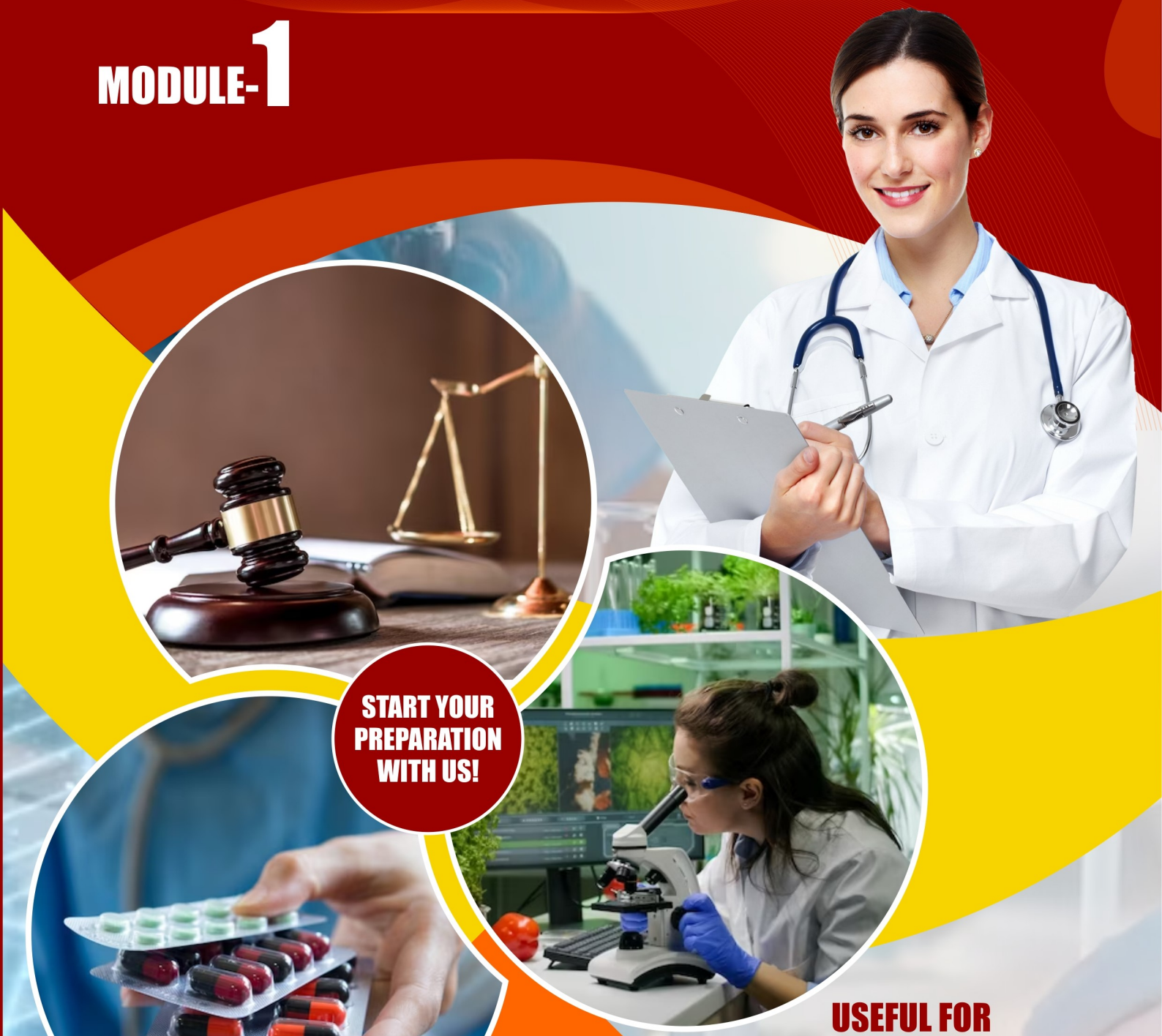
PHARMACY INDIA

PHARMACEUTICS

Pharmaceutical Technology I Physical Pharmacy I Pharmaceutical Engineering I Microbiology I Pharmaceutical Jurisprudence I Biotechnology

MODULE-1



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Chapter 1

TABLET

DEFINITION

- According to the Indian Pharmacopoeia: - Pharmaceutical tablets are solid, flat or biconvex dishes, unit dosage form, prepared by compressing a drug or a mixture of drugs, with or without diluents.

TYPES & CLASSES OF TABLET

Types of Tablets

Oral Tablets for ingestion	Tablets used in the oral cavity	Tablets administered by other route	Tablets used to prepare solution
❑ Compressed tablets ❑ Multiple compressed tablets ❑ Chewable tablets ❑ Sugar/chocolate-coated tablets ❑ Film-coated tablets ❑ Repeat action tablet ❑ Delayed action tablet & enteric coated tablet ❑ Controlled-release tablet	❑ Buccal & sublingual tablets ❑ Troches & lozenges ❑ Dental cones	❑ Implantable tablet ❑ Vaginal tablet	❑ Effervescent tablet ❑ Dispensing tablet ❑ Hypodermic tablet ❑ Tablet triturates

ORAL TABLETS FOR INGESTION

COMPRESSED TABLET

- Uncoated tablet intended to provide rapid disintegration & drug release.

MULTIPLE COMPRESSED TABLET (Layered tablets & Compression coated tablet)

Two components or three-layer tablets

- Tablets with in a tablet
- To produce repeat action & Prolonged action products
- Complete physical separation is required for stability purpose in case of three-layer tablets

CHEWABLE TABLET

- Intended to be chewed in mouth.
- Most commonly used chewable tablet in market for children.
- Example - "Chewable Aspirin tablet" Antacid tablets, Anthelminthics
- Disintegrant not required

SUGAR & CHOCLATE COATED

(2) Product Identification
(3) Production of more elegant product

- All coloring agents must be approved and certified by FDA.
- Two forms of colors are used in tablet preparation – FD &C and D & C dyes.
- These dyes are applied as solution in the granulating agent or Lake form of these dyes.

FLAVORING AGENTS

- For chewable tablet- flavor oil is used.

SWEETENING AGENTS

SWEETENERS	PROPERTIES
Cyclamate	Carcinogenic, 70 times sweeter than sugar
Mannitol	72 times sweeter than sugar, used in chewable tablets
Saccharine	Carcinogenic, 500 times sweeter than sugar
Aspartame	Non-Carcinogenic, 200 times sweeter than sugar
Neotame	Also known by the trade name Newtame, is a non-caloric artificial sweetener
Sucralose	It is an artificial sweetener and sugar substitute. The majority of ingested sucralose is not broken down by the body, so it is noncaloric.
Acesulfame potassium	Also known as acesulfame K or Ace K, is a calorie-free sugar substitute often marketed under the trade names Sunett and Sweet One.

TABLET COATING

- "Tablet coating is the application of coating material to the exterior of a tablet with the intention of conferring benefits and properties to a dosage form over the uncoated variety."
- As per I.P "Tablet coated with mixture of various substances such as resins, gums, inactive and insoluble fillers, sugars, waxes, etc."

WHY TO COAT?

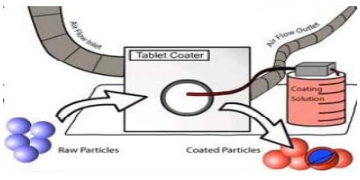
• Mask bitter taste • Protect the drug • Increase stability	• Mechanical stability • In element core	• Product identity • Mask unpleasant odour

TYPES OF COATING

Types of Tablet Coating	Equipments used in Coating
• Sugar coating • Film coating • Enteric coating	• Perforated coating pans • Standard coating pans • Fluidized bed coater

1. SUGAR COATING

- Sugar coating is the most conventional multistep coating process.
- As the name suggests, this process involves the application of sugar (sucrose) based coating solution to the tablets.
- Sugar coating involves following steps -
  - Sealing
  - Sub-coating
  - Syruping(smoothing)



$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

WEIGHT VARIATION

IP	% VARIATION	USP
Less than 85 mg	±10%	Weighing 130 mg or less
85mg – 250 mg	±7.5%	Weighing 130-324 mg
Greater than 250	±5%	Weighing 324 mg or more

CONTENT UNIFORMITY

- The potency of tablets is expressed in the terms of grams, milligrams, or micrograms of drug per tablet and is given as the label strength of the product.

DISINTEGRATION

Limits of Disintegration Test IP & USP

Tablet/ Capsule	Liquid	Disintegration Time
Uncoated tablet	Water (19-21°C)	15 minutes (USP – 30 min)
Sugar-coated tablet	Water	60 minutes
Film coated tablet	Water or 0.1N HCl	30 minutes
Dispersible and effervescent tablets	Water (19-21°C)	3 minutes
Enteric coated tablet	0.1N HCl with Phosphate buffer	3 hours (2hrs in GI fluid & 1hr in intestinal fluid)
Hard gelatin capsule	Water	30 minutes
Soft gelatin capsule	Wayer	60 minutes

DISSOLUTION

- Dissolution is the process by which a solid solute enters a solution.

Types of Dissolution Apparatus According to USP

USP Apparatus	Description	Rotating Speed	Dosage Form
Type 1	Rotating basket apparatus	50-120rpm	Conventional tablet, chewable tablet, controlled release
Type 2	Paddle apparatus	25-50rpm	Orally disintegrating tablet, chewable tablet, controlled release, suspension
Type 3	Reciprocating cylinder	6-35 rpm	Controlled release, chewable tablet
Type 4	Flow through cell	N/A	ER, poorly soluble API, Powder, granules, microparticles, implants
Type 5	Paddle over disk	25-50 rpm	Transdermal
Type 6	Rotating cylinder	NA	Transdermal
Type 7	Reciprocating disc	30rpm	CR

Types of Dissolution Apparatus According to IP & BP

Apparatus	BP	IP
Type 1	Rotating basket apparatus	Paddle apparatus

Chapter 3

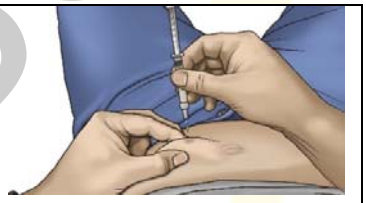
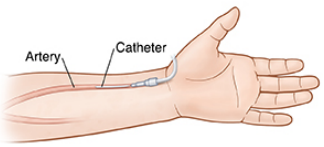
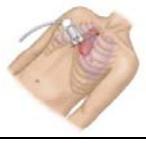
PARENTERALS

INTRODUCTION

- The term derived from Greek word 'Para' outside & 'Enterone' intestine.
- Parenterals are sterile solutions or suspension of drug in aqueous or oily vehicle.
- Parenteral drugs are administered directly in to the veins, muscles or under the skin, or more specialized tissues such as spinal cord.
- B.P.: "Parenteral preparations are sterile preparations intended for administration by injection, infusion or implantation into human or animal bodies"

PARENTERAL ROUTES

- The term parenteral literally means to avoid the gut (gastrointestinal tract) and refers to any route of administration outside of or beside the alimentary tract.

Subcutaneous injections	• Administer medications below the skin into the subcutaneous fat outside of the upper arm • Given at a 45-degree angle, 2 5 - or 26-gauge needle, 3/8 to5/8-inch length.	
Intramuscular injections	• Care must be taken with deep IM injections to avoid hitting a vein, artery, or nerve. • Typical needle is 22- 25-gauge ½- to 1-inch needle. • IM injections are administered at a 90-angle volume limited to less than 3 ml.	
Intravenous injections or Infusions	• Fast-acting route because the drug goes directly into the bloodstream, often used in the emergency department and in critical care areas. • Intravenous (IV) injections are administered at a 15- to 25-degree angle.	
Intra-arterial injection	• The injection is given directly in to the artery.	
Intracardiac injection	• These are given into the heart muscle or ventricle at the time of emergency only.	

Chapter 6

SUPPOSITORIES

INTRODUCTION

- Suppositories are ovoid or conical medicated solids intended for insertion into one of the several orifices of the body, excluding mouth. This term derives from the Latin term suppositum meaning to place under
- It is solid dosage form meant to be inserted into body cavity like rectum, urethra, vagina, where they melt or soften to release the drugs and produce their local or systemic effect.

IDEAL PROPERTIES

- Should be completely non-toxic & non-irritant.
- Should be compatible with a broad variety of drugs.
- Should be non-sensitizing.
- Should have wetting & emulsifying properties.
- Should be stable on the storage i.e., does not change colour, Odor or drug release pattern.
- Should have **acid value below 0.2.**
- Should have **iodine value less than 7.**
- Should have "saponification value" ranges from **200 to 245.**
- The water no. is high i.e., high percentage of water can be incorporated in it.

TYPES OF SUPPOSITORIES

Types of Suppositories	Size of Suppository	Shape of Suppository
Rectal Suppositories	Adult- 2gm, Children – 1 gm	Torpedo shape
Vaginal Suppositories (Pessaries)	Vaginal tablets & Capsules 3 to 5 gm	Conical shape
Urethral Suppositories (Bogies)	Male -4gm, Female 2gm, length 60-75 mm	Pencil shaped
Nasal Suppositories	Weight 1 gm, length 9-10 cm	Cylindrical shape
Ear Cones (Aurinaries)	Weight 1 gm	Bullet shape

SUPPOSITORIES FORMULATION

Formulation of Suppositories

Drug

- Should have sufficient absorption from particular body cavity (if for systemic use).

Additives

- Suppository bases plays important role in maintaining their shape, solidity & also play important role when inserted into the body cavity.
- There are large number of bases used but Theobroma oil, glycero gelatin base & polyethylene glycol fulfill the above-mentioned requirements.

SUPPOSITORY BASE

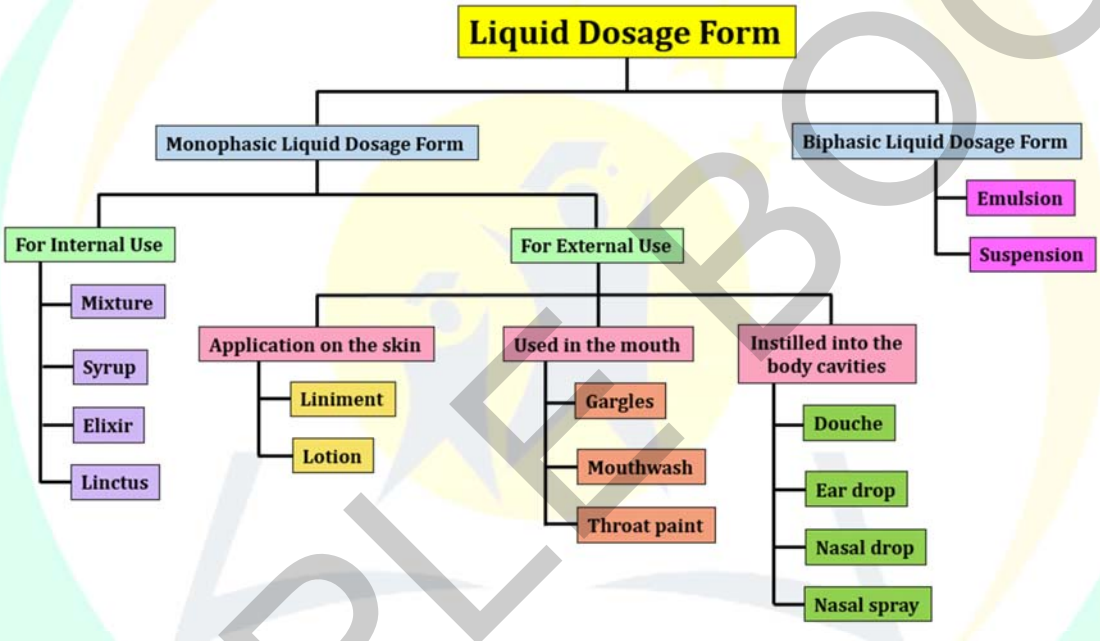
Chapter 10

MONOPHASIC LIQUID DOSAGE FORM & SEMI SOLID DOSAGE FORM

MONOPHASIC LIQUID DOSAGE FORM

Introduction

- Dosage forms meant either for internal, external or parenteral use may be sub-classified into monophasic or biphasic liquid dosage forms. The monophasic liquid dosage forms consist of either true or colloidal solutions or solubilised system.



Liquid Dosage forms	Description
Aromatic water	Solution of aromatic material in water.
Syrup	Aqueous solution containing sugar. • Simple syrup I.P contains 66.7% w/w sucrose in purified water (100 ml) • Simple syrup USP contains 85%w/v or 64.74% w/w sucrose in purified water (100 m.)
Spirit	Solution of aromatic material in alcohol
Injection	Prepared to be sterile and pyrogen free and intended for parenteral administration.
Elixir	They are sweetened hydroalcoholic solution
Linctuses	They are generally prescribed for relief of cough
Liniment	They are alcoholic and oily liquid preparations, they are intended for external application by rubbing onto the affected area.
Lotions	They are aqueous, alcoholic or oily liquid preparation, they are intended for external application without rubbing onto the affected area.
Drops	Liquid preparation meant for oral, nasal or for eye administration.
Collodions	They are liquid preparation containing in a mixture of ethyl ether and ethanol.

Chapter 12

COSMETIC TECHNOLOGY

SHAMPOO

1. **Surfactants:** anionic surfactant , example :- SLS
2. **Conditioning agent**: improve manageability, feel and lustre of hair. E.g., lanolin, mineral oil, egg albumin, amino acids, lecithin and herbal extract shikakai & henna.
3. **Thickening agent**: make shampoos viscous so they are easy to pour and handle. E.g., gum, CMC, HPMC, PVA, carbopol 934P.
4. **Chelating agent**: prevents deposition of calcium and magnesium salts of soap on hairs. E.g., disodium edetate, polyphosphates, citric acid etc.
5. **Anti-dandruff agent**: zinc pyridinium thiol–N-oxide (ZPTO), selenium sulphide, bithinol, resorcinol etc.

TYPES OF SHAMPOOS

- Liquid shampoo
- Powder shampoo
- Cream shampoo
- Gel shampoo

EVALUATION OF SHAMPOOS

- Changing power
- Foaming ability
- Eyes irritation potential

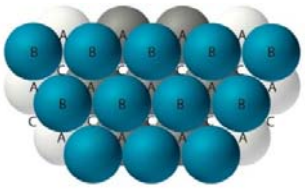
LIPSTICK

- Moulded sticks composed of colouring materials dispensed in a blend of fatty bases (oil and waxes).

Formulation

1. **Bases:** waxes and oil
   - **Waxes:** employed to obtain desired melting point viscosity. E.g., Hard paraffin (1-5%), ozokerite wax (1-10%), carnauba wax (1-3%), white beeswax (5-20%), lanolin (5-15%), cetyl alcohol (2-3%) (Emollient action).
   - **Oil:** Used for-
     1. Dispensing insoluble pigments.
     2. Dissolving eosin dye.
     3. Provide a thin film to the lips.

     E.g., Castor oil (30 -40%), Liquid paraffin (1-5%), IPM (2-3%).
2. **Bromomixture:** When a product is having a high staining property desired, bromo acid like tetrabromo fluorescence (2-3%) is used.
3. **Color mixture:** Insoluble dyes and lake colors are used as main color. E.g., Ti02 is used to modify the shades of basic pigment.
4. **Antioxidants:** BHA, BHT, Propyl gallate



closest or rhombohedral packing (26% porosity)

most open, loosest, or cubic packing (48% porosity)

4. Flow properties

A. Angle of repose-

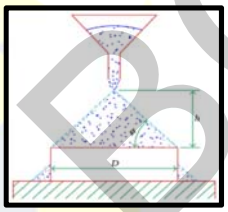
- It is the maximum angle possible between surface of the pile of the powder and horizontal plane.
- Methods used for determination-
  - **Fixed cone method**

    $\theta = \tan^{-1} \frac{h}{r}$

    where, $\theta \rightarrow$ angle of repose

    r = radius of the base of pile

    h = height of pile
  - **Rotating cylinder method**
  - **Tilted box method**



Angle of repose	Powder flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

B. Carr's consolidation index

- A volume of powder is filled into a graduated glass cylinder and repeatedly tapped for a known duration. The volume of powder after tapping is measured.

$$\textbf{Carr's index} = \frac{\textbf{Tapped density} - \textbf{bulk density}}{\textbf{Tapped density}} \times 100$$

- **Also known as compressibility.**
- It is the relationship between powder flowability and % compressibility.
- In free-flowing powder the bulk density and tapped density would be close in value. Therefore, the Carr's index would be small.
- In poor flowing powder where there are greater interparticle interactions, the difference between the bulk and tapped density observed would be greater. Therefore, the carr's index would be larger.

C. **Hausner's ratio-** It predicts the flow properties of powder by using interparticle friction.

$$\textbf{Hausner's ratio} = \frac{\textbf{Tapped density}}{\textbf{Bulk density}}$$

Flow of powder	Carr's index	Hausner's ratio
Excellent	5-15	1-1.11
Good	12-16	1.12-1.18
Fair	18-21	1.19-1.25

	Pyridinium compounds	Dodecyl pyridinium chloride
Anionic	Alkali soap	Potassium stearate, Triethanol amine acetate
Non-ionic	Hydrophobic	Span (Sorbitan fatty acid ester)
	Hydrophilic	Tweens (Polysorbates)
	Polyoxy ethylene mono laurate → 20 Polyoxy ethylene mono myristate → 40 Polyoxy ethylene mono palmitate → 60 Polyoxy ethylene mono oleate → 80	L → tween 20 M → tween 40 P → tween 60 O → tween 80
Ampholytic		N-dodecylalanine

Hydrophilic Lipophilic Balance (HLB) system

- Developed by Griffin in 1949.
- **Definition:** The hydrophile lipophile balance (HLB)system is an arbitrary scale for expressing the hydrophilic and lipophilic characteristics of an emulsifying agent.
- Agents with HLB value of 1-8 are lipophilic and suitable for preparation of w/o emulsion,
- Those with HLB value of 8-18 are hydrophilic and good for o/w emulsion.

HLB value		Application
1 -3	-	Anti-foaming agent.
3 -6	-	**W/O emulsifying agents**.
7 -9	-	Wetting agents.
8 -18	-	**O/W emulsifying agents**.
13 -15	-	Detergents.
15 -18	-	Solubilizing Agents.

HLB values of some common Surface Active Agents

Surface Active Agents	HLB Value
Oleic acid	1
Polyoxyethylene sorbitol beeswax derivative (G-1706)	2
Sorbitan tristearate	2.1
Glyceryl monostearate	3.8
Sorbitan monooleate (Span 80)	4.3
Diethylene glycol monostearate	4.7
Sorbitan monolaurate (Span 20)	8.6
Polyethylene lauryl ether (Brij 30)	9.5
Polyoxyethylene monostearate (Myrj 45)	11.1
Triethanolamine oleate	12
Polyoxyethylene sorbitan monooleate (Tween 80)	15
Polyoxyethylene sorbitan monolaurate (Tween 20)	16.7
Polyoxyethylene lauryl ether (Brij 35)	16.9
Sodium oleate	18
Potassium oleate	20
Sodium lauryl sulfate	40

Detergency

- Phenomenon of removal of foreign materials from solid surface by the use of surfactants.
- HLB value: 13-16

Chapter 8

KINETICS AND DRUG STABILITY

INTRODUCTION

- Chemical kinetics is the study of the rate of chemical changes taking place during chemical reactions.
- In pharmaceutical formulations, it is the study of –
  - physical and chemical reactions in drugs and dosage forms
  - factors influencing the rate of these chemical reaction
  - accelerated stability testing and prediction of shelf life of formulations.

Rate of Reaction

- The rate of chemical reaction is defined as the velocity with which a reactant or reactants undergo chemical change. The rate of reaction is given by:

$$\pm\frac{dc}{dt}$$

- The + or – sign indicates an increase or decrease respectively in concentration dc with a time interval dt.

Rate constant or order of reaction

- Acc. To law of mass action, the rate of a chemical reaction is proportional to the product of the molar concentration of the reactants each raised to a power usually equal to the number of molecules, a and b of the substances A and B undergoing reaction.

$$aA + bB \rightarrow \text{products}$$

- the rate of reaction is given by:

$$\text{Rate} = -\frac{1}{a}\frac{d\,[A]}{dt}$$

$$\text{Rate} = -\frac{1}{a}\frac{d\,[A]}{dt}$$

$$\text{Rate} = k\,[A]^a\,[B]^b$$

$$k \rightarrow \text{rate constant}$$

- **Order of reaction →** the sum of the powers of the concentration terms involved in the rate equation. Thus, the order of the above reaction is (a + b).

Molecularity of the reaction

- The molecularity of a reaction refers to the number of molecules, atoms or ions reacting in an elementary process to give the reactants.
- **Unimolecular reaction –** If only one type of molecule undergoes a change to yield the product.

$$Br_2 \rightarrow 2Br$$

- **Bimolecular reaction –** two types of molecules are stoichiometrically involved in reaction.

$$H_2 + I_2 \rightarrow 2HI$$

- **Half-life –** It is the time required for the concentration of the reactant to reduce to half of its initial concentration.
- **Shelf life (t_{90}) –** It is defined as the concentration of the reactant to reduce to 90% of its initial concentration.

Chapter 9

SOLUBILITY AND RELATED PHENOMENON

INTRODUCTION

- The concentration of substance in a saturated solution at a certain temperature.
- **Saturated solution –** it contains the maximum amount of solute that a solvent can dissolve at a particular temperature.
- **Unsaturated solution –** it contains the dissolved solute in a concentration less than that required for complete saturation at a particular temperature.
- **Supersaturated solution –** it contains more concentration of solute in the dissolved state that would normally dissolve at a definite temperature.

Solubility expressions

1. Percent weight by weight (% w/w) which is the number of grams of solute dissolved in 100 grams of solution.
2. Percent volume by volume (% v/v) which is the number of ml of solute dissolved in 100 grams of solution.
3. Percent weight by volume (% w/w) which is the number of grams of solute dissolved in 100 ml of solution.

General terms used for expressing solubility

Terms	Parts of solvent required to dissolve 1 part of solute
Very soluble	Less than 1 part
Freely soluble	1 to 10 parts
Soluble	10 to 30 parts
Sparingly soluble	30 to 100 parts
Slightly soluble	100 to 1000 parts
Very slightly soluble	1000 to 10000 parts
Practically insoluble	More than 10000 parts

Factors affecting solubility

Factors	Description
Temperature	↑ in temperature ↑ses solubility
Molecular structure	Slight modification in molecular structure leads to marked changes in solubility.
Particle size	↓ in particle size ↑ses solubility
Nature of solvent	Polar solute dissolve in polar solvent and non-polar solutes in non-polar solvents (like dissolve like).
pH	• Solubility of unionized drugs ↓ses with ↓se in pH. • Solubility of weakly basic drugs or their salts ↑ses with ↓se in pH.

S.NO.	TYPE OF DRYER AND MECHANISM	EXAMPLE	ADVANTAGES	DIADVANTAGES
1.	**Static Bed Dryer** No relative movement among the solid particle being dried, but bulk motion of entire mass may be there	Tray dryer Freeze dryer	no attrition	Batch process
2.	**Moving Bed Dryer** Movement occurs in system in which drying particles are separated so they can flow over each other	Drum dryer (Roller dryer or ex film drum dryer)	Entire matter is exposed to heat continuously	Attrition occurs
3.	**Fluidized Bed Dryer** Upward moving heated gas system is installed	F.B.D. (Plug flow dryer is its variant)	Uniform drying	Attrition occurs
4.	**Pneumatic Dryer** Particles are entrained and conveyed at high velocity gas stream	Spray dryer	Rapid & efficient drying	-

SOME OTHER DRYERS

S.NO.	DRYER NAME	PRINCIPLE	ADVANTAGES	DISADVANTAGES
1.	**Vacuum dryer**	Material is dried by the application of vacuum	1. Easy handing 2. Large surface area for heating	1. Limited capacity 2. Expensive 3. Batch process
2.	**Freeze dryer (lyophilization)**	Water is removed from the frozen state by sublimation	1. Thermolabile materials can be heated 2. No denaturation 3. Loss of volatile material is less	1. High cost 2. High period of drying 3. Product is prove to oxidation

EVAPORATION

INTRODUCTION

- It is simply vaporization from surface of liquid. Means the removal of liquid from solution by boiling the liquor in suitable vessel and withdrawing vapour, leaving concentrate liquid residue and heat supply is latent heat of vaporization.

TYPES OF EVAPORATORS

S.NO.	EVAPORATION	SUB TYPE	MECHANISM

1.	**Mortar and pestle**	Small scale	Trituration
2.	**Double cone blender, V cone mixer, Cube mixer**	Tumbling or cylindrical mixer without mixing blade	Tumbling action.
3.	**V cone blender, Double cone blender with mixing blade**	Centrifugal force Tumbling Mixer with blade	Tumbling + Shearing
4.	**Rubber blender, sigma blender, planetary paddle**	Static mixer	Stationary shell and rotating blade
5.	**Fluidized mixer**	Air mixer	Air supported blending
6.	**Barrel type, Zigzag type**	Large scale	Rotating shell with rotating blade

LIQUID MIXER

MIXER	CHARACTERISTIC AND USE
Propeller mixer	Use for low viscous liquid and rotate at<8000 RPM Not use for glycerin, liquid paraffin, castor oil. Various offset, angled, push-pull, baffled type propeller is use for liquid mixing
Turbine mixer	It contains impeller and use for viscous liquid like liquid glucose and due to high shear force use in emulsification. And not for suspension.
Paddle mixer	Agitator used for mixing and rotate at 100 at R.PM

SOLID MIXER

MIXER	CHARACTERISTIC AND USE
Ribbon blender mixer (Dry mixer)	It is convective mixing. Use for blending free flow material of uniform size and density.
Tumbling -mixer	It is shear and diffusion mixing. Rotation speed is 30 100RPM various twin V-shape, double cone, cubicle, Y shaped and cylindrical type tumbler is used for mixing.

SEMI SOLID MIXER

(A)AGITATOR MIXER

MIXER	CHARACTERISTIC AND USE
Planetary motion mixer	It contains Anchor type paddle which provide pulling and kneading action.
Sigma blade mixer (z-blade/double cone mixer)	It is KNEDING machine which contain open trough and blade. Use for pill mass, ointment and tablet granulation mass. Banbury mixer is modified sigma blade mixer

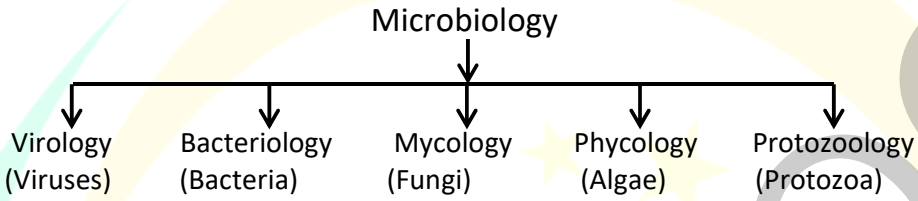
(B)SHEAR MIXER

MIXER	CHARACTERISTIC AND USE
Triple roller mixer	3 to 5 roller is used for Cream and Ointment

MICROBIOLOGY

INTRODUCTION OF MICROBIOLOGY

- Microorganisms are living organisms that are usually too small to be seen clearly with the naked eye.
- Microorganisms are used to make different products. (e.g., Penicillin, Streptomycin, Chloromycetin), vaccines, vitamins, enzymes and many more important products.
- At present there is general agreement to include five major groups as microorganisms. The subdivisions are:



DISCOVERY OF MICROBES & THE DAWN OF MICROBIOLOGY

- The term microbiology was given by French chemist Louis Pasteur (1822-95).
- The term microbe was first used by Sedillot (1878).
- Robert Hooke was the first to coined the term "cells."
- Antonie van Leeuwenhoek is considered as the "Father of microbiology" & "Father of bacteriology".
- George Schroeder and Theodor Von Dusch (1854) were the first to introduce the idea of using cotton plugs for plugging microbial culture tubes.
- Pasteur in 1862 suggested that mild heating at 62.8°C (145°F) for 30 minutes
- The process was called Pasteurization.
- Domagk was awarded Nobel prize in 1939 for the discovery of the first sulpha drug.
- Recombinant Hepatitis B vaccine developed in 1982.
- The discovery of microbiology as a discipline could be" traced along the following historical eras:

TYPES OF MICROORGANISM:

1. **Psychrophiles (cold-loving):** m/o grow at cold temperature below 25ºC.eg., Pseudomonas
2. **Mesophiles**: m/o grow at moderate temperature between 25ºC- 45ºC.e.g., Salmonella, Proteus
3. vulgaris
4. **Thermophiles (heat-loving):** m/o grow above 45ºC, optimum 55-65ºC. Bacillus stearothermophiles
5. **Acidophil**: m/o which can tolerate highly acidic conditions. E.g., Lactobacilus
6. **Basophil**: m/o which can tolerate alkaline conditions. E.g., Vibrio cholera
7. **Obligate aerobes**: they require oxygen for growth. e.g., Mycobacterium tuberculosis
8. **Obligate anaerobes**: they do not require oxygen for growth. e.g., Clostridium species.
9. **Facultative anaerobes**: aerobic bacteria that can grow in the absence of air. e.g., E. coli
10. **Microaerophile**: Microorganisms require very low concentration of oxygen. e.g., Streptococcus pyogenes, Helicobacter pylori.

PROKARYOTES & EUKARYOTES

Characteristics	Prokaryotes	Eukaryotes
Type of Cell	Always unicellular	Unicellular and multi-cellular

4.	**IgD**	185,000	1	Found in serum and on lymphocytes, controls antigen stimulation of b-cells, fetal antigen receptor.
5.	**IgE**	190,000	002	Combat parasitc disease, causes allergies, drug sensitivity, anaphylaxis and immediate hypersensitivity

VACCINES

- A vaccine is a biological preparation that improves immunity to a particular disease.
- A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe.
- The agent stimulates the body's immune system to recognize the agent as foreign, destroy it, and keep a record of it.
- So that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters.
- The terms vaccine and vaccination are derived from Variolae vaccinae (smallpox of the cow), the term devised by Edward Jenner to denote cowpox

Types:

1. Live, attenuated vaccines
2. Inactivated vaccines
3. Subunit vaccines
4. Toxoid vaccines
5. Conjugate vaccines
6. DNA vaccines
7. Recombinant vector vaccines

1. LIVE, ATTENUATED VACCINES:

- Live, attenuated vaccines contain a version of the living microbe that has been weakened in the lab so it can't cause disease.
- Because a live, attenuated vaccine is the closest thing to a natural infection, these vaccines are good "teachers" of the immune system.
- Example: Vaccines against measles, mumps, and chickenpox

2. INACTIVATED VACCINES:

- Scientists produce inactivated vaccines by killing the disease-causing microbe with chemicals, heat, or radiation. Such vaccines are more stable and safer than live vaccines.
- Because dead microbes can't mutate back to their disease-causing state.
- Example: Vaccines against influenza, polio, hepatitis A, and rabies.

3. SUBUNITS VACCINES:

- Instead of the entire microbe, subunit vaccines include only the antigens that best stimulate the immune system.
- In some cases, these vaccines use epitopes the very specific parts of the antigen that antibodies or T cells recognize and bind to.
- Because subunit vaccines contain only the essential antigens and not all the other molecules that make up the microbe.
- Example: Plague immunization.

4. TOXOID VACCINES:

4.	Medical preparation not containing alcohol but containing narcotic drug	20% ad valorem
5.	Homeopathic preparation containing alcohol	4% ad valorem
6.	Toilet preparation containing alcohol or narcotic drug or narcotic	50% ad valorem

THE DRUGS (PRICE CONTROL) ORDER (DPCO), 1995

INTRODUCTION

- The drug (Price control) order forms of a part of the new drug policy formed by govt. of India **1987, 1995, 2013**.
- DOPC act was **passed on 6th January 1995** by Ministry of Chemical and Fertilizer by virtue of **section 3** of essential commodities act.
- DOPC 2013 act was passed by Ministry of Chemical and Fertilizer (Department of Pharmaceutics).
- Objective of this act was to **ensure equitable distribution of essential bulk drugs and to fix the maximum retail prices of drug formulation** in order to curb the exorbitant.
- **Important Dates**

Essential commodities act	1955
National list of essential medicine	2011
National pharmaceutical pricing policy	2012
DPCO Came into force	15th may, 2013

- Any new drug patented in India will be exempted from DOPC for 5 year.
- **Power of entry, search, seize** – Paragraph 30
- **Power of review** - Paragraph 30

SCHEDULE OF DPCO

Schedule I	It contain the national list of medicines 2011 and divided into 27 section.
Schedule II	Various form for approval or revision of price of scheduled formulation.
Schedule III	Maximum par tax return as sales turnover of manufactured importer of formulation- A, B and C category.

DEFINITIONS

Terms	Definitions
Ceiling Price	This is the price fixed by Government for Scheduled formulations in accordance with the provisions of the Order.
Scheduled Bulk Drug	It means the bulk drug specified in First schedule to the DPCO.
Non-Scheduled Bulk Drug	It means a bulk drug not specified in the First Schedule to DPCO.
Pre-tax Return	It means profits before payment of income tax and sur-tax and includes such other expenses as do not form part of the cost of the formulation.

IMPORTANT DATES

Factories bill passed	23rd September, 1948
Came inti force	1st APRIL 1949
Factories act passed	1948
Amendment	1950, 1951, 1954, AND 1976

- In order to maintain the working conditions of factories and provide some minimum benefits and relief of workers.
- The main objectives of this act are –
  - To afford protection to human being from long hour of work
  - To provide healthy and sanitary conditions in the factories
  - To take precaution for the safety of the workers
  - To regulate and control its working by appointment of inspectors by the state govt.
- The rules and regulation was extended to whole of India **except Jammu and Kashmir.**

WORKING HOURS

- ✓ **Adult**
  - Not more than 48hrs/ week
  - Not more than 9hrs/ day (Max. $10_{1/2}$ hrs/ day)
  - For more than 5hrs (need interval of ½ hr)
- ✓ **Woman –** 6 am to 7pm
- ✓ **Child**
  - Not more than 4.5hrs/ day
  - Night shift → 10pm to 6am
  - Time of work of adolescent male and female → 6am to 7pm
  - No female child allowable to work in any factory except between 8am and 7pm
- ✓ **Holiday –** No work on the 1st day of the week (unless will have holiday for a whole days on one of the 3days immediately before or after said days)
- ✓ **Shift –** No worker shall be required or allowed to work continuously in two consecutive shift
- ✓ **Overtime –** If any worker for more than 9hrs in any days and 48hrs in a week → he shall entitled to wages at the rate of twice his ordinary rate of wages for overtime

ANNUAL LEAVES AND WAGES

- **Adult –** 1day for every 24days of work
- **Child –** 1day for every 15days of work
- **Excluding Sunday of week**

OFFENCES AND PENALTIES

Offences	Penalties
1. General penalties for offences	Imprisonment 2-3M/ fine 2,000/-
2. Enhanced penalty after previous conviction	Imprisonment 6M/ fine 1,000/-
3. Penalty for obstructing inspector	Imprisonment 3M/ fine 5,000/-
4. Offence by worker	Fine 20/-
5. Penalty for using false certificate of fitness	Imprisonment 1M/ fine 50/-

THE MINIMUM WAGES ACT, 1948

AIIMS

RRB

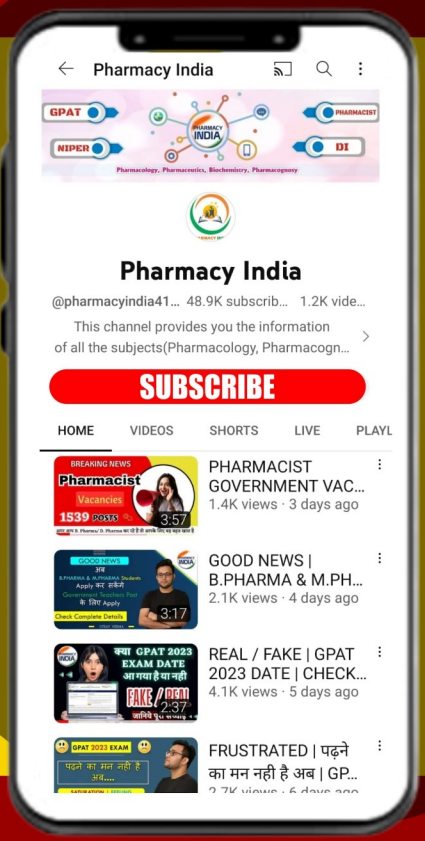
CGHS,
HPPSC, BTSC, ISRO,
KERALA PSC,
MP PHARMACIST,
SECL, DSSSB,
BCCL

ESIC

UP NHM

ABOUT PHARMACY INDIA

Our classes set up with an aim to provide coaching to the aspiring students who are dedicated and want to achieve excellence in their career. we nurture aspirants and facilitated achievement and we specialized in providing correct and relevant information related to Pharma institute admission for higher education.



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