1. PHARMACEUTICS

Pharmaceutics is the branch of pharmaceutical sciences that deals with the formulation, preparation, and dispensing of drugs. It ensures that medications are safe, effective, and stable for patient use.

It combines principles of chemistry, biology, and engineering to transform active pharmaceutical ingredients (APIs) into safe, effective, and stable medications that can be administered to patients.

Key Aspects of Pharmaceutics:

- Drug formulation development (tablets, capsules, injections, etc.)
- Drug delivery systems (controlled-release, targeted drug delivery)
- Biopharmaceutics & Pharmacokinetics (drug absorption, distribution, metabolism, excretion)
- Pharmaceutical technology (manufacturing processes, quality control)
- Physical pharmacy (principles of solubility, dissolution, stability)

2. Classification of Pharmaceutics

Pharmaceutics can be broadly classified into several sub-disciplines:

(A) Physical Pharmacy

- Studies the physicochemical properties of drugs (solubility, dissolution, polymorphism, rheology).
- Applies principles of thermodynamics, kinetics, and surface chemistry to drug formulation.

(B) Pharmaceutical Technology (Dosage Form Design)

- Involves the development of different dosage forms:

  Solid dosage forms (tablets, capsules, powders)

  Liquid dosage forms (solutions, suspensions, emulsions)

  Semisolid dosage forms (ointments, creams, gels)

  Sterile dosage forms (injections, ophthalmic preparations)

  Novel drug delivery systems (liposomes, nanoparticles, transdermal patches)

(C) Biopharmaceutics & Pharmacokinetics

- Biopharmaceutics: Studies how drug properties (solubility, dissolution rate) affect bioavailability.
- Pharmacokinetics (ADME):

  Absorption (how drugs enter systemic circulation)

  Distribution (drug movement in the body)

  Metabolism (drug breakdown by enzymes)

  Excretion (drug elimination via kidneys/liver)

(D) Pharmaceutical Microbiology

- Deals with microbial contamination in drugs.
- Involves sterilization techniques and preservatives.

(E) Industrial Pharmacy

- Focuses on large-scale drug manufacturing, quality control (GMP), and regulatory compliance.

(F) Clinical Pharmaceutics (Pharmacy Practice)

- Ensures safe and effective drug use in hospitals and community pharmacies.

Pharmaceutics is a dynamic field that integrates chemistry, biology, engineering, and medicine to develop safe and effective drug products. From ancient herbal remedies to modern nanotechnology-based formulations, the evolution of pharmaceutics has significantly improved healthcare. Today, it continues to advance with innovations in drug delivery, personalized medicine, and regulatory sciences.

DOSAGE FORMS

Drugs are rarely used in the form of pure chemical substances but are given in the formulated preparations i.e. dosage forms. The formulations vary from simple solutions to complex drug delivery systems and are prepared by using one or more non-drug additives or excipients that have specialized pharmaceutical function. These additives are used in dosage forms to solubilize, suspend, thicken, preserve, emulsify, to improve the organoleptic properties and to improve the compressibility and to give an efficacious and appealing dosage form.

Need for Dosage Forms

Many drug substances are administered in very small (milligram) quantities, which require these substances to be weighed on sensitive balance. Due to the low dosage and potent nature of the drugs, it cannot be taken by the patient by himself, when the dose of drug is minute e.g. 0.05 mg of drug, for some drugs. Solid dosage forms such as tablets and capsules must be prepared with fillers or diluents so that the size of dosage form is large enough to be handled easily.

Dosage forms are needed to:

i) provide a method for safe and convenient delivery of accurate doses of drugs.

ii) protect the drug from destructive effects of atmospheric oxygen or moisture i.e. from oxidation, hydrolysis and reduction e.g. the tablet may be given coating.

iii) protect the drug from degradation by gastric acid after oral administration e.g. enteric coating may be given to tablets and capsules (enteric coating does not dissolve in acid but it will dissolve in alkaline pH).

iv) obscure the bitter, salty or offensive taste or odour of a drug e.g. drug may be given in capsules or in the form of flavoured syrups.

v) give the drugs (which are insoluble or unstable) in the form of liquid preparations e.g. suspensions.

vi) give the drugs in the clear liquid forms e.g. solution.

SURA'S

vii) obtain rate controlled and sustained release drug action e.g. controlled release tablets. viii)obtain drug action from topical application e.g. creams, transdermal patch etc.

ix) obtain drug action by insertion into various body cavities e.g. suppositories.

x) obtain the drug action by placing the drug directly into the bloodstream or in body tissues e.g. injections.

xi) obtain drug action through inhalation therapy e.g. inhalation aerosols.

Classification of Dosage Forms

Dosage forms may be classified in different way:

a) On the basis of physical form of the product

b) On the basis of the different administration routes

a) On the basis of physical form of the product

i) Solid dosage forms: The solid dosage forms are mostly unit dosage forms and they are taken by number consisting of a single dose. Sometimes solid dosage forms are supplied in bulk.

ii) Liquid dosage forms: The liquid dosage forms may be monophasic or biphasic liquid dosage forms are for internal, external or parenteral use.

iii) Semisolid dosage forms: Semisolid dosage forms are mostly for external use having semi solid consistency.

b) On the basis of the different administration routes

i) Orally administered dosage forms: Solutions, syrups, elixirs, suspensions, emulsions, gels, powders, granules, capsules, tablets

ii) Parenteral: Injections which may be in solution, suspension or emulsion form, implants, irrigation and dialysis solution.

iii) Rectals routes: Suppositories, creams, ointments, powers and solutions.

iv) Topical: Ointment, creams, pastes, lotion, gels, solutions, aerosols.

v) Lungs: Aerosols, inhalations.

vi) Nosal: Solutions, inhalations.

vii) Eye: Solutions (lotions, eye drops), ointments.

viii) Ear: Solutions, suspensions and ointments.

Additives in Dosage Forms

The action of a dosage form and the form depends on the additives added. An additive is a non-drug component having a definite function to perform in a formulation.

The additives generally used in formulations are classified as

i) Vehicles

ii) Disintegrating agents

iii) Form givers

iv) Organoleptic additives (colouring, flavouring and sweetening)

v) Stabilizers

vi) Manufacturing additives

i) Vehicles

Vehicle is a term which can be used for any solid, semisolid or liquid material used in formulation for carrying a drug. These additives form the bulk of a dosage form and help to give a desired dosage form. Solvents are used to dissolve the drugs. These solvent may be aqueous or non-aqueous.

For example: Base – These are semisolid vehicles into which drug substances may be incorporated in the formulation of ointment, paste suppositories etc. Diluents are the material added to increase the bulk or reduce the drug concentration.

ii) Disintegrating Agents

The dosage form once ingested must disintegrate into smaller particles to give its drug contents to the body. For example in tablets, disintegrating agents are added to break the tablet into smaller particles.

iii) Form Givers

These additives are added to give a desired physical form e.g. surfactants and hydrocolloids, emulsions and suspensions are stabilized by the emulsifying agents and suspending agents respectively. Lactose is used in the preparation of tablets if the quantity of the drug is small.

iv) Organoleptic additives

These are the materials which are added in dosage forms to make them acceptable to the patient's. Examples:.

- Colouring agent - to give a good, appropriate colour to the dosage form
- Flavouring agent - to give a suitable pleasant flavour to the preparation and is specially important in liquid dosage form
- Sweetening agents - to give a sweet taste to the preparation

v) Stabilizers

These are substances or additives which are added in the dosage forms to give physical, chemical and microbiological stability to the product e.g. antioxidants are added to prevent oxidation of the drug. Antimicrobial preservatives are added to prevent the growth of microorganisms in the product.

vi) Manufacturing Additives

These additives are added to facilitate the processing of dosage forms. These additives are generally required in the preparation of compressed tablets e.g. lubricants, anti-adhesives and glidants. These additives facilitate uniform flow of granules into the die and help in the ejection of compressed tablets.

Many other additives such as adsorbent, buffering agent, humectant, plasticizer, tonicity agents and

viscosity increasing agents are used in formulation of dosage form as per the requirement.

Some Commonly used Dosage Forms

Some commonly used dosage forms are given below:

i) Tablets

Tablets are solid dosage forms for oral medication made by compaction of suitably prepared medicament (granules) by tabletting machines. They are available in various shapes and sizes, in coated or uncoated form.

ii) Capsules

Capsules are solid dosage forms for oral medication in which the drug is enclosed in a water soluble shell. There are two types of capsules:

- Hard gelatin capsules
- Soft gelatin capsules

Hard gelatin capsule is used for the administration of solids e.g. becosule/b-complex etc. Soft capsules are used for liquid or semi-solid e.g. pudin hara capsules. Hard gelatin capsules are cylindrical and made of body and cap. Soft gelatin capsules are spherical, ovoid or cylindrical.

iii) Emulsion

Emulsion is a heterogeneous system consisting of two immiscible liquid, one of the liquid is dispersed in another in the form of droplets. These liquid droplets known as the emulsion globules form the dispense phase or the internal phase while the liquid in which they are dispersed is known as the continuous phase or external phase. There are two types of emulsions:

- Oil in water emulsion in which the oil globules are dispersed in water
- Water in oil emulsion in which water droplets are dispersed in oil.

iv) Suspensions

Suspensions are biphasic liquid dosage forms, consisting of finely divided insoluble solid particles suspended in a liquid medium. The solid particles settle on standing and a uniform dose may not be obtained so a suspending agent is added which helps in the formation of uniform suspension and the particle will remain suspended for longer time so a uniform dose can be obtained.

v) Liniments

Liniments are liquid preparations for external use. Liniments may be alcoholic solutions, oily solutions or emulsions. They are applied with friction on the skin. They are used for counter irritant and rubefacient action.

vi) Lotions

Lotions are aqueous solutions or suspensions used for application to the skin surface. They are applied to the unbroken skin without friction. On application to the skin, the water evaporates leaving a residue of the medicament on the skin surface. The evaporation causes cooling.

vii) Paints

Paints are also liquid preparation for external application. They may be aqueous or alcoholic solution and sometimes prepared by using viscous solvents.

viii) Ear drops

Ear drops are mostly aqueous solutions dispensed in small quantities and are intended for instillation into the ear. Sometimes they may contain glycerine or alcohol as solvent.

ix) Gargles

Gargles are aqueous solutions which are to be used after dilution with warm water. They bring the medication in contact with the mucous membrane of the throat to give symptomatic relief and may also have some analgesic effect.

x) Mouth washes

Mouth washes are liquid preparation used to wash out the mouth and buccal cavity. Antiseptics are generally added in these preparations and they are useful in oral hygiene especially in bed ridden patients.

xi) Nasal drops

Nasal drops are aqueous solution for instillation into the nostrils. Oily solutions can not be used as nasal drops as they may cause lipoid pneumonia. Nasal drops contain antiseptic substances or vasoconstrictors to relieve nasal congestion.

xii) Spray solutions

Spray solutions are aqueous, alcohol or glycerine solutions for application to the membrane of the throat or nose by means of an atomizer.

xiii) Inhalations

Inhalations are the solution or suspension of volatile, aromatic or antiseptic substances; the vapours of these substances are inhaled by pouring them into hot water. Inhalations are useful for the relief of nasal congestion.

xiv) Aromatic waters

Aromatic waters are clear saturated aqueous solutions of volatile oils or other aromatic or volatile substances. They are also known as medicated waters and are mostly used as flavoured or perfumed vehicles.

xv) Solutions

Solutions are liquid dosage forms that contain one or more soluble drugs dissolved in water. Solutions may be used internally or externally for the specific therapeutic effect of the drug.

xvi) Douches

Douches are an aqueous solution used for cleansing and as antiseptic agent into a body cavity. Douches are mostly dispensed in the form of a powder with directions for dissolving in a specific quantity of warm water.

xvii) Enemas

Enemas are preparations for rectal administration and used to evacuate the bowel, to affect a local disease or to produce affect by absorption.

xviii) Gargles

Gargles are aqueous solutions used for treating the pharynx and nasophrynx. They generally contain antiseptics, antibiotics or anaesthetic substances. Many gargles must be diluted with water before use.

xix) Irrigation solutions

Irrigation solutions are used to wash or bathe surgical incisions, wounds or body tissues. They are sterile solutions and prepared by dissolving active ingredients in water for injection.

xx) Syrups

Syrups are concentrated solutions of sugars like sucrose in water. When only purified water is used for making sucrose solution, it is known as simple syrup. When the syrup contains some medicinal substance, it is known as medicated syrup. Sometimes glycerine or sorbital is added in syrups to retard crystallization of sucrose or to increase the solubility of active ingredients.

xxi) Mucilages

Mucilages are thick, viscous, adhesive liquid prepared by dispersing gum in water or by extracting mucilaginous ingredients from vegetable substances by water.

xxii) Elixirs

Elixirs are clear, sweetened and flavoured hydroalcoholic liquids for oral use. The solvents are used to increase the solubility of drugs. Elixir's main ingredients are ethanol and water but they may also contain glycerine, sorbital propylene glycol, preservatives and flavouring agents. Elixirs are less viscous than syrups.

xxiii) Glycerines (Glycerites)

Glycerines (Glycerites) are solutions or mixtures of drug substances in glycerine. These preparations contain not less than 50% by weight of glycerine and are extremely viscous.

xxiv) Suppositories

Suppositories are specially formulated solid dosage forms for insertion into rectum, vagina, urethra or other body cavities except mouth. They melt or dissolve in the body to release the medicament and produce local or systemic action.

PACKAGING OF DOSAGE FORMS

The proper packaging, labelling and storage of pharmaceutical products are essential for product stability and efficacious use. Different specifications are required for parenteral, non-parenteral, pressurized and bulk containers and for those made of glass, plastic and metal. Container is defined as a device which holds the pharmaceutical preparation. The immediate container is that which is in direct contact with the preparation at all times. Desirable features of a containers are:

i) The container must be rigid enough to withstand wear and tear during normal handling and to prevent damage to the contents e.g. breaking of tablets.

ii) The container material should not react with the contents.

iii) The container must protect the contents from deterioration by environmental factors like oxygen and moisture.

iv) The container must prevent loss of moisture from the contents.

v) The container must prevent leakage of contents.

vi) The container must prevent entry of dirt, other chemical or microbiological contamination.

vii) The container should be sterilizable without any change.

viii) The container should give protection from light when required.

ix) The container must not absorb anything i.e. medicament or additives from the contents.

x) The container must not impart anything to the contents.

xi) The container must be easy to label.

xii) The container must be pharmaceutically elegant.

Types of Container

Containers are classified in two ways:

a) According to their ability to protect the contents from external condition

b) According to number they contain

a) According to their ability to protect the contents from external condition: In this category they can be classified into six groups i.e.

i) Well closed containers

This type of container protects the contents from external solids and from loss of the contents under ordinary conditions of handling, shipment, storage and distribution.

ii) Tight container

This type of container protects the contents from contamination by external liquid, solid and vapour. It should prevent changes due to efflorescence, deliquescence or evaporation.

iii) Hermetically sealed

These containers will not allow air and other gases to pass through the container under normal condition of handling. These containers are sterile and used for holding sterile preparation.

Popular Brand Names

- Fasigyn (tablets).
- Tindamax (tablets).

2. Anthelmintic Drugs

Anthelmintic drugs are used to treat infections caused by parasitic worms, including nematodes (roundworms), cestodes (tapeworms), and trematodes (flukes).

Albendazole

Nomenclature

- IUPAC Name: Methyl [5-(propylthio)-1H-benzimidazol-2-yl]carbamate.
- Common Name: Albendazole.

Chemical Structure

S-CH2-CH2-CH3
|
C12H15N3O2S

Uses

- Anthelmintic: Treats infections caused by roundworms, tapeworms, and flukes.
- Antiparasitic: Effective against Echinococcus and Neurocysticercosis.

Physical and Chemical Properties

- Appearance: White to off-white crystalline powder.
- Solubility: Insoluble in water; soluble in organic solvents.
- Stability: Stable under normal conditions; sensitive to light.
- Chemical Properties:

  Inhibits microtubule synthesis, disrupting glucose uptake in parasites.

Stability and Storage Conditions

- Storage: Store in airtight, light-resistant containers at room temperature.
- Protection: Protect from light and moisture.

Pharmaceutical Formulations

- Tablets: 200–400 mg for oral administration.
- Suspensions: For pediatric use.

Popular Brand Names

- Albenza (tablets).
- Zentel (tablets).

Mebendazole

Nomenclature

- IUPAC Name: Methyl (5-benzoyl-1H-benzimidazol-2-yl)carbamate.
- Common Name: Mebendazole.

Chemical Structure

CO-C6H5
|
C16H13N3O3

Uses

- Anthelmintic: Treats infections caused by roundworms, whipworms, and hookworms.
- Antiparasitic: Effective against Trichuris trichiura and Enterobius vermicularis.

Physical and Chemical Properties

- Appearance: White to yellowish crystalline powder.
- Solubility: Insoluble in water; soluble in organic solvents.
- Stability: Stable under normal conditions; sensitive to light.
- Chemical Properties:

  Inhibits microtubule synthesis, disrupting glucose uptake in parasites.

Stability and Storage Conditions

- Storage: Store in airtight, light-resistant containers at room temperature.
- Protection: Protect from light and moisture.

Pharmaceutical Formulations

- Tablets: 100 mg for oral administration.
- Chewable Tablets: For pediatric use.

Popular Brand Names

- Vermox (tablets).
- Emverm (chewable tablets).

Praziquantel

Nomenclature

- IUPAC Name: 2-(Cyclohexylcarbonyl)-1,2,3,6,7,11b-hexahydro-4H-pyrazino[2,1-a]isoquinolin-4-one.
- Common Name: Praziquantel.

Chemical Structure

CO-C6H11
|
C19H24N2O2

Uses

- Anthelmintic: Treats infections caused by tapeworms and flukes.
- Antiparasitic: Effective against Schistosoma species.

Physical and Chemical Properties

- Appearance: White to off-white crystalline powder.
- Solubility: Insoluble in water; soluble in organic solvents.

- Stability: Stable under normal conditions; sensitive to light.
- Chemical Properties:

  Increases permeability of parasite cell membranes to calcium, causing paralysis and death.

Stability and Storage Conditions

- Storage: Store in airtight, light-resistant containers at room temperature.
- Protection: Protect from light and moisture.

Pharmaceutical Formulations

- Tablets: 600 mg for oral administration.

Popular Brand Names

- Biltricide (tablets).
- Praziquantel (tablets).

Key Points

- Antiamoebic Drugs:

  Metronidazole: Treats amoebiasis, giardiasis, and trichomoniasis.

  Tinidazole: Similar to metronidazole with a longer half-life.
- Anthelmintic Drugs:

  Albendazole: Broad-spectrum anthelmintic; treats roundworms, tapeworms, and flukes.

  Mebendazole: Treats roundworms, whipworms, and hookworms.

  Praziquantel: Effective against tapeworms and flukes.

Chemistry and Nomenclature

(A) Antiamoebic Drugs

Drug Name	IUPAC Name	Chemical Formula
Metronidazole	2-Methyl-5-nitroimidazole-1-ethanol	$C_6H_9N_3O_3$
Tinidazole	1-(2-Ethylsulfonylethyl)-2-methyl-5-nitroimidazole	$C_8H_{13}N_3O_4S$
Diloxanide Furoate	2,2-Dichloro-N-(furan-2-ylmethyl)acetamide	$C_{14}H_{11}Cl_2NO_4$
Paromomycin	4-O-(2,6-Diamino-2,6-dideoxy-α-D-glucopyranosyl)-D-streptamine	$C_{23}H_{47}N_5O_{18}$

(B) Anthelmintic Drugs

Drug Name	IUPAC Name	Chemical Formula
Albendazole	Methyl [5-(propylthio)-1H-benzimidazol-2-yl]carbamate	$C_{13}H_{15}N_3O_2S$
Mebendazole	Methyl [5-(benzoyl)-1H-benzimidazol-2-yl]carbamate	$C_{16}H_{13}N_3O_3$
Praziquantel	2-(Cyclohexylcarbonyl)-1,2,3,6,7,11b-hexahydro-4H-pyrazino[2,1-a]isoquinolin-4-one	$C_{19}H_{24}N_2O_2$
Ivermectin	22,23-Dihydroavermectin B1a/B1b mixture	$C_{48}H_{74}O_{14}$

Mechanism of Action

Drug	Mechanism
Metronidazole	Produces free radicals that damage protozoal DNA.
Tinidazole	Similar to metronidazole; disrupts DNA synthesis.
Albendazole	Inhibits microtubule synthesis in worms, leading to paralysis.
Mebendazole	Disrupts glucose metabolism in helminths.
Ivermectin	Enhances chloride influx, leading to paralysis of nematodes.
Praziquantel	Increases calcium permeability, causing spastic paralysis in tapeworms.

Pharmacological Uses

Drug	Indications
Metronidazole	Amoebiasis, giardiasis, trichomoniasis
Tinidazole	Amoebiasis, bacterial vaginosis
Albendazole	Roundworm, hookworm, hydatid disease
Mebendazole	Pinworm, whipworm, hookworm
Ivermectin	Strongyloidiasis, filariasis
Praziquantel	Schistosomiasis, tapeworm infections

Dosage and Formulations

Drug	Formulations	Brand Names
Metronidazole	Tablets, IV, suspensions	Flagyl, Metrogyl
Tinidazole	Tablets, IV	Fasigyn, Tindamax
Albendazole	Tablets, suspension	Zentel, Alworm
Mebendazole	Chewable tablets, suspension	Vermox, Mebex
Ivermectin	Tablets, lotion	Stromectol, Iverfast
Praziquantel	Tablets	Biltricide, Distocide

Adverse Effects and Precautions

Drug	Common Side Effects
Metronidazole	Nausea, metallic taste, disulfiram-like reaction with alcohol.
Tinidazole	Dizziness, dry mouth, neuropathy.
Albendazole	Liver enzyme elevation, bone marrow suppression.
Mebendazole	Mild gastrointestinal discomfort.
Ivermectin	Dizziness, hypotension, itching.
Praziquantel	Abdominal pain, drowsiness.

Drug Interactions

Drug Interaction	Effect
Metronidazole + Alcohol	Severe nausea, flushing, tachycardia.
Albendazole + Cimetidine	Increases albendazole concentration.
Ivermectin + Warfarin	Enhances anticoagulant effect.

Antiamoebic and anthelmintic drugs play a crucial role in treating parasitic infections. Understanding their mechanisms, formulations, and precautions ensures effective and safe treatment.

(F) ANTIBIOTICS - PENICILLINS GENTAMICIN, NEOMYCIN, ERYTHROMYCIN, TETRACYCLINES, CEPHALOSPORINS EXIN, CEPHALORIDINE, CEPHALOTHIN, GRISEOFULVIN, CHLORAMPHENICOL

1. Penicillins

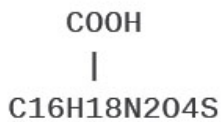
Penicillins are β-lactam antibiotics that inhibit bacterial cell wall synthesis.

Benzylpenicillin (Penicillin G)

Nomenclature

- IUPAC Name: (2S,5R,6R)-3,3-Dimethyl-7-oxo-6-[(phenylacetyl)amino]-4-thia-1-azabicyclo[3.2.0] heptane-2-carboxylic acid.
- Common Name: Penicillin G.

Chemical Structure



Uses

- Antibacterial: Treats streptococcal, pneumococcal, and meningococcal infections.
- Prophylaxis: Used to prevent rheumatic fever and bacterial endocarditis.

Physical and Chemical Properties

- Appearance: White crystalline powder.
- Solubility: Soluble in water and alcohol.
- Stability: Unstable in acidic conditions; sensitive to β-lactamases.
- Chemical Properties:

  Inhibits transpeptidase, preventing cross-linking of peptidoglycan in bacterial cell walls.

Stability and Storage Conditions

- Storage: Store in airtight containers at 2–8°C (refrigerated).
- Protection: Protect from light and moisture.

Pharmaceutical Formulations

- Injections: For intramuscular or intravenous use.

Popular Brand Names

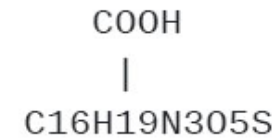
- Penicillin G (injections).

Amoxicillin

Nomenclature

- IUPAC Name: (2S,5R,6R)-6-{[(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl]amino}-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid.
- Common Name: Amoxicillin.

Chemical Structure



Uses

- Antibacterial: Treats respiratory, urinary, and gastrointestinal infections.
- Combination Therapy: Used with clavulanic acid to overcome β-lactamase resistance.

Physical and Chemical Properties

- Appearance: White to off-white crystalline powder.
- Solubility: Soluble in water; slightly soluble in alcohol.
- Stability: Stable under normal conditions; sensitive to β-lactamases.
- Chemical Properties:

  Broad-spectrum penicillin; inhibits bacterial cell wall synthesis.

Stability and Storage Conditions

- Storage: Store in airtight containers at room temperature.
- Protection: Protect from light and moisture.

Pharmaceutical Formulations

- Capsules/Tablets: 250–500 mg for oral administration.
- Suspensions: For pediatric use.

Popular Brand Names

- Amoxil (capsules, suspensions).
- Augmentin (amoxicillin + clavulanic acid).

2. Aminoglycosides

Aminoglycosides inhibit bacterial protein synthesis by binding to the 30S ribosomal subunit.

Gentamicin

Nomenclature

- IUPAC Name: 2-{4,6-Diamino-3-[3-amino-6-(1-methylaminoethyl)oxan-2-yl]oxy-2-hydroxycyclohexyl}oxy-5-methyl-4-methylaminooxane-3,5-diol.
- Common Name: Gentamicin.

Chemical Structure

OH
|
C21H43N5O7

Uses

- Antibacterial: Treats severe Gram-negative bacterial infections.
- Topical: Used in creams and ointments for skin infections.

Physical and Chemical Properties

- Appearance: White to off-white powder.
- Solubility: Soluble in water; insoluble in alcohol.
- Stability: Stable under normal conditions; sensitive to heat.
- Chemical Properties:

  Binds to the 30S ribosomal subunit, causing misreading of mRNA.

Stability and Storage Conditions

- Storage: Store in airtight containers at room temperature.
- Protection: Protect from light and moisture.

Pharmaceutical Formulations

- Injections: For intramuscular or intravenous use.
- Creams/Ointments: For topical use.

Popular Brand Names

- Garamycin (injections, creams).
- Gentamicin (injections).

Neomycin

Nomenclature

- IUPAC Name: 2,6-Diamino-2,6-dideoxy-α-D-glucopyranosyl-(1→4)-O-[2,6-diamino-2,6-dideoxy-β-L-idopyranosyl-(1→3)]-β-D-ribofuranoside.
- Common Name: Neomycin.

Chemical Structure

OH
|
C23H46N6O13

Uses

- Antibacterial: Treats skin and gastrointestinal infections.
- Topical: Used in creams and ointments.

Physical and Chemical Properties

- Appearance: White to off-white powder.
- Solubility: Soluble in water; insoluble in alcohol.
- Stability: Stable under normal conditions; sensitive to heat.
- Chemical Properties:

  Binds to the 30S ribosomal subunit, inhibiting protein synthesis.

Stability and Storage Conditions

- Storage: Store in airtight containers at room temperature.
- Protection: Protect from light and moisture.

Pharmaceutical Formulations

- Creams/Ointments: For topical use.
- Tablets: For oral administration (rarely used due to toxicity).

Popular Brand Names

- Neosporin (topical cream).
- Neomycin (topical ointment).

3. Macrolides

Macrolides inhibit bacterial protein synthesis by binding to the 50S ribosomal subunit.

Erythromycin

Nomenclature

- IUPAC Name:

  (3R,4S,5S,6R,7R,9R,11R,12R,13S,14R)-14-Ethyl-7,12,13-trihydroxy-4-[(2R,4R,5S,6S)-5-hydroxy-4-methoxy-4,6-dimethyloxan-2-yl]oxy-3,5,7,9,11,13-hexamethyl-6-{[(2S,3R,4S,6R)-3-hydroxy-6-methyloxan-2-yl]oxy}oxacyclotetradecane-2,10-dione.
- Common Name: Erythromycin.

Chemical Structure

OH
|
C37H67NO13

Uses

- Antibacterial: Treats respiratory, skin, and soft tissue infections.
- Alternative: Used in patients allergic to penicillin.

Physical and Chemical Properties

- Appearance: White to off-white crystalline powder.
- Solubility: Slightly soluble in water; soluble in alcohol.
- Stability: Stable under normal conditions; sensitive to acidic pH.
- Chemical Properties:

  Binds to the 50S ribosomal subunit, inhibiting protein synthesis.

Stability and Storage Conditions

- Storage: Store in airtight containers at room temperature.
- Protection: Protect from light and moisture.

Pharmaceutical Applications

- Antitussive: Used in cough syrups and lozenges.
- Expectorant: Helps in clearing respiratory secretions.
- Flavoring Agent: Used in food and pharmaceutical preparations.

3. Tulsi (Ocimum sanctum)

Occurrence and Distribution

- Tulsi is derived from the leaves of Ocimum sanctum (Holy Basil).
- It is native to India and is widely cultivated in tropical and subtropical regions.

Organoleptic Evaluation

- Color: Green (fresh leaves) to brownish-green (dried leaves).
- Odor: Strong and aromatic.
- Taste: Pungent and slightly bitter.
- Texture: Leaves are soft and slightly hairy.

Chemical Constituents

- Essential oils:

  Eugenol: The major component with antiseptic and anti-inflammatory properties.

  Ursolic acid: Contributes to its antitussive effects.
- Flavonoids: Such as orientin and vicenin.
- Tannins: Present in smaller amounts.

Mechanism of Action

- Eugenol and ursolic acid have anti-inflammatory and antitussive properties, reducing irritation in the respiratory tract.
- Tulsi also has immunomodulatory effects, enhancing the body's resistance to infections.

Identification Tests

1. Ferric Chloride Test:

   Tannins in Tulsi react with ferric chloride to produce a blue-black color.
2. TLC:

   Used to identify eugenol and ursolic acid.
3. Odor Test:

   The strong aromatic odor confirms the presence of essential oils.

Pharmaceutical Applications

- Antitussive: Used to relieve cough and cold symptoms.
- Immunomodulator: Enhances immunity and resistance to infections.
- Anti-inflammatory: Reduces inflammation in the respiratory tract.
- Traditional Medicine: Used in Ayurveda for respiratory and digestive disorders.

Comparison of Antitussives

Drug	Major Active Components	Primary Action	Pharmaceutical Uses
Vasaka	Vasicine, Flavonoids	Expectorant, Bronchodilator	Cough syrups, Asthma remedies
Tolu Balsam	Cinnamic acid, Vanillin	Demulcent, Mild Expectorant	Lozenges, Syrups
Tulsi	Eugenol, Flavonoids	Cough suppressant, Immune booster	Herbal tea, Cough drops

Summary of Pharmaceutical Applications

Drug	Primary Use	Other Uses
Vasaka	Antitussive, bronchodilator	Expectorant, traditional medicine
Tolu Balsam	Antitussive, expectorant	Flavoring agent, mild antiseptic
Tulsi	Antitussive, immunomodulator	Anti-inflammatory, traditional medicine

Vasaka, Tolu Balsam, and Tulsi are valuable natural remedies for respiratory disorders, particularly for their antitussive and expectorant properties. They are widely used in traditional and modern medicine for their ability to soothe the respiratory tract, reduce coughing, and clear mucus.

(H) ANTIRHEUMATICS - GUGGUL, COLCHICUM

Antirheumatics are drugs used to treat rheumatic disorders, such as arthritis, gout, and inflammation. These drugs work by reducing pain, swelling, and stiffness associated with rheumatoid arthritis (RA), osteoarthritis, and gout.

1. Guggul (Commiphora wightii)

Occurrence and Distribution

- Guggul is derived from the oleo-gum resin of Commiphora wightii (syn. Commiphora mukul).
- It is native to India, Pakistan, and Bangladesh, particularly in arid regions like Rajasthan and Gujarat.

Organoleptic Evaluation

- Color: Yellowish-brown to golden-brown (resin).
- Odor: Balsamic and aromatic.
- Taste: Bitter and pungent.
- Texture: Sticky and viscous.

Chemical Constituents

- Steroids:

  Guggulsterones: The major active constituents (e.g., E-guggulsterone, Z-guggulsterone).
- Essential oils: Such as myrcene and eugenol.
- Guggul lipids: Complex lipids with anti-inflammatory properties.

- Flavonoids: Present in smaller amounts.

Mechanism of Action

- Guggulsterones act as anti-inflammatory and lipid-lowering agents.

  They inhibit the NF-κB pathway, reducing inflammation.

  They also modulate thyroid hormone receptors, enhancing lipid metabolism.

Identification Tests

1. Thin Layer Chromatography (TLC):

   Used to identify guggulsterones (E and Z isomers).

2. Foam Test:

   The presence of saponins is confirmed by shaking the extract with water, which produces a stable foam.

3. Ferric Chloride Test:

   Tannins in Guggul react with ferric chloride to produce a blue-black color.

Pharmaceutical Applications

- Antirheumatic: Used to treat rheumatoid arthritis and osteoarthritis.
- Hypolipidemic: Lowers cholesterol and triglyceride levels.
- Anti-inflammatory: Reduces inflammation in joints and tissues.
- Traditional Medicine: Used in Ayurveda for joint disorders and weight management.

2. Colchicum (Colchicum autumnale)

Occurrence and Distribution

- Colchicum is derived from the seeds and corms of Colchicum autumnale (Autumn Crocus).
- It is native to Europe and North Africa and is cultivated in temperate regions.

Organoleptic Evaluation

- Color: Brownish-black (seeds) or yellowish-white (corms).
- Odor: Slight and characteristic.
- Taste: Bitter and acrid.
- Texture: Seeds are hard and corms are fleshy.

Chemical Constituents

- Alkaloids:

  Colchicine: The major alkaloid responsible for its antirheumatic effects.

  Demecolcine: Present in smaller amounts.

- Flavonoids: Present in trace amounts.

Mechanism of Action

- Colchicine acts by inhibiting microtubule polymerization, which disrupts the migration of inflammatory cells.

  It also inhibits the release of inflammatory mediators and cytokine production.

  This results in reduced inflammation and pain in rheumatic conditions.

Identification Tests

1. Dragendorff's Test:

   The sample is treated with Dragendorff's reagent.

   An orange precipitate indicates the presence of alkaloids.

2. Thin Layer Chromatography (TLC):

   Used to identify colchicine and demecolcine.

3. Van Urk's Test:

   The sample is treated with Van Urk's reagent (p-dimethylaminobenzaldehyde in sulfuric acid).

   A blue-violet color indicates the presence of indole alkaloids.

Pharmaceutical Applications

- Antirheumatic: Used to treat acute gout and familial Mediterranean fever.
- Anti-inflammatory: Reduces inflammation in rheumatic disorders.
- Caution: Colchicine has a narrow therapeutic index and can be toxic in high doses.

Comparison of Guggul and Colchicum

Parameter	Guggul (Commiphora wightii)	Colchicum (Colchicum autumnale)
Active Compounds	Guggulsterones, Myrrhanol	Colchicine
Action	Anti-inflammatory, Lipid-lowering	Anti-gout, Anti-inflammatory
Uses	Arthritis, Osteoarthritis, Rheumatism	Gout, Rheumatic pain
Toxicity Risk	Low	High (Toxic in overdose)

Summary of Pharmaceutical Applications

Drug	Primary Use	Other Uses
Guggul	Antirheumatic, hypolipidemic	Anti-inflammatory, traditional medicine
Colchicum	Antirheumatic, anti-inflammatory	Treatment of gout, familial Mediterranean fever

Guggul and Colchicum are important natural remedies for rheumatic disorders. Guggul is widely used in Ayurveda for its anti-inflammatory and lipid-lowering properties, while Colchicum is a potent antirheumatic used in modern medicine for gout and inflammatory conditions.

(I) ANTITUMOUR - VINCA

Antitumor drugs inhibit cancer cell growth by interfering with cell division, DNA synthesis, or

metabolic pathways. Vinca alkaloids are a major class of natural chemotherapeutic agents derived from Vinca species. Vinca, also known as Periwinkle, is a well-known medicinal plant with significant antitumor properties.

1. Vinca (Catharanthus roseus)

Occurrence and Distribution

- Vinca is derived from the whole plant of Catharanthus roseus (formerly known as Vinca rosea).
- It is native to Madagascar but is widely cultivated in tropical and subtropical regions, including India, the United States, and parts of Africa.

Organoleptic Evaluation

- Color: Green (leaves and stems) with pink or white flowers.
- Odor: Slight and characteristic.
- Taste: Bitter.
- Texture: Leaves are smooth, and stems are slightly woody.

Chemical Constituents

- Indole alkaloids: The primary active constituents responsible for its antitumor effects.

  Vinblastine: Used to treat Hodgkin's lymphoma and other cancers.

  Vincristine: Used to treat leukemia and lymphoma.

  Vindesine and Vinorelbine: Semi-synthetic derivatives with antitumor activity.
- Other alkaloids: Ajmalicine, serpentine, and catharanthine.

Mechanism of Action

- Vinblastine and Vincristine act as mitotic inhibitors by binding to tubulin, a protein required for microtubule formation.

  This prevents the assembly of microtubules, which are essential for cell division (mitosis).

  As a result, cancer cells are unable to divide and proliferate.

Identification Tests

1. Van Urk's Test:

   The sample is treated with Van Urk's reagent (p-dimethylaminobenzaldehyde in sulfuric acid).

   A blue-violet color indicates the presence of indole alkaloids.
2. Thin Layer Chromatography (TLC):

   Used to identify vinblastine, vincristine, and other alkaloids.
3. Dragendorff's Test:

   The sample is treated with Dragendorff's reagent.

   An orange precipitate indicates the presence of alkaloids.

Pharmaceutical Applications

- Antitumor:

  Vinblastine: Used to treat Hodgkin's lymphoma, testicular cancer, and breast cancer.

  Vincristine: Used to treat acute lymphoblastic leukemia, Hodgkin's lymphoma, and non-Hodgkin's lymphoma.

  Vinorelbine: Used to treat non-small cell lung cancer and breast cancer.
- Hypoglycemic: Used in traditional medicine to manage diabetes.
- Antimicrobial: Exhibits activity against certain bacteria and fungi.

Administered via intravenous infusion under strict medical supervision.

Side Effects & Precautions

- Neurotoxicity (Peripheral nerve damage) – Vincristine causes neuropathy.
- Bone marrow suppression – Leads to low WBC count and anemia.
- Gastrointestinal disturbances – Nausea, vomiting, constipation.
- Hair loss (Alopecia) – Common during chemotherapy.

Dose adjustment is required based on patient response and toxicity levels.

Vinca is a highly valuable medicinal plant with potent antitumor properties. Its alkaloids, particularly vinblastine and vincristine, are widely used in modern medicine to treat various cancers , including lymphomas, leukemia, and solid tumors. However, their toxicity profile requires careful administration.

(J) ANTILEPROTICS - CHAULMOOGRA OIL

Antileprotic drugs are used in the treatment of leprosy (Hansen's disease), a chronic infectious disease caused by Mycobacterium leprae.

Chaulmoogra oil is a traditional remedy used for the treatment of leprosy, a chronic infectious disease caused by Mycobacterium leprae.

Chaulmoogra oil, obtained from the seeds of Hydnocarpus species, was historically one of the first effective treatments for leprosy.

1. Chaulmoogra Oil

Occurrence and Distribution

- Chaulmoogra oil is obtained from the seeds of trees belonging to the genus Hydnocarpus, primarily Hydnocarpus wightianus and Hydnocarpus anthelmintica.
- These trees are native to South and Southeast Asia, particularly in India, Myanmar, and Thailand.
- The oil has been used for centuries in traditional medicine for treating skin diseases and leprosy.

Organoleptic Evaluation

- Color: Yellowish-brown to greenish-brown.
- Odor: Characteristic and slightly unpleasant.
- Taste: Bitter and acrid.
- Texture: Thick and viscous liquid.

Chemical Constituents

- Fatty acids: The primary active constituents responsible for its antileprotic properties.

  Chaulmoogric acid: A cyclopentenyl fatty acid.

  Hydnocarpic acid: Another cyclopentenyl fatty acid.

  Gorlic acid: Present in smaller amounts.
- Glycerides: Esters of the above fatty acids.
- Other lipids: Present in trace amounts.

Mechanism of Action

- The cyclopentenyl fatty acids in Chaulmoogra oil have antimicrobial properties against Mycobacterium leprae.

  They disrupt the cell membrane of the bacteria, leading to cell death.

  They also have anti-inflammatory effects, reducing the symptoms of leprosy, such as skin lesions and nerve damage.

Identification Tests

1. Saponification Test:

   The oil is treated with alcoholic potassium hydroxide.

   The formation of soap indicates the presence of glycerides.
2. Thin Layer Chromatography (TLC):

   Used to identify chaulmoogric acid, hydnocarpic acid, and gorlic acid.
3. Iodine Value Test:

   The high iodine value of Chaulmoogra oil confirms the presence of unsaturated fatty acids.

Pharmaceutical Applications

- Antileprotic: Used to treat leprosy by inhibiting the growth of Mycobacterium leprae.
- Topical Applications: Applied to skin lesions to reduce inflammation and promote healing.
- Traditional Medicine: Used in Ayurveda and Chinese medicine for skin diseases and infections.

Modern Replacements:

- Dapsone, Rifampicin, and Clofazimine have replaced Chaulmoogra oil in the WHO multidrug therapy (MDT) for leprosy.
- Still used in herbal medicine for skin infections.

Side Effects & Precautions

- Gastrointestinal discomfort when taken orally.
- Skin irritation in some individuals.
- Not commonly used today due to better synthetic alternatives.

Chaulmoogra oil is a traditional remedy with significant antileprotic properties. Its active constituents, particularly chaulmoogric acid and hydnocarpic acid, are effective against Mycobacterium leprae.

Chaulmoogra oil is one of the first effective treatments for leprosy, acting through bacteriostatic and immune-modulating mechanisms. While it has been replaced by modern antibiotics, it still holds historical significance in antileprotic therapy.

(K) ANTIDIABETICS -PTEROCARPUS, GYMNEMA, SYLVESTRO

Antidiabetic drugs help regulate blood sugar levels and improve insulin function. Natural antidiabetics, like Pterocarpus and Gymnema sylvestre, have been used in traditional medicine for diabetes management.

1. Pterocarpus (Pterocarpus marsupium)

Occurrence and Distribution

- Pterocarpus is derived from the heartwood and bark of Pterocarpus marsupium, commonly known as Indian Kino Tree or Vijayasar.
- It is native to India, Sri Lanka, and Nepal, and is found in deciduous forests.

Organoleptic Evaluation

- Color: Reddish-brown (heartwood) to dark brown (bark).
- Odor: Slight and characteristic.
- Taste: Bitter and astringent.
- Texture: Hard and woody.

Chemical Constituents

- Flavonoids:

  Epicatechin: The major active constituent with antidiabetic properties.

  Marsupin: Another important flavonoid.
- Tannins: Contribute to its astringent properties.
- Pterostilbene: A stilbenoid with antioxidant and hypoglycemic effects.

Mechanism of Action

- Epicatechin and pterostilbene enhance insulin secretion and improve insulin sensitivity.
- They also have antioxidant properties, protecting pancreatic β-cells from oxidative damage.

Identification Tests

1. Ferric Chloride Test:

   The sample is treated with ferric chloride solution.

   A blue-black color indicates the presence of tannins.
2. Thin Layer Chromatography (TLC):

   Used to identify epicatechin and pterostilbene. Rf value ~0.5 in chloroform-methanol solvent.

At first, the cooperative movement was started by Robert Owen, in the year 1844. He formed a consumer's cooperative society in England with 28 workers as members, called "Rochdale Society of Equitable Pioneers". This gradually led to world-wide movement of organising, cooperatives in various fields of economic activity such as credit, farming, marketing, processing, housing, transport, insurance, fisheries, poultry, dairying, etc., The main object of the cooperative movement was to bring solace and comfort to the needy persons by pursuing common economic interests through cooperative trading. Profit is not a main objective.

Cooperation is a form of organization in which persons voluntarily associate together as human beings on the basis of equality for the promotion of the economic interests of themselves. - H.Calvert

Cooperation is "better farming, better business and better living" - Sir Horace Plunkett

Principles of Cooperation

Voluntary and Open Membership

Cooperatives are voluntary organizations, open to all people able to use its services and willing to accept the responsibilities of membership, without gender, social, racial, political or religious discrimination.

Democratic Member Control

Cooperatives are democratic organizations controlled by their members—those who buy the goods or use the services of the cooperative—who actively participate in setting policies and making decisions.

Member's Economic Participation

Members contribute equally to, and democratically control, the capital of the cooperative. This benefits members in proportion to the business they conduct with the cooperative rather than on the capital invested.

Autonomy and Independence

Cooperatives are autonomous, self-help organizations controlled by their members. If the co-operative organisation enters into agreements with other organizations or raises capital from external sources, it is done so based on terms that ensure democratic control by the members and maintains the cooperative's autonomy.

Education, Training, and Information

Cooperatives provide education and training for members, elected representatives, managers and employees so they can contribute effectively to the development of their cooperative. Members also inform the general public about the nature and benefits of cooperatives.

Cooperation among Cooperatives

Cooperatives serve their members most effectively and strengthen the cooperative movement by working together through local, national, regional and international structures.

Concern for Community

While focusing on member needs, cooperatives work for the sustainable development of communities through policies and programs accepted by the members.

Features of Cooperatives

The following are some of the important principles of co-operative societies.

Voluntary Membership

Any person can become the member of the society and can leave it any time.

Equal Rights

Each member of the society has an equal right to vote and ownership. Each shareholder has one vote.

Democracy

The principle of democracy is adopted while making the decisions. The decision of the majority is honored.

Honesty

It is the basic principle of this society. Its members should be honest. Selfish people can not run the business of cooperative society.

Mutual Confidence

The foundation of Cooperative society is laid on mutual confidence. Members of the society should trust each other and work like a team.

Welfares

Its main objective is to provide goods and services to its members at lower price.

Cash Payment

Credit team is prohibited and goods are supplied to its members on cash payment.

Economy

The member of the society should act upon the principle of economy. They should not misuse capital of the society and always keep in view best interest of the society.

Distribution of Profit

The profit can be distributed among the members according the cooperative act. One fourth (1/4) of the profit can be kept in reserve. Then (10%) of the profit can be used for providing facilities to the members.

Self Service

All the business activities are conducted by the members themselves. All are the owner and all are the consumers. So self-service rule is employed in the organization.

Advantages and Disadvantages

Advantages

The following are some of the important advantages of co-operative societies.

Voluntary organization

The membership of a cooperative society is open to all. Any person with common interest can become a member. The membership fee is kept low so that everyone would be able to join and benefit from cooperative societies. At the same time, any member who wants to leave the society is free to do so. There are no entry or exit barriers.

Easy formation

Cooperatives can be formed much easily when compared to a company. Any 25 members who have attained majority can join together for forming a cooperative society by observing simple legal formalities.

Democracy

A co-operative society is run on the principle of 'one man one vote'. It implies that all members have equal rights in managing the affairs of the enterprise. Members with money power cannot dominate the management by buying majority shares.

Equal distribution of surplus

The surplus generated by the cooperative societies is distributed in an equitable manner among members. Therefore all the members of the cooperative society are benefited. Further the society is also benefited because a sum not exceeding 10 per cent of the surplus can be utilized for promoting the welfare of the locality in which the cooperative is located.

Limited liability

The liability of the members in a cooperative society is limited to the extent of their capital contribution. They cannot be personally held liable for the debts of the society.

Separate legal entity

A cooperative society enjoys separate legal entity which is distinct from its members. Therefore its continuance is in no way affected by the death, insanity or insolvency of its members. It enjoys perpetual existence.

Each for all and all for each

Co-operative societies are formed on the basis of self help and mutual help. Therefore members contribute their efforts to promote their common welfare.

Greater identity of interests

It operates in a limited geographical area and there is greater identity of interest among members. Members would be interacting with each other. They can cooperate and manage the activities of the society in a more effective manner.

Government support

The government with a view to promote the growth of cooperative societies extends all support to them. It provides loans at cheap interest rates, provides subsidies etc.

Elimination of middlemen

Cooperatives societies can deal directly with the producers and with the ultimate consumers. Therefore they are not dependent on middlemen and can save the profits enjoyed by the middlemen.

Tax concessions

To promote the co-operative movement and also because of the fact that it is a non-profit enterprise, government provides various exemptions and tax concessions.

Rural credit

Co-operative societies have contributed significantly in freeing villagers from money lenders. Earlier, money lenders used to charge high rates of interest and the earnings of the villagers were spent on payment on interest alone.

Co-operatives provide loans at cheaper interest rates and have benefited the rural community. After the establishment of cooperatives, the rural people were able to come out of the grip of money lenders.

Disadvantages

i. Limited funds

Co-operative societies have limited membership and are promoted by the weaker sections. The membership fees collected is low. Therefore the funds available with the co-operatives are limited. The principle of one-man one-vote and limited dividends also reduce the enthusiasm of members. They struggle to expand their activities beyond a particular level because of the limited financial resources.

ii. Over reliance on Government funds

Co-operative societies are not able to raise their own resources. Their sources of financing are limited and they depend on government funds. The funding and the amount of funds that would be released by the government are uncertain. Therefore co-operatives are not able to plan their activities in the right manner.

iii. Imposed by Government

In the Western countries, co-operative societies were voluntarily started by the weaker sections. The objective is to improve their economic status and protect themselves from exploitation by businessmen. But in India, the co-operative movement was initiated and established by the government. Wide participation of people is lacking. Therefore the benefit of the co-operatives has still not reached many poorer sections.

iv. Benefit to rural rich

Co-operatives have benefited the rural rich and not the rural poor. The rich people elect themselves to the managing committee and manage the affairs of the co-operatives for their own benefit. The agricultural produce of the small farmers is just sufficient to fulfill the needs of their family. They do not have any surplus to market.

The rich farmers with vast tracts of land produce in surplus quantities and the services of co-operatives such as processing, grading, correct weighment and fair prices actually benefit them.

v. Inadequate rural credit

Co-operative societies give loans only for productive purposes and not for personal or family expenses. Therefore the rural poor continue to depend on the money lenders for meeting expenses of marriage, medical care, social commitments etc. Co-operatives have not been successful in freeing the rural poor from the clutches of the money lenders.

vi. Lack of managerial skills

Co-operative societies are managed by the managing committee elected by its members. The members of the managing committee may not have the required qualification, skill or experience. Since it has limited financial resources, its ability to compensate its employees is also limited. Therefore it cannot employ the best talent. Lack of managerial skills results in inefficient management, poor functioning and difficulty in achieving objectives.

vii. Government intervention

Co-operative societies are subject to excessive government regulation which affects their autonomy and flexibility. Adhering to various regulations takes up much of the management's time and effort.

viii. Misuse of funds

If the members of the managing committee are corrupt they can swindle the funds of the co-operative society. Many cooperative societies have faced financial troubles and closed down because of corruption and misuse of funds.

ix. Inefficiencies leading to losses

Co-operative societies operate with limited financial resources. Therefore they cannot recruit the best talent, acquire latest technology or adopt modern management practices. They operate in the traditional mold which may not be suitable in the modern business environment and therefore suffer losses.

x. Lack of secrecy

Maintenance of business secrets is the key for the competitiveness of any business organization. But business secrets cannot be maintained in cooperatives because all members are aware of the activities of the enterprise. Further, reports and accounts have to be submitted to the Registrar of Cooperative Societies. Therefore information relating to activities, revenues, members etc becomes public knowledge.

xi. Conflicts among members

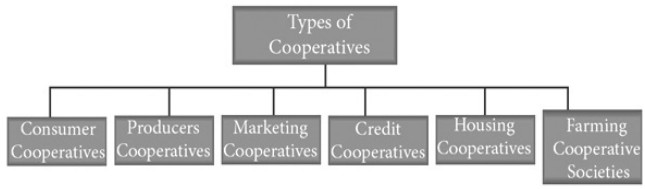
Cooperative societies are based on the principles of co-operation and therefore harmony among members is important. But in practice, there might be internal politics, differences of opinions, quarrels etc. among members which may lead to disputes. Such disputes affect the functioning of the cooperative societies.

xii. Limited scope

Co-operative societies cannot be introduced in all industries. Their scope is limited to only certain areas of enterprise. Since the funds available are limited they cannot undertake large scale operations and is not suitable in industries requiring large investments.

Types of Cooperatives

The Cooperatives can be broadly classified into two viz., Credit Cooperatives and Non- Credit Cooperatives. The credit cooperatives can be further classified into Agricultural credit and non-Agricultural credit cooperatives.



Consumers Cooperatives

Consumer cooperatives are organized by consumers that want to achieve better prices or quality in the goods or services they purchase. In contrast to traditional retail stores or service providers, a consumer cooperative exists to deliver goods or services rather than to maximize profit from selling those goods or services. They also supply essential commodities through Public Distribution System (PDS). Nationally, the most widely used cooperative form is the credit union, with some 90 million members. Credit union assets have grown a hundredfold in three decades. Credit unions are essentially cooperatives of people that use banking services.

Producers Cooperatives

Producer cooperatives are established and operated by producers. Producers can decide to work together or as separate entities to help increase marketing possibilities and production efficiency. They are organized to process, market, and distribute their own products. This helps lessen costs and strains in each area with a mutual benefit to each producer.

Example, Cooperative weavers' societies, Cooperative carpeting units, Cooperative match factories.

Marketing Cooperatives

Cooperative marketing societies are associations of small producers formed for the purpose of marketing their produce. The marketing cooperatives perform certain marketing functions such as grading, warehousing, advertising etc., they secure better prices for their members by transporting goods even to distant markets. Advance is also given to members against produce deposited with the society. Thus they are a boon to agriculturists, small producers and artisans, who in the absence of these cooperatives would be forced to sell at low prices to middlemen.

Credit Cooperatives

Cooperative credit societies are those formed for the purpose of providing short-term financial help to their members. Agriculturists, artisans, industrial workers, salaried employees, etc., form these credit societies. Being unable to obtain financial accommodation from banks they are at the mercy of money-lenders who charge exorbitant rates of interest. Ending this exploitation and encouraging thrift among members is the objective of these societies. Credit societies may be agricultural credit societies or non-agricultural credit societies.

Housing Cooperatives

These cooperative housing societies are meant to provide residential accommodation to their members on ownership basis or on rent. People who intend to build houses of their own join together and form housing societies. These societies advance loans to members, repayable over a period of 15 to 20 years. Housing building societies, on the other hand, construct houses for their members instead of granting loans to them. These are house construction societies which acquire land, construct houses and rent them to members. The member-tenant, however, can own the houses after paying the cost.

Cooperative Farming

Societies When various farmers in a village pool their land together and agree to treat the pooled piece of land as one big farm for the purpose of cultivation, purchase the necessary inputs for the cultivation, and market the crops jointly, they are assumed to have formed a cooperative farming society. Such a society, for its proper working elects its office bearers on the basis of one member-one-vote. The office bearers look after the proper cultivation of new farm that emerges after the land of various farmers has been pooled. The ownership of the land still lies with the respective members of the society and they withdraw from the society whenever they so like. Besides the land, farmers also contribute various productive assets as well as their labour for the purpose of cultivations. Whereas they get rent for their land and productive assets, they get wages, for their labour.

MULTI NATIONAL CORPORATIONS (MNCs)

A Multinational Corporation (MNC) is a company that operates in multiple countries beyond its home nation. These corporations have headquarters in one country while managing production, operations, or services in several others. MNCs play a crucial role in globalization by bringing foreign investments, technology, and employment opportunities to different economies. Some well-known examples include Apple, Microsoft, and Toyota.

In the Indian scenario, Multinational Corporations (MNCs) have played a significant role in shaping the country's economic landscape. After the economic liberalization of 1991, India opened its doors to foreign investment, leading to the rapid expansion of MNCs across various sectors such as IT, pharmaceuticals, automobiles, retail, and manufacturing. Companies like Google, Amazon, Microsoft, Nestlé, Hyundai, and Unilever have established a strong presence in India, contributing to employment, technology transfer, and economic growth.

The working method of Multinational Corporations (MNCs) involves expanding business operations across multiple countries while maintaining centralized control from their headquarters. Their functioning can be categorized into several key aspects:

Business Expansion and Entry Strategies:

MNCs enter foreign markets through:

- Foreign Direct Investment (FDI): Setting up wholly owned subsidiaries, joint ventures, or mergers with local firms.
- Franchising & Licensing: Allowing local businesses to use their brand and business model (e.g., McDonald's, KFC).
- Outsourcing & Offshoring: Shifting operations to countries with lower costs (e.g., IT services in India).

Organizational Structure:

MNCs operate using different management models:

- Centralized Structure: Decision-making happens at the headquarters, with limited autonomy for subsidiaries.
- Decentralized Structure: Local branches have decision-making power to adapt to regional markets.
- Hybrid Model: A mix of central control and local autonomy, balancing efficiency and flexibility.

Global Operations & Supply Chain Management:

- MNCs source raw materials from multiple countries to optimize cost.
- They set up manufacturing units in cost-effective regions (e.g., China, India, Vietnam).
- Logistics and distribution networks ensure seamless product delivery across markets.

Marketing and Consumer Adaptation:

- MNCs follow glocalization—a mix of global brand identity and local customization (e.g., McDonald's in India offers vegetarian options).
- They invest heavily in branding, digital marketing, and customer engagement to establish a strong presence.

Financial Management:

- MNCs manage finances across different currencies and taxation systems.
- They use transfer pricing to allocate profits efficiently among subsidiaries.
- They reinvest earnings in profitable markets or repatriate them to their home country.

volume and intended use. Below is a comprehensive and detailed explanation of both, including their definitions, uses, manufacturing processes, quality control, and key differences.

1. Large Volume Parenterals (LVPs)

Definition

- LVPs are sterile solutions or emulsions administered in large volumes, typically 100 mL or more.
- They are primarily used for fluid replacement, nutrition, and electrolyte balance.

Key Characteristics

- Volume: 100 mL to several liters (e.g., 1000 mL bags of IV fluids).
- Administration Route: Usually administered via intravenous (IV) infusion.
- Packaging: Packaged in flexible bags or rigid bottles.
- Examples:

  IV Fluids: Normal saline (0.9% NaCl), Ringer's lactate, dextrose solutions (e.g., 5% dextrose).

  Nutritional Solutions: Total parenteral nutrition (TPN) solutions containing amino acids, lipids, and glucose.

  Electrolyte Solutions: Potassium chloride, magnesium sulfate.

Uses

1. **Fluid Replacement:**

   Used to treat dehydration, shock, or blood loss.

   Examples: Normal saline, Ringer's lactate.
2. **Nutritional Support:**

   Provides essential nutrients to patients unable to eat (e.g., post-surgery, critically ill patients).

   Examples: TPN solutions.
3. **Electrolyte Balance:**

   Corrects electrolyte imbalances (e.g., hypokalemia, hypomagnesemia).

   Examples: Potassium chloride, magnesium sulfate.
4. **Medication Delivery:**

   Used as a vehicle to deliver medications in a diluted form.

   Examples: Antibiotics or analgesics mixed with IV fluids.

Manufacturing Process

1. **Formulation:**

   Ingredients (e.g., water, electrolytes, nutrients) are mixed in precise proportions.
2. **Filtration:**

   The solution is filtered to remove particulate matter and microorganisms.
3. **Filling:**

   The solution is filled into sterile bags or bottles under aseptic conditions.
4. **Sterilization:**

   The filled containers are sterilized using autoclaving or other methods.
5. **Labeling and Packaging:**

   Containers are labeled with essential information (e.g., contents, expiration date) and packaged for distribution.

Quality Control

- Sterility Testing: Ensures the absence of microorganisms.
- Particulate Matter Testing: Ensures the solution is free from visible particles.
- Pyrogen Testing: Ensures the absence of fever-causing substances.
- Stability Testing: Ensures the solution remains stable and effective throughout its shelf life.

2. Small Volume Parenterals (SVPs)

Definition

- SVPs are sterile solutions or suspensions administered in small volumes, typically less than 100 mL.
- They are used for direct medication administration, vaccinations, and diagnostic purposes.

Key Characteristics

- Volume: Less than 100 mL (e.g., 1 mL, 5 mL, 10 mL).
- Administration Route: Administered via IV push, IV infusion, intramuscular (IM), or subcutaneous (SC) routes.
- Packaging: Packaged in vials, ampoules, or prefilled syringes.
- Examples:

  Antibiotics: Ceftriaxone, vancomycin.

  Analgesics: Morphine, fentanyl.

  Vaccines: Hepatitis B vaccine, influenza vaccine.

  Diagnostic Agents: Contrast media for imaging studies.

Uses

1. **Medication Administration:**

   Delivers medications directly into the bloodstream or tissues.

   Examples: Antibiotics, pain relievers, chemotherapy drugs.
2. **Vaccinations:**

   Used for immunizations in outpatient and inpatient settings.

   Examples: Hepatitis B vaccine, influenza vaccine.
3. **Diagnostics:**

   Administers contrast media for imaging studies (e.g., CT scans, MRIs).

   Examples: Iodinated contrast media, gadolinium-based contrast agents.

Manufacturing Process

1. **Formulation:**
   Active pharmaceutical ingredients (APIs) and excipients are mixed in precise proportions.
2. **Filtration:**
   The solution is filtered to remove particulate matter and microorganisms.
3. **Filling:**
   The solution is filled into sterile vials, ampoules, or prefilled syringes under aseptic conditions.
4. **Sterilization:**
   The filled containers are sterilized using autoclaving or other methods.
5. **Labeling and Packaging:**
   Containers are labeled with essential information (e.g., contents, expiration date) and packaged for distribution.

Quality Control

- Sterility Testing: Ensures the absence of microorganisms.
- Particulate Matter Testing: Ensures the solution is free from visible particles.
- Pyrogen Testing: Ensures the absence of fever-causing substances.
- Potency Testing: Ensures the medication is effective at the specified dose.

3. Key Differences Between LVPs and SVPs

Aspect	Large Volume Parenterals (LVPs)	Small Volume Parenterals (SVPs)
Volume	100 mL or more	Less than 100 mL
Purpose	Fluid replacement, nutrition, electrolyte balance	Direct medication administration, vaccinations
Administration Route	Intravenous (IV) infusion	IV push, IV infusion, IM, SC
Packaging	Bags or bottles (100 mL to 1000 mL or more)	Vials, ampoules, prefilled syringes
Examples	Normal saline, Ringer's lactate, TPN solutions	Antibiotics, analgesics, vaccines
Frequency of Use	Often used for continuous or prolonged therapy	Used for single-dose or short-term therapy
Storage	Requires larger storage space	Requires less storage space

4. Applications in Healthcare

a. LVPs

- Critical Care: Used in ICUs for fluid resuscitation and electrolyte management.
- Surgery: Administered during and after surgery to maintain hydration.
- Nutritional Support: Provides TPN for patients unable to eat.

b. SVPs

- Medication Administration: Delivers antibiotics, pain relievers, and other medications.
- Vaccinations: Used for immunizations in outpatient and inpatient settings.
- Diagnostics: Administers contrast media for imaging studies.

5. Manufacturing and Quality Control

Both LVPs and SVPs require sterile manufacturing and strict quality control to ensure safety and efficacy.

a. Sterility

- Both must be produced in cleanroom environments to prevent contamination.
- Sterility testing is performed using biological indicators.

b. Particulate Matter

- Must be free from visible particles to prevent complications (e.g., embolism).

c. Pyrogen Testing

- Ensures the absence of fever-causing substances (pyrogens).

Large Volume Parenterals (LVPs) and Small Volume Parenterals (SVPs) are essential components of modern healthcare, each serving distinct purposes. LVPs are used for fluid replacement, nutrition, and electrolyte balance, while SVPs are used for direct medication administration, vaccinations, and diagnostics. Understanding their differences in terms of volume, purpose, administration, and packaging is crucial for their appropriate use in clinical settings. Both require sterile manufacturing and strict quality control to ensure patient safety and therapeutic efficacy.

FACILITIES AND REQUIREMENTS NEEDED FOR STERILE MANUFACTURING

Sterile manufacturing is a critical process in the pharmaceutical and biotechnology industries, where products must be free from microbial contamination. The facilities and requirements for sterile manufacturing are stringent and must comply with regulatory standards such as Good Manufacturing Practices (GMP), US FDA guidelines, and European Medicines Agency (EMA) regulations. Below is a detailed list of the facilities and requirements necessary for sterile manufacturing:

1. Facility Design and Layout

- Cleanrooms:
  Classified as per ISO 14644-1 standards (e.g., ISO Class 5 for aseptic processing areas).

Designed to minimize contamination through HEPA (High-Efficiency Particulate Air) filtration and laminar airflow.

- Airlocks and Pass-Throughs:

  To control the movement of personnel and materials, preventing contamination.
- Segregation of Areas:

  Clear separation between clean, gray, and black zones to prevent cross-contamination.
- Material Flow:

  Unidirectional flow of materials and personnel to minimize contamination risks.
- Pressure Cascades:

  Higher pressure in cleaner areas to prevent the ingress of contaminants from less clean areas.

2. Environmental Controls

- Temperature and Humidity Control:

  Maintained within specified limits to ensure product stability and prevent microbial growth.
- Air Handling Systems:

  Equipped with HEPA filters to remove particulate matter and microorganisms.

  Regular monitoring of air quality (e.g., particulate counts, microbial counts).
- Ventilation:

  Proper ventilation to ensure adequate air exchange rates and prevent the buildup of contaminants.

3. Equipment and Utilities

- Sterilization Equipment:

  Autoclaves, dry heat sterilizers, and depyrogenation tunnels for sterilizing equipment and materials.
- Isolators and RABS (Restricted Access Barrier Systems):

  Used for aseptic processing to provide a controlled environment.
- Water Systems:

  Water for Injection (WFI) and Purified Water (PW) systems must meet pharmacopeial standards (e.g., USP, EP).
- Clean Steam:

  Used for sterilization and sanitization processes.
- Process Equipment:

  Stainless steel equipment designed for easy cleaning and sterilization (e.g., tanks, piping, filling machines).

4. Personnel Requirements

- Training:

  Comprehensive training on aseptic techniques, GMP, and sterile manufacturing procedures.
- Gowning:

  Proper gowning procedures with sterile garments (e.g., coveralls, gloves, masks, and hairnets).
- Hygiene:

  Strict personal hygiene practices, including hand sanitization before entering cleanrooms.
- Health Monitoring:

  Regular health checks to ensure personnel do not introduce contaminants.

5. Cleaning and Sanitization

- Cleaning Procedures:

  Validated cleaning procedures for equipment and facilities to ensure the removal of contaminants.
- Sanitization Agents:

  Use of approved disinfectants and sporicidal agents for surface sanitization.
- Cleaning Validation:

  Regular validation of cleaning processes to ensure effectiveness.

6. Sterilization Processes

- Heat Sterilization:

  Autoclaving (moist heat) and dry heat sterilization for equipment and materials.
- Filtration:

  Use of 0.22 μm or 0.1 μm filters for sterilizing liquids and gases.
- Radiation Sterilization:

  Gamma irradiation or electron beam sterilization for heat-sensitive materials.
- Chemical Sterilization:

  Use of ethylene oxide or hydrogen peroxide for sterilizing heat-sensitive equipment.

7. Process Controls

- Aseptic Processing:

  Strict adherence to aseptic techniques during manufacturing, filling, and packaging.
- Environmental Monitoring:

  Continuous monitoring of particulate and microbial levels in cleanrooms.
- Media Fills:

  Simulation of the aseptic process using microbial growth media to validate sterility.
- Process Validation:

  Validation of all critical processes to ensure consistent product quality.

8. Quality Control and Assurance

- Sterility Testing:

  Conducted on finished products to ensure they meet sterility requirements (e.g., USP <71>).
- Endotoxin Testing:

  Testing for bacterial endotoxins using the Limulus Amebocyte Lysate (LAL) test.

- Documentation:

  Comprehensive documentation of all processes, including batch records, cleaning records, and validation reports.

- Audits and Inspections:

  Regular internal and external audits to ensure compliance with regulatory standards.

9. Regulatory Compliance

- GMP Compliance:

  Adherence to GMP guidelines as per FDA, EMA, and other regulatory bodies.

- Validation and Qualification:

  Validation of equipment, processes, and facilities (e.g., Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ)).

- Change Control:

  Strict change control procedures to manage any changes in processes, equipment, or facilities.

- Regulatory Submissions:

  Submission of documentation to regulatory agencies for product approval.

10. Risk Management

- Risk Assessment:

  Conducting risk assessments to identify and mitigate potential contamination risks.

- Contamination Control Strategy:

  Implementing a comprehensive strategy to prevent contamination at all stages of manufacturing.

- Incident Management:

  Procedures for handling and investigating contamination incidents.

11. Packaging and Labeling

- Sterile Packaging:

  Use of sterile packaging materials to maintain product sterility until use.

- Labeling:

  Accurate labeling of products with batch numbers, expiration dates, and storage conditions.

12. Storage and Distribution

- Controlled Storage:

  Storage of sterile products in controlled environments to maintain sterility.

- Cold Chain Management:

  For temperature-sensitive products, ensuring proper temperature control during storage and distribution.

- Transport Validation:

  Validation of transportation processes to ensure product integrity.

13. Continuous Improvement

- Process Optimization:

  Continuous improvement of processes to enhance efficiency and reduce contamination risks.

- Technology Upgrades:

  Adoption of advanced technologies (e.g., isolators, robotics) to improve sterility assurance.

- Training and Development:

  Ongoing training programs to keep personnel updated on the latest sterile manufacturing practices.

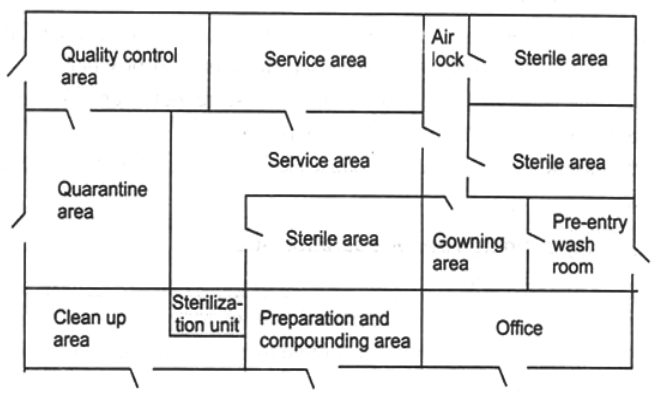
LAYOUT OF STERILE PRODUCT AREA

The sterile manufacturing requires specific and particular areas for different purposes. The product runs through these areas sequentially before it is finished. These areas should be well coordinated with each other and areas should be free from microbial and particulate matter.

The sterile product areas can be subdivided as follows:

1. Clean up area
2. Preparation or compounding area
3. Aseptic area
4. Quarantine area
5. Finishing and packaging area
6. Service area
7. Quality control area
8. Office
9. Pre-entry washroom
10. Growning area.

The floor plan of the sterile products area is given below:



IDEAL PROPERTIES OF PARENTERALS

1. It should be sterile.
2. It should be free from pyrogens.
3. It should be non-toxic and non-irritant.
4. It should be isotonic with body fluids.
5. It should be clear.

corrective measures where warranted and their includes the power to fix and regulate such prices.

Allowed Margins

For scheduled (controlled) drugs the margin is fixed at 16% as per para 19 of the DPCO, 1995 which is reproduced below :

1. "A Manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of this order or any order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen per cent thereof in the case of Scheduled drugs"
2. "Notwithstanding anything contained in sub-paragraph (1), the Government may by a general or special order fix, in public interest, the price of formulations sold to the wholesaler or retailer in respect of any formulation the price of which has been fixed or revised under this Order". For non-scheduled formulations the companies are at liberty to decide the margin. However, it is reported by the industry that the prevailing normal trade margin in respect of some decontrolled formulations is 20% for retailers and 10% for wholesalers.

Retail Price

A retail price is a price at which a formulation / medicine is sold to a consumer/user. The manufacturer of the formulation is required to print such a price on the label of the product. In case of controlled formulations the retail price is a price arrived at or fixed in accordance with the provisions of Drugs (Prices Control) Order, 1995.

Violation of the DPCO, 1995

Contravention of any of the provisions of DPCO, 1995 is punishable in accordance with the provision of the Essential Commodities Act, 1955. As per Sec. 7 of Essential Commodities Act, the penalty for contravention of DPCO is minimum imprisonment of 3 months, which may extend to seven years and the violator is also liable to a fine.

If a manufacturer sells a medicine at a price higher than the price approved/ fixed for the product the manufacturer is liable for prosecution under Essential Commodities Act and also liable to deposit the amount with the Government accrued due to charging of prices higher than those fixed or notified by the Government.

The National Pharmaceutical Pricing Authority, the FDA/ Drugs Controller of the State, and Drugs Inspector of the District are the enforcing authorities at National / State/ District Levels.

The area State Drug Controller/Joint Drug Controller/ Deputy Drug Controller/Assistant Drug Controller / Drugs Inspector etc. of the state concerned. Complaints can be lodged with anyone of these.

Methodology for fixation of bulk drug price

Methodology for fixation/revision of bulk drug prices is as under : As per para 3 of DPCO, 1995, bulk drug prices are fixed by the NPPA to make it available at a fair price from different manufacturers. These prices are fixed from time to time by notification in the official gazette. The following steps are involved in fixation/revision of bulk drug prices :-

- Collection of data by issuing questionnaire/Form I of DPCO, 1995 to the companies and from cost-audit report etc.
- Verification of data by plant visits, when required.
- Preparation of actual cost statement.
- Preparation of technical parameters to be adopted for working out fair price of the bulk drug.
- Preparation of estimated cost based on actual cost and technical parameters. Fair price is calculated by providing returns as specified in sub para (2), para 3 of DPCO, 1995 as opted by the individual manufacturer.
- Fixation of fair price of bulk drug by considering weighted average cost, °rd cut-off level of production studied.
- Notification of bulk drug price in official Gazette.
- The fair prices may be further revised, if asked for by the manufacturers, based on escalation formula for change in major raw materials and utilities rates.

Suo-motu Pricing

The NPPA also fixes/revises prices of both bulk drugs and formulations on suo-motu basis, where it is felt that manufacturers are not filing their applications as per the provisions of the DPCO, 1995 after the decrease in bulk drug prices and statutory duties, etc. Hence, with a view to passing on the benefits of such decreases to the consumers, suo-motu price is fixed. For example, as per para 8(2) of DPCO, 1995, the manufacturers are to apply for price revision of formulations within a period of thirty days of price fixation/revision of bulk drug(s). If they fail to comply with this during the prescribed time, suo- motu action is taken as per para 9(2) of DPCO, 1995 for ceiling prices, and as per para 8(2) and para 11 of DPCO, 1995 for non-ceiling packs.

Pro-rata Pricing

NPPA has issued notification on pro -rata pricing on 27.01.98. According to this notification, the manufacturers of all the scheduled formulation pack sizes different from the notified pack sizes under sub-paragraphs (1) and (2) of the paragraph 9 of the DPCO, 1995, shall have to work out the price for such pack sizes, in respect of tablets and capsules of the same strength or composition packed in different strips or blisters, on pro-rata basis of the latest ceiling price fixed for such formulations under sub-paragraphs (1) and (2) of para 9 of the DPCO, 1995. This was done to ensure that :-

1. manufacturers are not forced to approach frequently for price approvals for different pack sizes and
2. the manufacturers do not change the pack sizes in a bid to remain out of price control.

Every formulation of a bulk drug included under schedule 1 of DPCO, irrespective of pack size, strength, dosage form must be marketed only at price fixed by Government, with adjustment for pro-rata price wherever required. However, the manufacturers in the Small Scale Industry (SSI) category may avail exemption from seeking price fixation from NPPA in respect of Scheduled Formulations not covered under ceiling prices provided they have submitted a declaration to NPPA as per S.O.No.134(E) dated 2nd March, 1995 and obtained approval for the same from NPPA.

Other Key Provisions of DPCO 2013

1. Applicability & Coverage

- Applies to all medicines listed in the **National List of Essential Medicines (NLEM)**.
- Covers all **strengths and dosages** of drugs mentioned in the **Schedule-I** of DPCO.
- Extends to both **formulations** (ready-to-use medicines) and **Active Pharmaceutical Ingredients (APIs)** under specific conditions.

2. Price Control Mechanism

- Ceiling Price Calculation:
  - Prices are calculated based on the market-based pricing (MBP) method instead of cost-based pricing.

  The formula:

  $Pc = Ps \times (1 + M/100)$

  - Where:

    PcP_cPc = Ceiling price

  PsP_sPs = Simple average of all brands having 1% or more market share

  - MMM = Retailer margin (usually 16%)
  - NPPA fixes prices and updates them periodically.
- Non-Scheduled Formulations:
  - The government allows a maximum 10% increase in the price of non-scheduled drugs annually.

3. Price Regulation for New Drugs

- If a new drug is introduced that is a variation of an existing drug, NPPA can regulate its price if it falls under NLEM or public interest cases.

Manufacturers' & Retailers' Responsibilities

1. Compliance with Price Controls

- Manufacturers cannot sell scheduled drugs above the fixed ceiling price.
- They must submit price lists to NPPA via the Integrated Pharmaceutical Database Management System (IPDMS).
- Updated price lists must be provided to state drug controllers & retailers.

2. Retailers' Obligations

- Retailers and wholesalers must display the price list at their premises.
- Cannot sell above Maximum Retail Price (MRP) fixed under DPCO.

Enforcement & Penalties

- Overcharging:
  - Any company selling above the ceiling price must return the overcharged amount along with interest & penalty.
- Legal Action:
  - Non-compliance can lead to penalties under the Essential Commodities Act, 1955.
- Inspection & Monitoring:
  - NPPA conducts random checks, audits & enforcement actions.

Recent Updates in 2023-2024

1. Price Control on Additional Drugs

- August 2023: NPPA added 44 new drugs under price control.
- January 2024: More essential drugs were brought under regulation.
- The newly controlled medicines include:
  - Painkillers (NSAIDs, Opioids)
  - Mental health medications (Antidepressants, Anxiolytics, Antipsychotics)
  - Gastrointestinal drugs (Acid reflux, Ulcers, Liver conditions)
  - Hypertension and cardiac drugs
  - Autoimmune disorder medications (Arthritis, Lupus, Psoriasis drugs)

2. NPPA Fixed Prices for 93 Essential Formulations

Examples:

- Digoxin 0.25 mg (Heart medicine) → 7.14 per tablet
- Pyrazinamide 1000 mg (Tuberculosis drug) → 9.39 per tablet
- Amoxicillin + Clavulanic Acid 625 mg (Antibiotic) → 22.50 per tablet

3. Revised Ceiling Prices for Commonly Used Medicines

- NPPA revised prices for existing scheduled drugs under NLEM 2022.
- Affected drugs include antibiotics, antivirals, insulin, and vaccines.

Impact of DPCO on Healthcare & Pharmaceuticals

1. Benefits

Affordable Medicines: Helps patients access essential drugs at reasonable prices.

Fair Market Competition: Prevents overpricing and price exploitation.

Transparency: Ensures uniform pricing & accountability in the pharma industry.

Encourages Domestic Production: Regulated pricing supports generic drug manufacturers.

2. Challenges & Criticism

Reduced Profit Margins for Pharma Companies May discourage innovation. Black Marketing & Shortages Some manufacturers withdraw low-profit drugs. Limited Control on Non-Essential Drugs Many high-cost medicines remain unregulated. Implementation Challenges Monitoring thousands of retailers and manufacturers is difficult.

Key Government Initiatives Supporting Price Control

- Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)
- Provides low-cost generic medicines at Janaushadhi Kendras.
- Ayushman Bharat Scheme
- Covers free treatment & essential medicines for poor families.
- Strengthening NPPA's Monitoring
- Government is enhancing digital tracking of medicine prices through IPDMS 2.0.

The Poisons Act, 1919

Introduction

- The Poisons Act, 1919 (Act No. 12 of 1919) was enacted to regulate the import, possession, sale, and use of poisons in India.
- It aims to prevent the misuse of poisons and ensure that they are used safely for medical, industrial, and scientific purposes.
- It provides state governments the power to regulate poisons within their respective territories.

Objectives of the Act

To prevent the misuse and illegal trade of poisons.

To regulate the sale, possession, and distribution of poisons.

To ensure that poisons are used only for legitimate purposes.

To empower the government to restrict or prohibit certain poisons based on public safety.

Key Provisions of The Poisons Act, 1919

1. Power of State Governments (Section 2)

- The State Government has the authority to regulate the possession, sale, and distribution of poisons.
- It can restrict, prohibit, or license poisons to control their misuse.

2. Rules for Import of Poisons (Section 3)

- The Central Government regulates importation of poisons into India.
- Only licensed dealers can import certain poisons.
- A ban can be imposed on the import of poisons if it is deemed dangerous to public safety.

3. Sale of Poisons (Section 4)

The State Government has the authority to:

- Regulate or prohibit the sale of poisons.
- Specify conditions under which poisons can be sold.
- Require that sales be recorded in a register.

4. Labeling and Packaging Regulations (Section 5)

Poisons must be labeled properly with:

- Name of the poison.
- Manufacturer's details.
- Proper usage instructions.
- Safety precautions and antidote information.
- Improper labeling can result in legal action.

5. Possession and Use of Poisons (Section 6)

The State Government can:

- Restrict the possession of poisons to authorized persons.
- Allow only licensed individuals (doctors, pharmacists, industrial users) to handle certain poisons.

6. Record Maintenance (Section 7)

- Every dealer, pharmacist, or authorized seller must maintain a register of poison sales.

The register must include:

- Buyer's details (Name, Address, Occupation).
- Purpose of purchase.
- Quantity sold.
- Date of sale.
- Signature of buyer & seller.

7. Penalties for Violation (Section 8)

Any person violating the rules can be punished with:

- Imprisonment up to 3 months.
- Fine up to ₹500 (can be revised by the government).
- Both imprisonment and fine in severe cases.

Schedules of The Poisons Act, 1919

The act divides poisons into two categories:

Schedule A – Poisons Under Government Control

Includes highly toxic substances such as:

- Arsenic
- Cyanide
- Mercury compounds
- Strychnine
- Hydrocyanic acid

These require special licenses for possession, sale, and import.

Schedule B – Poisons with Limited Restrictions

Includes mildly toxic substances like:

- Chloroform
- Phenol
- Formaldehyde
- Aniline

Can be sold without a special license but under certain restrictions.

Power to Issue Search Warrant

i) The District Magistrate, the Sub-Divisional Magistrate and in a presidencytown, the commissioner of police, may issue a warrant for the search of any place in which he has reason to believe or to suspect that any poison is possessed or sold in contravention of the poison Act or any rule there under. All of these people may also issue a warrant regarding any poison liable to confiscation under this Act is kept or concealed.

ii) The warrant permits entry and search and is governed by the Code of Bharatiya Nagarik Suraksha Sanhita (BNSS), 2024 relating to search warrants.

Responsibilities of Pharmacists Under the Act

Pharmacists must comply with the following:

Maintain a poison register for every sale.

Verify the identity of the buyer and purpose of purchase.

Ensure that poisons are properly labeled and packaged.

Follow State Government regulations for sale and possession.

Report any suspicious purchases to authorities.

Amendments & Recent Updates

- The Poisons (Amendment) Act, 1958 updated the penalty provisions to increase fines.
- State-specific rules: Different states have modified licensing and record-keeping requirements.
- Some industrial poisons now require strict monitoring due to their use in criminal activities (e.g., acid attacks, cyanide poisoning).
- In recent years, the government has increased regulations on acid sales (e.g., Sulfuric Acid, Hydrochloric Acid) due to their use in acid attacks.

Impact of The Poisons Act on Public Health & Safety

Advantages

Prevents illegal trade & misuse of poisons.

Ensures safe handling & disposal of toxic substances.

Helps in tracking the sale of dangerous chemicals.

Provides a legal framework for the control of poisons in medical, industrial, and agricultural sectors.

Challenges

Black Market Sales: Some poisons are still available illegally.

Lack of Awareness: Many small-scale sellers are unaware of proper regulations.

Inconsistent State Regulations: Different states have different rules, making enforcement difficult.

Improper Disposal Issues: Toxic waste disposal remains a concern.

Comparison with Other Poison Control Laws

Law	Purpose
Poisons Act, 1919	Regulates sale, possession, and use of poisons.
Drugs and Cosmetics Act, 1940	Controls the manufacture, sale, and distribution of drugs and cosmetics, including poisonous drugs.
Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985	Regulates narcotic drugs and psychotropic substances, which can also act as poisons.
Insecticides Act, 1968	Controls the use of pesticides and agricultural poisons.

Medicinal and Toilet Preparations (Excise Duties) Act, 1955

- The **Medicinal and Toilet Preparations (Excise Duties) Act, 1955** was enacted to **regulate and impose excise duties** on medicinal and toilet preparations that contain **alcohol, narcotic drugs, or psychotropic substances**.
- It ensures that **these preparations are taxed properly** and prevents the **misuse or illegal sale** of alcohol-based medicines and cosmetics.
- This Act is administered by the **Central Board of Indirect Taxes and Customs (CBIC)** under the **Ministry of Finance, Government of India**.
- The latest amendments have aligned it with **GST regulations** for better tax collection.

AIDS, or the use of immunosuppressive medication. In contrast, autoimmunity results from a hyperactive immune system attacking normal tissues as if they were foreign organisms. Common autoimmune diseases include Hashimoto's thyroiditis, rheumatoid arthritis, diabetes mellitus type 1, and systemic lupus erythematosus. Immunology covers the study of all aspects of the immune system.

Types of immune system

Innate immune system	Adaptive immune system
Response is non-specific	Pathogen and antigen specific response
Exposure leads to immediate maximal response	Lag time between exposure and maximal response
Cell-mediated and humoral components	Cell-mediated and humoral components
No immunological memory	Exposure leads to immunological memory
Found in nearly all forms of life	Found only in jawed vertebrates

- Both innate and adaptive immunity depend on the ability of the immune system to distinguish between self and non-self molecules. In immunology, self molecules are those components of an organism's body that can be distinguished from foreign substances by the immune system."! Conversely, non-self molecules are those recognized as foreign molecules.
- One class of non-self molecules are called antigens (short for antibody generators) and are defined as substances that bind to specific immune receptors and elicit an immune response. Newborn infants have no prior exposure to microbes and are particularly vulnerable to infection. Several layers of passive protection are provided by the mother.
- During pregnancy, a particular type of antibody, called IgG, is transported from mother to baby directly through the placenta, so human babies have high levels of antibodies even at birth, with the same range of antigen specificities as their mother. Breast milk or colostrum also contains antibodies that are transferred to the gut of the infant and protect against bacterial infections until the newborn can synthesize its own antibodies. This is passive immunity because the fetus does not actually make any memory cells or antibodies—it only borrows them.
- This passive immunity is usually shortterm, lasting from a few days up to several months. In medicine, protective passive immunity can also be transferred artificially from one individual to another via antibody-rich serum.

Innate Immune System

Microorganisms or toxins that successfully enter an organism encounter the cells and mechanisms of the innate immune system. The innate response is usually triggered when microbes are identified by pattern recognition receptors, which recognize components that are conserved among broad groups of microorganisms, or when damaged, injured or stressed cells send out alarm signals, many of which (but not all) are recognized by the same receptors as those that recognize pathogens. Innate immune defenses are non-specific, meaning these systems respond to pathogens in a generic way. This system does not confer long-lasting immunity against a pathogen. The innate immune system is the dominant system of host defense in most organisms.

Surface Barriers

- Several barriers protect organisms from infection, including mechanical, chemical, and biological barriers. The waxy cuticle of most leaves, the exoskeleton of insects, the shells and membranes of externally deposited eggs, and skin are examples of mechanical barriers that are the first line of defense against infection. However, as organisms cannot be completely sealed from their environments, other systems act to protect body openings such as the lungs, intestines, and the genitourinary tract. In the lungs, coughing and sneezing mechanically eject pathogens and other irritants from the respiratory tract.
- The flushing action of tears and urine also mechanically expels pathogens, while mucus secreted by the respiratory and gastrointestinal tract serves to trap and entangle microorganisms. Chemical barriers also protect against infection. The skin and respiratory tract secrete antimicrobial peptides such as the -defensins. Enzymes such as lysozyme and phospholipase A2 in saliva, tears, and breast milk are also antibacterials. Vaginal secretions serve as a chemical barrier following menarche, when they become slightly acidic, while semen contains defensins and zinc to kill pathogens.
- In the stomach, gastric acid serves as a powerful chemical defense against ingested pathogens. Within the genitourinary and gastrointestinal tracts, commensal flora serve as biological barriers by competing with pathogenic bacteria for food and space and, in some cases, by changing the conditions in their environment, such as pH or available iron. As a result of the symbiotic relationship between commensals and the immune system, the probability that pathogens will reach sufficient numbers to cause illness is reduced.

- However, since most antibiotics non-specifically target bacteria and do not affect fungi, oral antibiotics can lead to an "overgrowth" of fungi and cause conditions such as a vaginal candidiasis (a yeast infection). There is good evidence that re-introduction of probiotic flora, such as pure cultures of the lactobacilli normally found in unpasteurized yogurt, helps restore a healthy balance of microbial populations in intestinal infections in children and encouraging preliminary data in studies on bacterial gastroenteritis, inflammatory bowel diseases, urinary tract infection and post-surgical infections.

Cellular Components

- Human blood, as you are aware contains red blood cells, several knobby white blood cells including lymphocytes, a monocyte, a neutrophil, and many small disc-shaped platelets. Leukocytes (white blood cells) act like independent, single-celled organisms and are the second arm of the innate immune system. The innate leukocytes include the phagocytes (macrophages, neutrophils, and dendritic cells), innate lymphoid cells, mast cells, eosinophils, basophils, and natural killer cells.
- These cells identify and eliminate pathogens, either by attacking larger pathogens through contact or by engulfing and then killing microorganisms. Innate cells are also important mediators in lymphoid organ development and the activation of the adaptive immune system. Phagocytosis is an important feature of cellular innate immunity performed by cells called phagocytes that engulf, or eat, pathogens or particles.
- Phagocytes generally patrol the body searching for pathogens, but can be called to specific locations by cytokines. Once a pathogen has been engulfed by a phagocyte, it becomes trapped in an intracellular vesicle called a phagosome, which subsequently fuses with another vesicle called a lysosome to form a phagolysosome. The pathogen is killed by the activity of digestive enzymes or following a respiratory burst that releases free radicals into the phagolysosome. Phagocytosis evolved as a means of acquiring nutrients, but this role was extended in phagocytes to include engulfiment of pathogens as a defense mechanism. Phagocytosis probably represents the oldest form of host defense, as phagocytes have been identified in both vertebrate and invertebrate animals.

Phagocytes

- Neutrophils and macrophages are phagocytes that travel throughout the body in pursuit of invading pathogens. Neutrophils are normally found in the bloodstream and are the most abundant type of phagocyte, normally representing 50% to 60% of the total circulating leukocytes, and consisting of neutrophil-killer and neutrophil-cager subpopulations.
- During the acute phase of inflammation, particularly as a result of bacterial infection, neutrophils migrate toward the site of inflammation in a process called chemotaxis, and are usually the first cells to arrive at the scene of infection. Macrophages are versatile cells that reside within tissues and produce a wide array of chemicals including enzymes, complement proteins, and cytokines, while they can also act as scavengers that rid the body of worn-out cells and other debris, and as antigen-presenting cells that activate the adaptive immune system.

Dendritic Cell

Dendritic cells (DC) are phagocytes in tissues that are in contact with the external environment; therefore, they are located mainly in the skin, nose, lungs, stomach, and intestines. They are named for their resemblance to neuronal dendrites, as both have many spine-like projections, but dendritic cells are in no way connected to the nervous system. Dendritic cells serve as a link between the bodily tissues and the innate and adaptive immune systems, as they present antigens to T cells, one of the key cell types of the adaptive immune system.

Granulocytes

Mast cells reside in connective tissues and mucous membranes, and regulate the inflammatory response. They are most often associated with allergy and anaphylaxis. Basophils and eosinophils are related to neutrophils. They secrete chemical mediators that are involved in defending against parasites and play a role in allergic reactions, such as asthma.

Innate Lymphoid Cells

- Innate lymphoid cells (ILCs) are a group of innate immune cells that are derived from common lymphoid progenitor (CLP) and belong to the lymphoid lineage. These cells are defined by absence of antigen specific B or T cell receptor because of the lack of recombination activating gene (RAG). ILCs do not express myeloid or dendritic cell markers.
- Natural killer cells, one of member ILCs, are lymphocytes and a component of the innate immune system which does not directly attack invading microbes. Rather, NK cells destroy compromised host cells, such as tumor cells or virus-infected cells, recognizing such cells by a condition known as "missing self." This term describes cells with low levels of a cell-surface marker called MHC I (major histocompatibility complex)—a situation that can arise in viral infections of host cells.
- They were named "natural killer" because of the initial notion that they do not require activation in order to kill cells that are "missing self." For many years it was unclear how NK cells recognize tumor

cells and infected cells. It is now known that the MHC makeup on the surface of those cells is altered and the NK cells become activated through recognition of "missing self". Normal body cells are not recognized and attacked by NK cells because they express intact self MHC antigens. Those MHC antigens are recognized by killer cell immunoglobulin receptors (KIR) which essentially put the brakes on NK cells.

Inflammation

- Inflammation is one of the first responses of the immune system to infection. The symptoms of inflammation are redness, swelling, heat, and pain, which are caused by increased blood flow into tissue. Inflammation is produced by eicosanoids and cytokines, which are released by injured or infected cells. Eicosanoids include prostaglandins that produce fever and the dilation of blood vessels associated with inflammation, and leukotrienes that attract certain white blood cells (leukocytes). Common cytokines include interleukins that are responsible for communication between white blood cells; chemokines that promote chemotaxis; and interferons that have anti-viral effects, such as shutting down protein synthesis in the host cell. Growth factors and cytotoxic factors may also be released.
- These cytokines and other chemicals recruit immune cells to the site of infection and promote healing of any damaged tissue following the removal of pathogens.

Complement System

- The complement system is a biochemical cascade that attacks the surfaces of foreign cells. It contains over 20 different proteins and is named for its ability to "complement" the killing of pathogens by antibodies.
- Complement is the major humoral component of the innate immune response. In humans, this response is activated by complement binding to antibodies that have attached to these microbes or the binding of complement proteins to carbohydrates on the surfaces of microbes. This recognition signal triggers a rapid killing response. The speed of the response is a result of signal amplification that occurs after sequential proteolytic activation of complement molecules, which are also proteases. After complement proteins initially bind to the microbe, they activate their protease activity, which in turn activates other complement proteases, and so on.
- This produces a catalytic cascade that amplifies the initial signal by controlled positive feedback. The cascade results in the production of peptides that attract immune cells, increase vascular permeability, and opsonize (coat) the surface of a pathogen, marking it for destruction. This deposition of complement can also kill cells directly by disrupting their plasma membrane.

Adaptive Immune System

The adaptive immune response is antigen-specific and requires the recognition of specific "non-self" antigens during a process called antigen presentation. Antigen specificity allows for the generation of responses that are tailored to specific pathogens or pathogen-infected cells. The ability to mount these tailored responses is maintained in the body by "memory cells". If a pathogen infects the body more than once, these specific memory cells are used to quickly eliminate it.

The Recognition of Antigen

- The cells of the adaptive immune system are special types of leukocytes, called lymphocytes. B cells and T cells are the major types of lymphocytes and are derived from hematopoietic stem cells in the bone marrow. B cells are involved in the humoral immune response, whereas T cells are involved in cell-mediated immune response. Killer T cells only recognize antigens coupled to Class I MHC molecules, while helper T cells and regulatory T cells only recognize antigens coupled to Class IT MHC molecules. These two mechanisms of antigen presentation reflect the different roles of the two types of T cell. A third, minor subtype are the yd T cells that recognize intact antigens that are not bound to MHC receptors. The double-positive T cells are exposed to a wide variety of selfantigens in the thymus, in which iodine is necessary for its thymus development and activity.
- In contrast, the B cell antigen-specific receptor is an antibody molecule on the B cell surface, and recognizes whole pathogens without any need for antigen processing. Each lineage of B cell expresses a different antibody, so the complete set of B cell antigen receptors represent all the antibodies that the body can manufacture.

Antigen Presentation to T-lymphocytes

Both B cells and T cells carry receptor molecules that recognize specific targets. T cells recognize a "non-self" target, such as a pathogen, only after antigens (small fragments of the pathogen) have been processed and presented in combination with a "self" receptor called a major histocompatibility complex (MHC) molecule.

CELL MEDIATED IMMUNITY

There are two major subtypes of T cells: the killer T cell and the helper T cell. In addition there are regulatory T cells which have a role in modulating immune response.

Killer T Cells

- Killer T cells are a sub-group of T cells that kill cells that are infected with viruses (and other pathogens),

or are otherwise damaged or dysfunctional. As with B cells, each type of T cell recognizes a different antigen.

- Killer T cells are activated when their T-cell receptor (TCR) binds to this specific antigen in a complex with the MHC Class I receptor of another cell. Recognition of this MHC:antigen complex is aided by a co-receptor on the T cell, called CD8. The T cell then travels throughout the body in search of cells where the MHC I receptors bear this antigen. When an activated T cell contacts such cells, it releases cytotoxins, such as perforin, which form pores in the target cell's plasma membrane, allowing ions, water and toxins to enter.
- The entry of another toxin called granulysin (a protease) induces the target cell to undergo apoptosis. T cell killing of host cells is particularly important in preventing the replication of viruses. T cell activation is tightly controlled and generally requires a very strong MHC/antigen activation signal, or additional activation signals provided by "helper" T cells.

Helper T Cells

- Antigen-presenting cells (APCs) present antigen on their Class II MHC molecules (MHC2). Helper T cells recognize these, with the help of their expression of CD4 co-receptor (CD4+). The activation of a resting helper T cell causes it to release cytokines and other stimulatory signals that stimulate the activity of macrophages, killer T cells and B cells, the latter producing antibodies.
- The stimulation of B cells and macrophages succeeds a proliferation of T helper cells. Helper T cells regulate both the innate and adaptive immune responses and help determine which immune responses the body makes to a particular pathogen. These cells have no cytotoxic activity and do not kill infected cells or clear pathogens directly.
- They instead control the immune response by directing other cells to perform these tasks. Helper T cells express T cell receptors (TCR) that recognize antigen bound to Class I MHC molecules. The MHC:antigen complex is also recognized by the helper cell's CD4 co-receptor, which recruits molecules inside the T cell (e.g., Lck) that are responsible for the T cell's activation.
- Helper T cells have a weaker association with the MHC:antigen complex than observed for killer T cells, meaning many receptors (around 200-300) on the helper T cell must be bound by an MHC:antigen in order to activate the helper cell, while killer T cells can be activated by engagement of a single MHC:antigen molecule. Helper T cell activation also requires longer duration of engagement with an antigen-presenting cell.
- The activation of a resting helper T cell causes it to release cytokines that influence the activity of many cell types. Cytokine signals produced by helper T cells enhance the microbicidal function of macrophages and the activity of killer T cells. In addition, helper T cell activation causes an upregulation of molecules expressed on the T cell's surface, such as CD40 ligand (also called CD154), which provide extra stimulatory signals typically required to activate antibody-producing B cells. An antibody is made up of two heavy chains and two light chains. The unique variable region allows an antibody to recognize its matching antigen.

THE HUMORAL IMMUNE RESPONSE

A B cell identifies pathogens when antibodies on its surface bind to a specific foreign antigen. This antigen/antibody complex is taken up by the B cell and processed by proteolysis into peptides. The B cell then displays these antigenic peptides on its surface MHC class IT molecules. This combination of MHC and antigen attracts a matching helper T cell, which releases lymphokines and activates the B cell. As the activated B cell then begins to divide, its offspring (plasma cells) secrete millions of copies of the antibody that recognizes this antigen. These antibodies circulate in blood plasma and lymph, bind to pathogens expressing the antigen and mark them for destruction by complement activation or for uptake and destruction by phagocytes. Antibodies can also neutralize challenges directly, by binding to bacterial toxins or by interfering with the receptors that viruses and bacteria use to infect cells.

IMMUNOLOGICAL MEMORY

- 'When B cells and T cells are activated and begin to replicate, some of their offspring become long-lived memory cells. Throughout the lifetime of an animal, these memory cells remember each specific pathogen encountered and can mount a strong response if the pathogen is detected again.
- This is "adaptive" because it occurs during the lifetime of an individual as an adaptation to infection with that pathogen and prepares the immune system for future challenges. Immunological memory can be in the form of either passive short-term memory or active long-term memory. The time-course of an immune response begins with the initial pathogen encounter, (or initial vaccination) and leads to the formation and maintenance of active immunological memory.

PHYSIOLOGICAL REGULATION

The immune system is involved in many aspects of physiological regulation in the body. The immune system interacts intimately with other systems, such as the endocrine and the nervous systems. The immune system also plays a crucial role in embryogenesis (development of the embryo), as well as in tissue repair and regeneration.