.

Part gum / acacia is placed in a dry bottle.

↓
Part of oil are added

↓
Shake the mixture thoroughly after capping.

↓
A volume of water (approx. equal to oil) is added in portions.

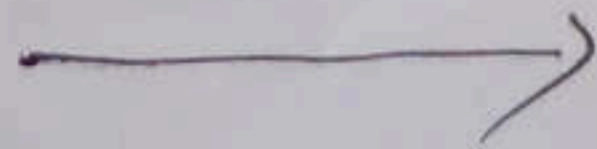
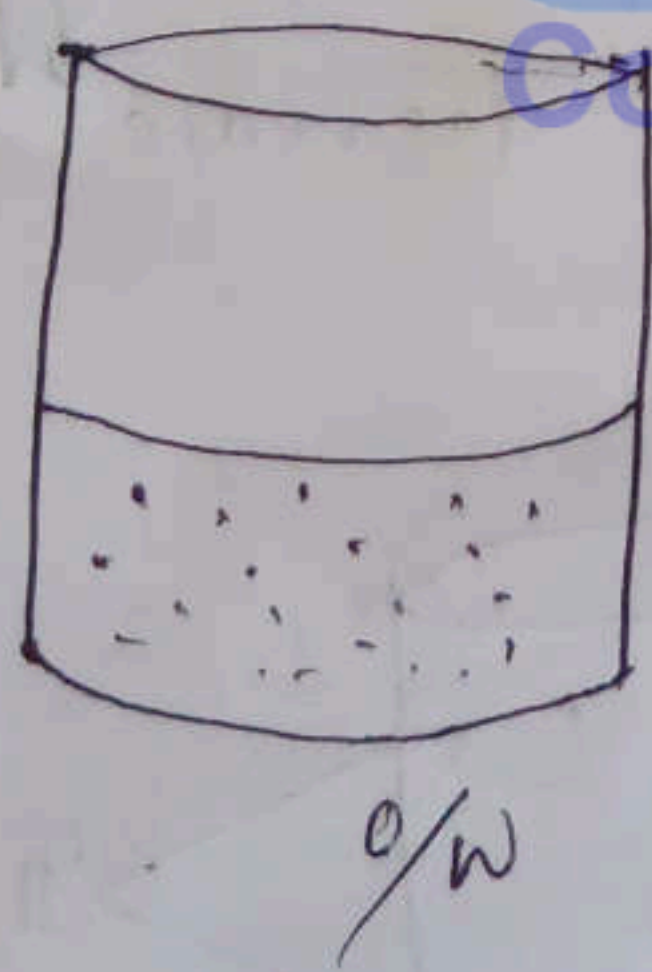
↓
Again shake the mixture thoroughly until the primary emulsion is formed.

↓
Dilute it with proper volume of water.

Stability problems and methods to overcome

1) Coalescence

The oily particles (Dispersed phase) because of sticky nature attract each other and they aggregate to form big particles.



Oily particles aggregated.

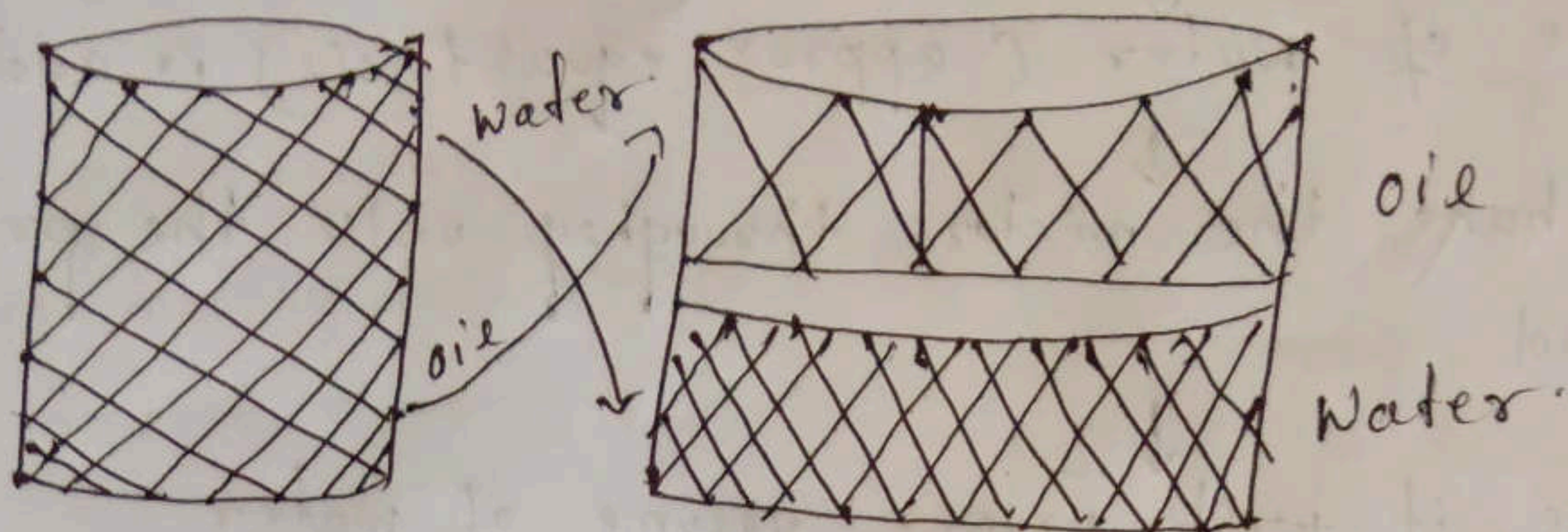
Overcome

-> Suitable emulsifying machinery should be employed in the preparation.

-> Precaution should be undertaken while adding emulsifying agent.

(2) Breaking (cracking)

Due to improve mixing of oil and water in emulsion, emulsion get separated into two layers oil and water.
→ It is also occurred due to improper ratio of oil & water.

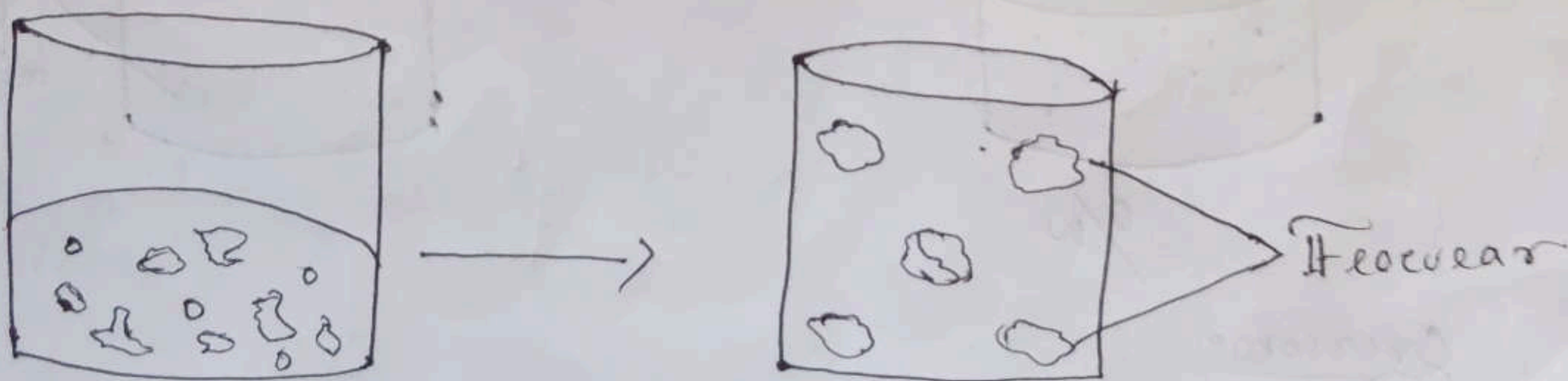


Overcome

- More emulsifying agents should be added in the preparation.
- The temp. at which the emulsion are store should be under control.
 -) Regulate the conc. of disperse phase.

(3) Flocculation

In this, due to increased surface free energy particles get aggregated to form flocs to decrease surface area.



Overcome

A high energy barrier exist in the presence of high charged on the dispersed droplets.

4)

Creeping

It is a reversible phenomenon in which droplets of dispersed phase come together or deposit at the surface of the emulsion.

Overcome?

The viscosity of continuous phase can be improved by adding viscosity enhancers.

→ The density difference b/w the two phases should be reduced.

→ The emulsion should be stored in a cool place at a low temperature.

5) Phase Inversions

In this the phase of emulsion gets inverted

$o/w \rightarrow w/o$ / $w/o \rightarrow o/w$

It happens due to mixing problem or by choosing wrong dispersed phase during formulation.

Overcome

Add adequate quantity of preservative in the preparation.

→ Suitable preservative for each oil and aqueous phase should be used.

INCOMPATIBILITY

- When two or more ingredients are mixed together to prepare a medicine and on undesired change takes place which affect the physical, chemical and therapeutic properties of medicament then the phenomenon is termed as incompatibility.
- Incompatibilities are usually unintentional.

Incompatibilities may occur during:

- Compounding
- Formulation
- Manufacturing

- Packaging
- Dispensing
- Storage
- Administration

Incompatibilities can Affect:

- Safety of medicament
- Efficacy of product
- Appearance of medicine
- Purpose of medicament

Types of Pharmaceutical incompatibilities

- ① Physical incompatibility
- ② Chemical incompatibility
- ③ Therapeutic incompatibility

Physical incompatibility

When two or more than two substances are combined together and a physical change takes place which results in the formation of an unacceptable product, then this phenomenon is known as physical incompatibility.

- Physical incompatibility involves interaction between two or more substances which leads to change in colour, taste, viscosity or appearance of the product.
- The changes that occur due to physical incompatibility are usually visible and can be corrected by taking proper action.

Example of physical incompatibility

- Immiscibility
- Insolubility
- Precipitation
- Liquefaction

immiscibility

oil and water immiscible with each other, but they can be made miscible by emulsification.

Ex:

| | |
|------------------|---------|
| • Castor oil | — 15 ml |
| • Water | — 60 ml |
| Make an emulsion | |

Now in the above prescription castor oil is immiscible with water to overcome this incompatibility an emulsifying agent is used to make a good emulsion.

insolubility

insolubility takes place when a drug is insoluble in a particular solvent.

example:

| | |
|--------------------|-----------|
| Ephedrine Sulphate | — 0.25 gm |
| Menthol | — 0.2 ml |
| Liquid paraffin | — 30 ml |

Now the above prescription ephedrine Sulphate is not soluble in liquid paraffin but anhydrous ephedrine is soluble in it, Hence ephedrine Sulphate is substituted with anhydrous ephedrine in the above prescription to make a clear solution.

Precipitation

A drug in a solution may be precipitated, if it is insoluble in the solvent in which it is added.

example:

- Resins are insoluble in water, when it is added in the water it gets precipitated.
- It can be prevented by adding a suitable thickening agent.

Liquifaction

When two or more solid having low melting point are mixed then get converted into liquid.

Example

- gt medicament containing menthol, thymol, camphor, phenol etc mixed together, they gets converted in to liquid.
- To prevent liquefaction, ingredients should be either dispensed separately or may be mixed with enough quantity of absorbent powder.

3) Factor influencing dermal penetrating drug:-

→ These are the factor which may effect the permeation class penetration of drugs.

→ They are classified into 2 types:-

(i) Biological factor

(ii) Physiological factor

(i) Biological factor:-

These are those factors which are related to body and effect the penetration.

- Skin condition

- Skin age

- Blood flow

- Resonal skin sites

- Skin metabolism

- Skin hydration

Skin condition!

- There are various skin related factors which may affect the drug permeation.

ex → Age, disease, climate, injury.

→ Absorption is greater in young skin than old.

→ Injured skin have great penetration.

Skin age!

- It is an important factor in drug absorption like children have more absorption of drug than adult to skin.

→ Drug absorption also tends to give more toxic effect in children compare to adults.

Blood flow!

- If the blood flow reduces then it increases the penetration of drug. As it increases the time of contact, so blood absorb more drug.

Resonal skin sites:

- It is also depends on the thickness of skin which various different places.

ex → Thinner skin, like facial skin have more penetration than thicker skin like palm & feet.

Skin metabolism!

- skin have the ability to metabolise some drug which may affect the drugs efficacy and absorption.

→ skin metabolises about high percent of topically applied blood.

ex → steroidal hormones.

Skin hydration!

- It is a condition when skin get saturated with water and skin tissue, swapp softness, wrinkles.
- so, it increases the rate of drug permeation.

(ii) Physiological chemical factors:-

These are those factor which has related to physical and chemical properties of drugs.

- (1) Temp. and pH
- (2) Diffusion coefficient
- (3) Drug concentration
- (4) Partition coefficient
- (5) molecular size & shape
- (6) percutaneous enhans

(1) Temp. & pH:

- Temp. is directly proportional to drug penetration, so if temp. increases the penetration.

→ unionised molecule have great penetration.

- Drugs with pH b/w 4.5-5.0 mostly below 5 are based for drug penetration through skin.

1) Diffusion coefficient?

- It mainly depends on nature and state of the drug.

2) Drug concentration?

- It mainly based on the conc. gradient.
- High conc. of drugs have more penetration than the normal conc.

3) Partition coefficient?

- It tells us about the nature of drugs either it is lipophilic or hydrophilic.

→ Hydrophilic drugs have more penetration.

4) Molecule size and shape?

- The smaller the size of molecules the greater will be its penetration rate.

5) percutaneous Enhancer?

- These are those substances which are basically used to enhance the absorption of drugs through skin,
ex → Acetone.

OINTMENT?

- These are the semi-solid preparation that are intended to be applied on the skin or certain mucous membrane.
- Their consistency is such that they easily spread on the skin.

ee → Li aloclno ointment.

- It is of 3 types
 1. Hydrophylic
 2. Emulsifying
 3. water soluble ointment
- It can be prepared by using trituration and fusion methods.

Semi-solid dosage form can be prepared by using following methods.

1. Trituration method
2. Fusion method

Trituration Method!

- It is widely used method.
- If large amount of liquid have to add in the base then this is sweetable.

Step-1!

- we have to reduce the size of drugs and make a fine powder i.e. size reduction.
- Now decrease the particle size of powder via trituration.
- add small amount of liquid.
- Now add sweetable base and add their required excipient via trituration.
- Now add remaining base to finalise weights.
- Now perform homogenisation to reduce sizes, make semi solid more stable and effective, fined it store it.

FUSION METHOD :-

This method involve heat and sweatable for waxy material and hard bodies and for those ointments bases which contain solid ingredient having different melting point. Melt substances by using decreasing order of their melting point.

Step-1

