B.PHARMA
1ST SEMESTER
PHARMACEUTICS-I
(BP103T)

PHARMACEUTICS-I MODEL PAPER

SECTION A

VERY SHORT ANSWERS TYPE QUESTIONS (10 × 2 = 20)

1. Define the term "Compendia"?

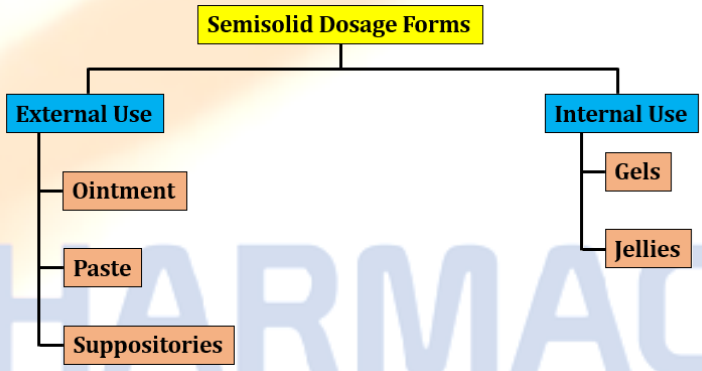
Answer

Compendia

- A compendium is defined "as a comprehensive listing of the Food and Drug Administration-approved drugs and biologicals (or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium - for example, a compendium of anti-cancer treatment)."

2. Classify Semi-solid dosage forms.

Answer



3. Design the formula for Calamine lotion.

Answer

Formula for Calamine Lotion

S. No.	Ingredients	Quantity Given	Quantity Taken
1.	Calamine	15 gm	3 gm
2.	Zinc Oxide	5 gm	1 gm
3.	Bentonite	3 gm	0.6 gm
4.	Sodium citrate	0.5 gm	0.1 gm
5.	Liq. Phenol	0.5 ml	0.1 ml
6.	Glycerin	5 ml	1 ml
7.	Purified water	Upto 100 ml	Upto 20 ml

4. Explain sedimentation volume.

Answer

Sedimentation Volume

- Sedimentation volume is a ratio of the ultimate volume of sediment (Vu) to the original volume of sediment (VO) before settling.

$$F = V u / Vo$$

where,

Vu = final or ultimate volume of sediment

Vo = original volume of suspension before settling

5. Give any two examples of gelling agents.

Answer

Example of Gelling agents

a. Carbopol
b. Sodium CMC

6. Enlist editions of Indian Pharmacopoeia.

Answer

Editions of Indian Pharmacopoeia

Edition	Year	Volume
1st	1955	1
2nd	1966	1
3rd	1985	2
4th	1996	2
5th	2007	3
6th	2010	3
7th	2014	4
8th	2018	4
9th	2022	4

7. Calculate the number of tablets may be prepared from 5 kg of aspirin? If, a tablet generally contains 325 mg of aspirin.

Answer

Total weight of raw aspirin = 5kg = 5000gm
1gm = 1000mg
5000gm = 50,00,000 mg
No. of tablets prepared from 5kg of aspirin = 50,00,000/325 = 15385

8. Classify bases used in suppositories.

Answer

Bases used in Suppositories

Oleaginous (fatty) base	Cocoa butter (Theobroma oil), Synthetic fats, Hydrogenated palm kernel oil
Aqueous base	Glycerinated gelatin (14% gelatin + 70% glycerine + Water), Soap glycerine, Polyethylene glycol (Macrogol).
Emulsifying base	Massa esterinum, Witepsol, Massupol

9. Outline the handling of prescription.

Answer

Handling of Prescription

The following steps are to be followed during handling of a prescription for compounding and dispensing:

- Receiving
- Reading and checking

- Collecting and weighing the material
- Compounding, labeling and packing

10. Calculate the dose for a child of 5 years old whose surface area is 1.5m2 and adult dose is 40mg.

Answer

$$\textbf{Dose for child} = \frac{Body\ surface\ area\ of\ child}{Body\ surface\ area\ of\ normal\ adult} \times adult\ dose$$

$$\textbf{Dose for child} = \frac{1.5}{1.73} \times 40$$

Dose for child = 34.68mg

SECTION B

LONG ANSWERS TYPE QUESTIONS (2 × 10 = 20)

1. Explain pharmaceutical incompatibilities in detail with examples.

Answer

Incompatibilities

- It is the result of prescribing or mixing two or more substances which are antagonist in nature and an undesirable product is formed which may affect the safety, purpose or appearance of the preparation.
- Incompatibilities are usually unintentional.
- It may occur in vitro between drugs & other components during preparation, storage or administration.
- Incompatibility may be:
  1. Pharmaceutical /Physical Incompatibility
  2. Therapeutic Incompatibility
  3. Chemical Incompatibility

Pharmaceutical Incompatibilities

- A visible physical change takes place.
- An unacceptable, non-uniform, unpalatable product is formed.
- Difficult to measure an accurate dose.
- Result of insolubility & immiscibility, precipitation, liquefaction, Adsorption and complexation of solid materials.
- Can be corrected by applying pharmaceutical skill.

Correction (Physical incompatibilities):

By one or more methods:

1. Order of mixing
2. Alteration of solvents
3. Change in the form of ingredients
4. Alteration of volume
5. Emulsification and addition of suspending agent,
6. Addition, substitution or omission of therapeutically inactive substances.

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1. Immiscibility:

- It is the result of the mixture of two or more immiscible liquid or an immiscible solid with a liquid.
- Acceptable liquid product can be obtained by emulsification or solubilization.

Rx

Olive oil 30ml
Water up to 120ml
Make an emulsion
Use a suitable emulsifying agent

2. Insolubility:

- Liquid preparation with indiffusible solids (e.g. Sulphamethoxasole, Phenacetin, Zinc oxide, calamine etc.)
- A suspending agent is required to uniform distribution of the solids in the liquid phase for sufficiently long time so as to facilitate accurate measurement of dose.

Rx

Sulphamethoxazole	4.0g
Trimethoprim	0.8g
Na- CMC	0.5g
Purified water qs to	100ml

Prepare a solution.

- Sulphamethoxazole &Trimethoprim are indiffusible in water.
- To make them diffusible a suspending agent is used.
- Insoluble Powders such as Sulphur, certain corticosteroids and Antibiotic is not get wetted with water & non–distributed in vehicle & hence wetting agents such as Saponins & Polysorbates are added for uniform distribution of it in vehicle.
- Insoluble non-wetted drug powders + water + wetting Agent (polysorbates/saponins)

3. Precipitation:

- A solubilized substance may precipitate from it solution if a non solvent for the substance is added to the solution.
  - Alcoholic solution of resins + water = precipitated resins
  - Aqueous dispersion of hydrophilic colloids (polysaccharide mucilage + high conc. of alcohol or salts = precipitated colloids
- But significant amount are tolerated if well diluted and added in small amount with vigorous stirring.

4. Liquefaction:

- Certain low melting point solids sometimes liquefy when mixed together due to the formation of eutectic mixture or liberation of water.
- E.g., if any 2 of the following medicaments are combined together, they form a eutectic mixture: Menthol, Thymol, Camphor, Phenol, Salol, Naphthol and chloral hydrate.

- Correction:-
  1. The eutectic forming ingredient may either be dispensed separately.
  2. These may be mixed separately with enough quantity of adsorbent powder like magnesium carbonate or Kaolin to form free flowing product.
  3. Alternately, if liquefaction has already occurred, the liquid may be adsorbed on a surface of sufficient quantity of powder, filled into capsule and dispensed.

  Example:

  Rx

Menthol	2.0g
Camphor	2.0g
Ammonium carbonate	20.0g

  Make a powder.
- In this case, if the ingredients are mixed together, they shall liquefy due to formation of a eutectic mixture.
- Hence, to dispense them in the form of a powder, it is necessary to mix them separately with sufficient quantity of a suitable adsorbent like magnesium carbonate.
- The three mixture then mix together to obtain a powder.

2. Illustrate the methods of preparation of emulsions, their stability problems, and methods to overcome these problems.

Answer

Methods of Preparation of Emulsions

1. Trituration method

A. Dry Gum Method

1. Measure the required quantity of oil in a dry measure and transfer it into a dry mortar.
2. Add the calculated quantity of gum acacia into it and triturate rapidly so as to form a uniform mixture.
3. Add required quantity of water and triturate vigorously till a clicking sound is produced and the product becomes white or nearly white due to the total internal reflection of light. The emulsion produced at this stage is known as primary emulsion.
4. Add more of water to produce required volume.

Proportion of oil, water and gum acacia required for different types of oils

Type of oil	Examples	atio of oil : Water : Gum
Fixed oil	Castor oil Almond oil Arachis oil Cod-liver oil	4 : 2 : 1
Volatile oil	Turpentine oil	2 : 2 : 1

	Peppermint oil Cinnamon oil	
Mineral oil	Liquid Paraffin	3 : 2 : 1

B. Wet Gum Method

1. Calculate the quantity of oil, water and gum required for preparing the primary emulsion.
2. Powder the gum acacia in a mortar. Add water and triturate t with gum so as to form a mucilage.
3. Add the required quantity of oil in small portions with rapid trituration until a clicking sound is produced and the product becomes white or nearly white. At this stage the emulsion is known as primary emulsion.
4. Add more of water in small portions to the primary emulsion with trituration to produce the required volume. Stir thoroughly so as to form a uniform emulsion.
5. Transfer the emulsion to a bottle, cork, label and dispense.

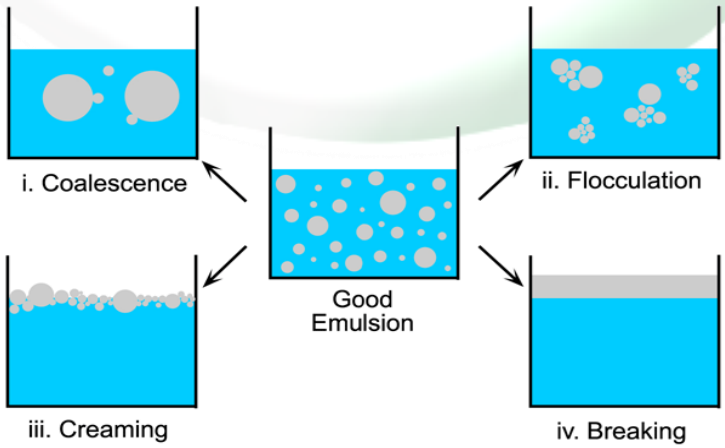
2. Bottle method

- Bottle method is used for the preparation of emulsions of volatile and other non-viscous oils. The proportion of oil water gum is 2:2:1.

1. Measure the required quantity of the oil and transfer into a large bottle Add the required quantity of powdered gum acacia.
2. Shake the bottle vigorously, until the oil and gum are mixed thoroughly
3. Add the calculated amount of water all at once.
4. Shake the mixture vigorously to form a primary emulsion.
5. Add more of water in small portions with constant agitation to produce the required volume.

Stability Problems and methods to overcome these problems

- ✓ Flocculation
- ✓ Creaming or sedimentation
- ✓ Aggregation or coalescence
- ✓ Phase inversion



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A. Flocculation

- Neighboring globules come closer to each other and form colonies in the continuous phase. This aggregation of globules is not clearly visible.
- This is the initial stage that leads to instability.
- Flocculation of the dispersed phase may take place before, during or after creaming.
- The reversibility of flocculation depends upon strength of interaction between particles as determined by:
    - the chemical nature of emulsifier,
    - the phase volume ratio,
    - the concentration of dissolved substances, specially electrolytes and ionic emulsifiers.
- The extent of flocculation of globules depends on
    (a) globule size distribution.
    (b) charge on the globule surface.
    (c) viscosity of the external medium.

(a) Globule size distribution

- Uniform sized globules prevent flocculation.
- This can be achieved by proper size reduction process.

(b) Charge on the globule surface

- A charge on the globules exert repulsive forces with globules in the neighboring.
- This can be achieved by using ionic emulsifying agent, electrolytes etc.

(c) Viscosity of the external medium.

- If the viscosity of the external medium is increased, the globules become relatively immobile and flocculation can be prevented.
- This can be obtained by adding viscosity improving agents (bodying agents or thickening agents) such as hydrocolloids or waxes.
- Flocs slowly move either upward or downward leading to creaming.
- Flocculation is due to the interaction of attractive and repulsive forces, whereas creaming is due to density differences in the two phases.

B. Creaming

- Creaming is the upward movement of dispersed droplets of emulsion relative to the continuous phase (due to the density difference between two phases).
- Creaming is of two types, upward creaming and downward creaming.
- **Upward creaming,** is due to the dispersed phase is less dense than the continuous phase. This is normally observed in o/w emulsions. The velocity of sedimentation becomes negative.
- **Downward creaming** occurs if the dispersed phase is heavier than the continuous phase. Due to gravitational pull, the globules settle down. This is normally observed in w/o emulsions.

- Since creaming involves the movement of globules in an emulsion, Stokes' law can be applied.

Creaming is influenced by,

- Globule size
- Viscosity of the dispersion medium
- Difference in the densities of dispersed phase and dispersion medium.

Creaming can be reduced or prevented by:

- Reducing the particle size by homogenization. Doubling the diameter of oil globules increases the creaming rate by a factor of four.
- Increasing the viscosity of the external phase by adding the thickening agents such as methyl cellulose tragacanth or sodium alginate.
- Reducing the difference in the densities between the dispersed phase and dispersion medium.

C. Coalescence

- Coalescence is the process by which emulsified particles merge with each to form large particles.
- This type of closed packing induces greater cohesion which leads to coalescence.
- Coalescence is observed due to:
  - ✓ Insufficient amount of the emulsifying agent.
  - ✓ Altered partitioning of the emulsifying agent.
  - ✓ Incompatibilities between emulsifying agents.
- Phase volume ratio of an emulsion has a secondary influence on the stability of the product and represents the relative volume of water to oil in emulsion.
- The major factor to prevent coalescence is the mechanical strength of the interfacial film.

D. Breaking

- Breaking is the destroying of the film surrounding the particles.
- Separation of the internal phase from the external phase is called breaking of the emulsion.
- This is indicated by complete separation of oil and aqueous phases, is an irreversible process, i.e., simple mixing fails. It is to re-suspend the globules into an uniform emulsion.
- In breaking, the protective sheath around the globules is completely destroyed and oil tends to coalesce.

E. Phase Inversion

- This involves the change of emulsion type from o/w to w/o or vice versa.
- When we intend to prepare one type of emulsion say o/w, and if the final emulsion turns out to be w/o, it can be termed as a sign of instability.

3. Describe various methods for preparation of ointments?

Answer

Methods for preparation of Ointments

A. Preparation of Ointments by Trituration:

This method is applicable in the base of a liquid present in a small amount.

a. Solids are finely powdered are passed through a sieve (# 250, # 180, #125).
b. The powder is taken on an ointment-slab and triturated with a small amount of the base. A steel spatula with a long, broad blade is used. To this additional quantities of the base are incorporated and triturated until the medicament is mixed with the base.
c. Finally, liquid ingredients are incorporated. To avoid loss from splashing, a small volume of liquid is poured into a depression in the ointment and thoroughly. Incorporated before more is added in the same way. Splashing is more easily controlled in a mortar than on a tile.

Example

Whitfield ointment (Compound benzoic acid ointment B.P.C.)

Formula:

Benzoic acid, in fine powder – 6 gm
Salicylic acid, in fine powder – 3gm
Emulsifying ointment – 91gm

Method: Benzoic acid and salicylic acid are sieved through No. 180 sieves. They are mixed on the tile with a small amount of base and levigated until smooth and dilute gradually.

B. Preparation of Ointments by Chemical Reaction:

- Chemical reactions were involved in the preparation of several famous ointments of the past, e.g. Strong Mercuric Nitrate Ointment of the 1959 B.P.C.
- An ointment containing free iodine
  - Iodine is only slightly soluble in most fats and oils. Lodine is readily soluble in a concentrated solution of potassium iodide due to the formation of molecular complexes KI-I2, KI-2I2, KI-3I2 etc.
  - These solutions may be incorporated in absorption-type ointment bases.

Example: Strong Iodine Ointment.
Iodine – 4 g
Woolfat-4 g
Yellow soft paraffin – 76 g
Potassium iodide – 4 g
Water – 12 g

Procedure

a. KI is dissolved in water. I_2 is dissolved in it.
b. Wool fat and yellow soft paraffin are melted together over a water bath. The melted mass is cooled to about 40°C.
c. I_2 solution is added to the melted mass in small quantities at a time with continuous stirring until a uniform mass is obtained.

d. It is cooled to room temperature and packed.

C. Preparation of Ointments/Cream by Emulsification:

- An emulsion system contains an oil phase, an aqueous phase and an emulsifying agent. For o/w emulsion systems the following emulsifying agents are used:
  (i) Water-soluble soap
  (ii) Cetyl alcohol
  (iii) Glyceryl monostearate
  (iv) Combination of emulsifiers: triethanolamine stearate + cetyl alcohol
  (v) Non-ionic emulsifiers: glyceryl monostearate, glyceryl monooleate, propylene glycol stearate

- For w/o emulsion creams the following emulsifiers are used:
  - Polyvalent ions e.g magnesium, calcium and aluminium are used.
  - Combination of emulsifiers: bees wax+ divalent calcium ion
- The viscosity of this type of creams prevent coalescence of the emulsified phases and helps in stabilizing the emulsion.

Example: Cold cream

Procedure

1. Water immiscible components e.g. oils, fats, waxes are melted together over the water bath (70°C).
2. Aqueous solution of all heat-stable, water-soluble components are heated (70°C).
3. Aqueous solution is slowly added to the melted bases with continuous stirring until the product cools down and a semi-solid mass is obtained.

SECTION C

SHORT ANSWERS TYPE QUESTIONS (5 × 7 = 20)

1. Explain Effervescent powders, Hygroscopic powders, and Eutectic mixtures with proper examples.

Answer

Effervescent Powders

- Pharmaceutical effervescent powders are a type of dosage form that contains a combination of active and inactive ingredients that effervesce when mixed with water, producing a fizzy and pleasant-tasting solution.

- The active ingredient in the powder can be a drug or a combination of drugs, and the inactive ingredients usually include a mixture of organic acids and carbonates.
- When the effervescent powder is dissolved in water, the acid and carbonate react to form carbon dioxide gas, causing the solution to fizz and bubble.

- This effervescence also increases the surface area of the drug, leading to faster dissolution and absorption in the body.
- Additionally, the effervescence can help mask the unpleasant taste of some drugs, making them easier to swallow.
- **Examples**
  - **Alka-Seltzer:** This effervescent powder contains aspirin, citric acid, and sodium bicarbonate and is commonly used for the relief of headaches, body aches, and fever.
  - **Eno:** Eno is a popular antacid effervescent powder that contains sodium bicarbonate, citric acid, and sodium carbonate. It is used for the relief of heartburn, acid indigestion, and upset stomach.
  - **Emergen-C:** This effervescent powder contains a combination of vitamins and minerals, such as vitamin C, vitamin B12, and zinc, that are dissolved in water to create a refreshing and fizzy drink. It is marketed as an immune system booster and energy enhancer.
  - **Zicam:** Zicam is an effervescent powder that contains zinc gluconate and is used for the treatment of colds and flu. It is dissolved in water to create a fizzy drink that is consumed orally.

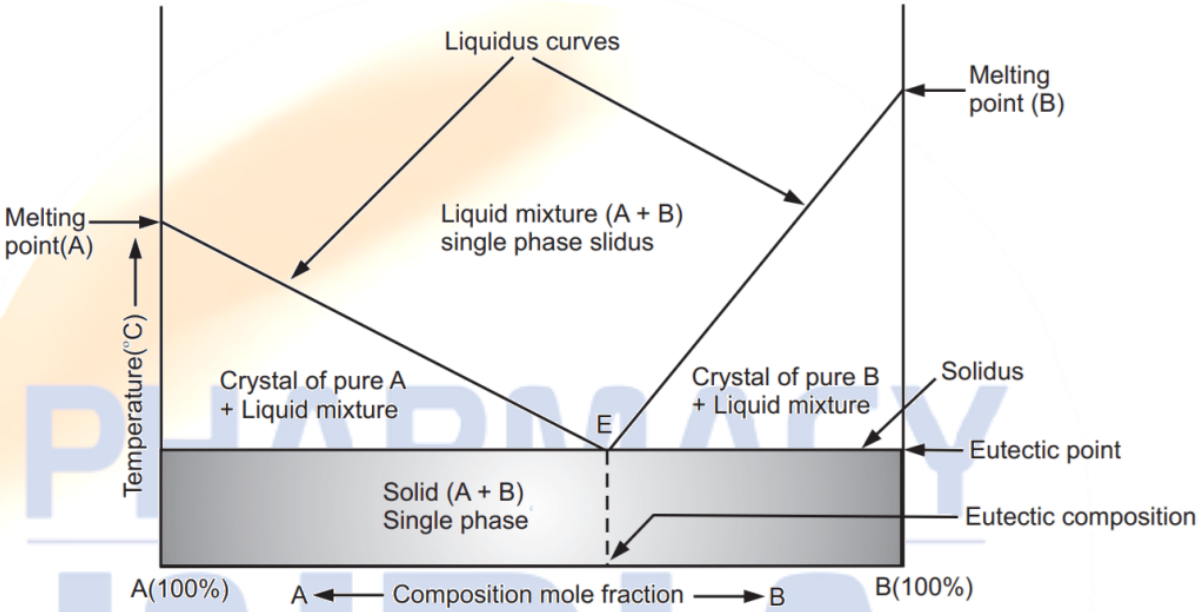
Hygroscopic Powders

- Hygroscopic powders have a property of absorbing moisture from the surrounding environment. When exposed to air, these powders can attract and retain water molecules, causing them to become damp or even dissolve.
- The absorption of moisture can lead to changes in the physical and chemical properties of the powder, such as altered particle size, texture, and stability.
- This property can pose challenges in the formulation and storage of hygroscopic drugs, as the absorbed moisture can affect the drug's potency, dissolution rate, and overall stability.
- To mitigate the hygroscopic nature of a powder, pharmaceutical manufacturers may take measures such as using desiccants in packaging or incorporating moisture-resistant coatings on tablets or capsules. These strategies help preserve the integrity and efficacy of the medication.
- **Examples** of such substances include ammonium citrate, pepsin, phenobarbitone, sodium bromide, sodium iodide, potassium citrate, zinc chloride etc. Such substances are usually supplied in granular from to expose less surface area to the atmosphere.

Eutectic Mixtures

- A two-component system containing a solid and liquid in which the two components are completely miscible in the liquid states and are completely immiscible in the solid-state.
- This is because the solid phase consists of pure components. This mixture is known as the eutectic mixture. The temperature at which such a system exists in the liquid phase is known as eutectic temperature.
- Above this temperature, the components are liquid and below this temperature they are solids. Physically eutectic systems are solid dispersions. Some examples of this type are thymol – salol, thymol – camphor, menthol – camphor, etc.

- The melting temperature of two substances A and B are plotted against mixture compositions. The curves separating the regions of A + Liquid and B + Liquid from regions of liquid AB are termed liquidus curves.
- The horizontal line separating the fields of A + Liquid and B + Liquid from A + B all solid is termed the solidus. Upon addition of B to A or A to B, their melting points are reduced.
- The point, E, where the liquidus curves and solidus intersect, is termed the eutectic point. At the eutectic point in this two-component system, all three phases, that is Liquid, crystals of A, and crystals of B, all exist in equilibrium.



- The eutectic point represents a composition (eutectic mixture composition) at which any mixture of A and B has the lowest melting point. Note that the eutectic is the only point on the diagram where this is true.
- At the eutectic point, the maximum numbers of allowable phases are in equilibrium. When this point is reached, the temperature must remain constant until one of the phases disappears. A eutectic is an invariant point. Below eutectic temperature, no liquid phase exists.

2. Demonstrate the parts of prescription with the help of a sample prescription.

Answer

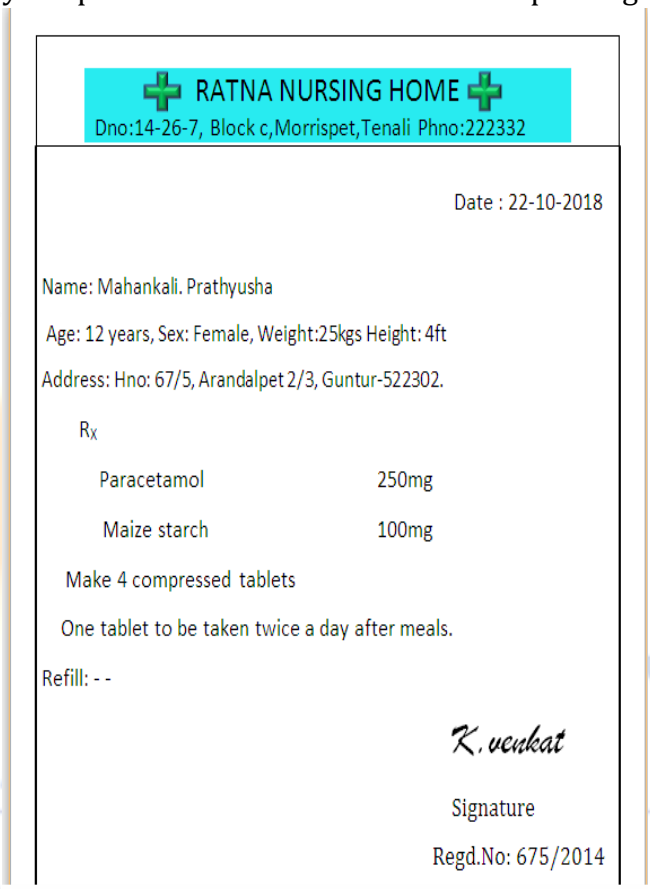
- A prescription is a written order from Registered Medical Practitioner ora Physician to a Pharmacist to compound and dispense a specific medication for the patient.

Parts of Prescription

❖ **Date:**

- Every prescription must bear the date on which the particular medicines are prescribed.
- This helps the pharmacist to keep day-day Patient's record in chronologic order which helps the pharmacist or a physician to refer the old case in future.

- To avoid misuse of the narcotic or other habitat forming drugs containing prescriptions by the patient a number of times for dispensing.



RATNA NURSING HOME
Dno:14-26-7, Block c,Morrispet,Tenali Phno:222332

Date : 22-10-2018

Name: Mahankali. Prathyusha

Age: 12 years, Sex: Female, Weight:25kgs Height: 4ft

Address: Hno: 67/5, Arandalpet 2/3, Guntur-522302.

R_X

Paracetamol 250mg

Maize starch 100mg

Make 4 compressed tablets

One tablet to be taken twice a day after meals.

Refill: - -

K. venkat

Signature

Regd.No: 675/2014

❖ Name, Age, Sex and Address of the patient:

- Name, Age, Sex and Address of the patient must be written on the prescription.
- Name helps the pharmacist to identify the correct Patients avoiding any chance of giving the medicine to a person other than the one it is dispensed for.
- Age of the patient becomes important in the case of the Pediatric(children) and Geriatric(old people) cases.
- Sex/Gender of the patient also plays major role in prescription because dose of drugs may also vary based on the sex/gender of the patient(as their abilities to metabolize/ response towards drugs may vary in many cases).
- Address of the patient is generally recorded to contact the person at the later stage or to deliver the medication personally.

❖ Superscription:

- This part of the prescription is represented by the symbol R_X.
- In the ancient times it is considered as a prayer to Jupiter the God of healing for the fast recovery of the patient.
- Now a days it is used as a abbreviation for the Latin term “Take Thou” which means “you take”.

❖ Inscription:

- This is considered as the main part of the prescription order.

- It contains the names and quantities of the prescribed ingredients.
- The name of each ingredient is written on a separate along with its quantity.

❖ **Subscription:**

- This part of the prescription contains directions of the prescriber to the pharmacist regarding the type and compounding of dosage form along with number of doses to be dispensed.
- This is important because dose of drug also depends on the type of the dosage form.

❖ **Signatura:**

- This part of the prescription contains directions to the patient regarding the administration of the drugs.
- It is generally represented as 'Sig' on the prescription.

3. Illustrate the various factors that affect the posology.

Answer

The Factors that affect the Posology

The factors affecting dose calculations are:

- Age
- Condition of patient
- Severity of the disease
- Tolerances
- Idiosyncrasy
- Route of administration
- Formulation used
- Drug interactions
- Rate of elimination

Factors	Description
Age	• The pharmacokinetics of many drugs changes with age. • So while determining the dose of an drug the age of an individual is of great significance. • Children and older people need lesser amount of dose than of adults because they are unable to excrete drugs to that extent. • Children can tolerate relatively larger amounts of belladonna, digitalis and ethanol, whereas elderly patients are sensitive to certain drugs e.g. hypnotics and tranquillizers which may produce confusion states in them.
Sex	• Women do not always respond to the action of drugs in the same manner as it is done to men. Morphine and barbiturates may produce more excitement in sedation in women. • Special care should be taken while drugs are administered during pregnancy, menstruation and lactation. • The strong purgatives such as aloes should be avoided during menstruation.

	• Similarly the drugs which may stimulate the uterine smooth muscle e.g. drastic purgatives, anti malarial drugs and ergot alkaloids are contra indicated during pregnancy.
Body Weight	• The average dose is mentioned in terms of mg per Kg or as a single dose for an adult weighing between 50-100 Kg. • However, the dose expressed in this fashion may not be applicable to obese patients, malnourished patients and children. • It should be calculated according to body weight.
Route of administration	• Intravenous doses are usually lesser than drugs of oral doses, because the drugs administered in intravenously since it enters the blood stream directly. • Due to this reason the onset of drug action is quick and it may enhance the chances of drug toxicity. • The effectiveness of drug formulation is usually controlled by the route of administration.
Time of administration	• The presence of food in the stomach delays the absorption of drugs. The drugs are rapidly absorbed in empty stomach. • So the amount of drug which is very effective on empty stomach may not be very effective during or after meals. • The irritating drugs are better tolerated if taken after meals. e.g. iron, arsenic and cod liver oil.
Environmental factors	• Daylight is a stimulant it enhances the effect of stimulant drugs and diminishes the effect of hypnotics whereas darkness is a sedative and hypnotics are more effective in darkness. • The amount of barbiturate required to produce sleep at day is much higher than the amount of barbiturate required to produce sleep at night. • Alcohol is better tolerated in winter than summer.
Emotional factors	• The personality and behavior of the physician may influence the effect of drug especially which are meant for psychosomatic disorder. • The females are more emotional than men and they require less dose of certain drugs.
Presence of Disease	• Drugs like barbiturates and chlorpromazine may produce unusually long effects in patients having liver cirrhosis. • Streptomycin is mainly excreted by kidney and may prove toxic if the kidney of the patient is not working properly.
Accumulation	• The drugs which are slowly administered may build up a sufficiently high concentration in the body and produce toxic symptoms if it is administered for a long time e.g. digitalis, emetine and heavy metals. • This occurs due to the accumulative effect of the drug.
Additive effects	• When the total pharmacological action of two or more drugs is equivalent to the sum of their individual pharmacological action, the phenomena is known as

	additive effect. • For example, combination of ephedrine and aminophylline in the treatment of bronchial asthma .

4. Describe the stability problems of Suspension and methods to overcome them.

Answer

Stability problems of Suspension and methods to overcome them

1. Particle size control
2. Wetting
3. Sedimentation
4. Brownian movement
5. Electokinetic
6. Aggregation

1. Particle size control:

- Particle size of any suspension is critical and must be reduced within the range.
- Too large or too small particles should be avoided.
- Larger particles will:
  - settle faster at the bottom of the container
  - particles > 5 um impart a gritty texture to the product and also cause irritation if injected or instilled to the eye
  - particles > 25 um may block the needle
  - Too fine particles will easily form hard cake at the bottom of the container.

2. Wetting of the particles

- Hydrophilic materials (talc, ZnO, Mg2CO3) are easily wetted by water while hydrophobic materials (sulphur , charcoal) are not due to the layer of adsorbed air on the surface.
- Thus, the particles, even high density, float on the surface of the liquid until the layer of air is displaced completely.
- The use of wetting agent allows removing this air from the surface and to easy penetration of the vehicle into the pores.
- However hydrophobic materials are easily wetted by non-polar liquids.

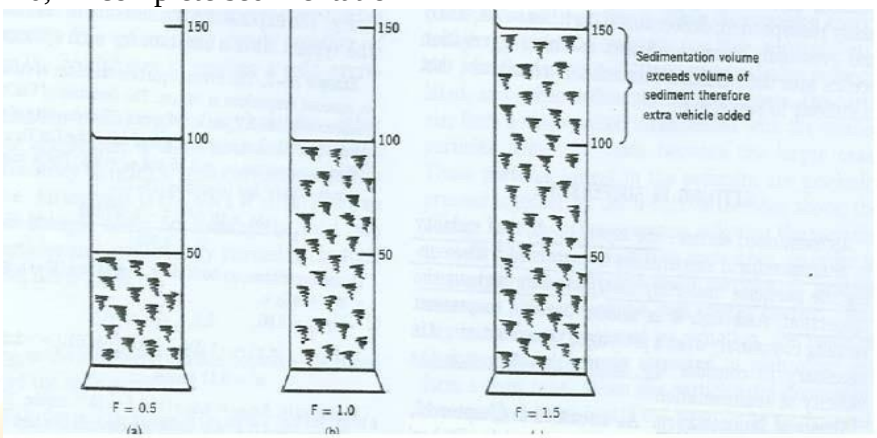
3. Sedimentation

- Flocculated suspension –
  - Initial state, F = 1.0
  - State of suspension on storage after some time F =0.6
- The extent of sedimentation is quantitatively expressed by two parameters:
- **Sedimentation volume (F)**

$$\mathbf{F} = \frac{Vu}{Vo} = \frac{\text{Final volume of sediment}}{\text{Initial volume of sediment}}$$

  - F is denoted as sedimentation volume.it is a dimension less number.
  - If sedimentation volume measured in measuring cylinder then the equation can be written as Hu/Ho where H represents height of sediment.

- F = 1, when there is no sedimentation which is a desirable property of an ideal suspension.
- F = 0 to 1 → higher the sedimentation volume better the physical stability.
- F = 0, → complete sedimentation



- **Degree of flocculation (B)**

$$B = \frac{F}{Fa} = \frac{\text{Sedimentation volume of flocculated system}}{\text{Sedimentation volume of deflocculated system}}$$

Or

$$B = \frac{Vu}{Va} = \frac{\text{ultimate sediment volume of flocculated system}}{\text{ultimate sediment volume of deflocculated system}}$$

- If F =Fa then B will be one.
- If the B value is nearer to one then the suspension does not represent a flocculated suspension. It indicates that the system under study is a deflocculated system.
- In general, higher the value of B the greater be the physical stability.
- It is a destructive method of testing because the flocculated system is converted to a deflocculated by the addition of deflocculating agents such as electrolytes.

Theory of sedimentation

- The rate of sedimentation of particles can be expressed by the stokes law, using this equation

$$\textbf{Rate of sedimentation (v)} = d^2(p_1\text{-}p_2)\, g/18\eta$$

where,

d= diameter of the particles, cm (m)
P_1= density of the dispersed phase, g/cm^3 (kg/m^3)
P_2= density of the dispersion medium, g/cm^3(kg/m^3)
N= viscosity of the dispersion medium
G=acceleration due to gravity, 980.7 cm/s^2

- **Stokes law is applicable in the following conditions**
  - (i) Particles should be spherical, but in the suspension, particles are largely irregular.
  - (ii) Particles should settle freely and independently such a condition can be satisfied by dilute suspension (0.5 to 2% solids per 100mL. But most suspensions contain dispersed solids in concentrations of 5 to 10 % or higher.
  - (iii) Applicable to deflocculated suspension where in particles settle independently.

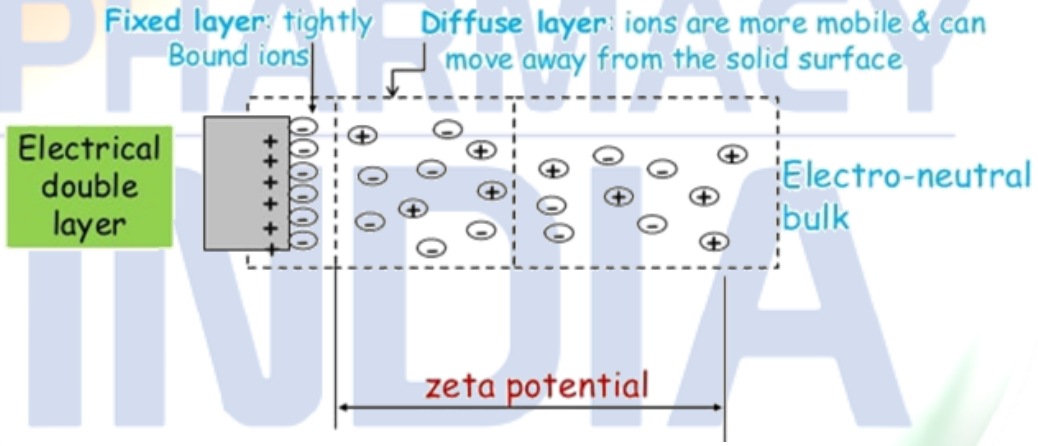
(iv) If particle size is 2-5µm, Brownian movement occurs, which prevents sedimentation.

4. Brownian Movement (Drunken walk)

- Brownian movement of particle prevents sedimentation by keeping the dispersed material in random motion.
- Brownian movement depends on the density of dispersed phase and the density and viscosity of the disperse medium.
- The kinetic bombardment of the particles by the molecules of the suspending medium will keep the particles suspending, provided that their size is below critical radius (r).
- Brownian movement can be observed,
  - If particle size is about 2 to 5mm,
  - When the density of particle & viscosity of medium are favorable.

5. Electrokinetic Properties

- Zeta Potential : The zeta potential is defined as the difference in potential between the surface of the tightly bound layer (shear plane) and electro-neutral region of the solution.



- As the potential drops off rapibdly at first, followed more gradual decrease as the distance from the surface increases.
- This is because the counter ions close to the surface acts as a screen that reduce the electrostatic attraction between the charged surface and those counter ions further away from the surface.
- Zeta potential has practical application in stability of systems containing dispersed particles .
- Since this potential, rather than the Nernst potential, governs the degree of repulsion between the adjacent, similarly charged, dispersed particles.
- If the zeta potential is reduced below a certain value , the attractive forces exceed the repulsive forces, and the particles come together. This phenomenon is known as flocculation.

5. Illustrate various solubility enhancement techniques.

Answer

Solubility Enhancement Techniques

Methods	Description
pH adjustment	• Most of the drugs are either weak acids or weak bases. • The aqueous solubility of a weak acid or a weak base is greatly influenced by the pH of the solution. Hence, the solubility of drug that is either a weak base or a weak acid may be altered by adjusting the pH of the solution. • The solubility of a weak base can be increased by lowering the pH of its solution whereas the solubility of a weak acid can be improved by increasing the pH. • e.g. Gatifloxacin is insoluble in water at higher pH but the same drug get solubized at the lower pH and attends maximum solubility below the pH of 5. Hence the parenteral preparation of Gatifloxacin is formulated at the pH of 3.5 to 5.5.
Cosolvency	• Cosolvency is the technique of increasing the solubility of poorly soluble drugs in a liquid by addition of a solvent miscible with the liquid in which the drug is also highly soluble. • Cosolvents such as ethanol, glycerol, propylene glycol or sorbitol decreases the interfacial tension or alter the dielectric constant of the medium and increases the solubility of weak electrolytes and non-polar molecules in water. • Example: Formulation of Diazepam injection using propylene glycol as cosolvent.
Complexation	• In certain cases, it may be possible to increase the solubility of a poorly soluble drug by allowing it to interact with a soluble material form a soluble intermolecular complex. • It is however essential that the complex formed is easily reversible so that the free drug is released readily during or before contact with biological fluids. • e.g. Interaction of Iodine with Povidone to form water soluble complex and preparation of Itraconazole injection by forming inclusion complex of itraconazole with hydroxy propyl beta cyclodextrin.
Surface active agents	• A surface active agent is a substance which reduces the interfacial tension between the solute and the solvent to form thermodynamically stable homogeneous system. • The mechanism involved in this solubilization technique involves micelle formation and due to formation of stable system it is widely used in pharmaceutical formulations. • Examples include polysorbate-80, polyoxyl 40

	stearate, sodium lauryl sulphate and PEG-40-Castor oil (Cremophor). • e.g.: Fat soluble vitamins A, D, E and K, antibiotics like griseofulvin and chloramphenicol and analgesics such as aspirin and phenacetin have been solubilized by using surface active agents.
Hydrotrophy	• Hydrotropism is the term used to describe the increase in aqueous solubility of a drug by the use of large concentrations (20% to 50%) of certain additives. • e.g.: Increase in solubility of caffeine and theophylline by addition of sodium benzoate and sodium salicylate respectively.
Microionization	• Surface area and particle size are inversely related to each other. Smaller the drug particle, larger the surface area and greater is the solubility. A decrease in particle size achieved through micronization, will result in higher solubilization of drug. • e.g.: Micronization of poorly aqueous soluble, but non-hydrophobic drugs such as griseofulvin and chloramphenicol results in enhanced solubility.
Solid Solution	• Solid solutions are prepared by melting of physical mixture of solute, a poorly water soluble drug and solid solvent, a highly water soluble compound or polymer followed by rapid solidification. • Solid solutions are also called as molecular dispersions or mixed crystals. • e.g.: Griseofulvin from succinic acid solid solution dissolves 6 to 7 times faster than pure griseofulvin and Digitoxin-PEG 6000 solid solution showed enhanced solubility.

6. Explain the development of profession of pharmacy in India.

Answer

Development of Profession of Pharmacy in India

- **Ancient Roots:** The origins of pharmacy in India can be traced back to ancient times when Ayurveda, the traditional system of medicine, was practiced. Pharmacy skills were an integral part of Ayurvedic practices, including the preparation of herbal medicines.
- **Colonial Era:** During the British colonial period, Western-style pharmacy education began to gain prominence. The first modern pharmacy institution in India, the Calcutta School of Pharmacy, was established in 1932. It aimed to provide education in pharmaceutical sciences along Western lines.
- **Post-Independence Expansion:** After India gained independence in 1947, there was a renewed focus on expanding and developing pharmaceutical education. The Pharmacy Act of 1948 was enacted to regulate the profession and education of

pharmacy in India.

- **Pharmacy Council of India:** The Pharmacy Council of India (PCI) was established in 1949 as the regulatory body responsible for maintaining the quality of pharmacy education and practice in the country. PCI played a pivotal role in standardizing pharmacy education and curriculum.
- **Growth of Institutions:** Over the decades, numerous pharmacy colleges and institutions were established across the country. These institutions offered programs such as Diploma in Pharmacy (D.Pharm), Bachelor of Pharmacy (B.Pharm), Master of Pharmacy (M.Pharm), and more recently, Doctor of Pharmacy (Pharm.D).
- **Advancements and Research:** With the advancement of science and technology, pharmacy education evolved to incorporate fields like pharmaceutical chemistry, pharmacology, pharmaceutics, clinical pharmacy, and more. Research in pharmaceutical sciences gained significance, contributing to the development of new drugs and healthcare innovations.
- **Global Recognition:** Indian pharmacists and pharmaceutical scientists began to contribute significantly to the global pharmaceutical industry. The country gained recognition as a hub for pharmaceutical research, development, and manufacturing.
- **Regulatory Changes:** The pharmacy education landscape has witnessed changes in curriculum, accreditation, and quality assurance processes. Regulatory bodies like the All India Council for Technical Education (AICTE) have also played a role in shaping pharmacy education.
- **Pharmacy Practice and Clinical Roles:** The concept of pharmacy practice and clinical pharmacy gained prominence, emphasizing the role of pharmacists in patient care, medication therapy management, and counseling.
- **Modernization and Technology:** Pharmacy education embraced modern technologies, such as e-learning, virtual laboratories, and online resources, enhancing the learning experience for students.
- **Global Collaboration:** Indian pharmacy institutions started collaborating with international universities, exchanging knowledge and expertise to stay current with global advancements.
- **Future Outlook:** The pharmacy education landscape in India continues to evolve, with a focus on research, innovation, and the integration of pharmaceutical sciences with healthcare delivery. Pharmacists are becoming more involved in patient care and public health initiatives.

7. Calculate the proportions may a manufacturing pharmacist mix 30%, 25%, 10%, and 6% zinc oxide ointments to produce a 15% ointment?

Answer

- Let the quantities of 30%, 25%, 10%, and 6% zinc oxide ointments required to produce 100g of 15% zinc oxide ointment be x, y, z, and w, respectively.
- Then, the amount of zinc oxide in each ointment can be expressed as follows:

  30% ointment: 0.3x
  25% ointment: 0.25y
  10% ointment: 0.1z
  6% ointment: 0.06w

- To produce 100g of 15% ointment, the total amount of zinc oxide required is:
  0.15 x 100g = 15g
- We can set up the following system of equations based on the amount of zinc oxide in each ointment:
  0.3x + 0.25y + 0.1z + 0.06w = 15 (equation 1)
  x + y + z + w = 100 (equation 2)
  We need to solve for x, y, z, and w.
- One possible method is to use substitution. From equation 2, we can express one of the variables in terms of the other three. For example, we can solve for w:
  w = 100 - x - y - z
  Substitute this expression for w into equation 1:
  0.3x + 0.25y + 0.1z + 0.06(100 - x - y - z) = 15
- Simplify and solve for one of the variables. For example, we can solve for x:
  0.24x + 0.19y + 0.04z = 3
- Similarly, we can solve for y, z, and w. One possible set of solutions is:
  x = 22.5g
  y = 35g
  z = 12.5g
  w = 30g
- Therefore, the proportions of 30%, 25%, 10%, and 6% zinc oxide ointments that the manufacturing pharmacist needs to mix to produce 100g of 15% zinc oxide ointment are 22.5g, 35g, 12.5g, and 30g, respectively.

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