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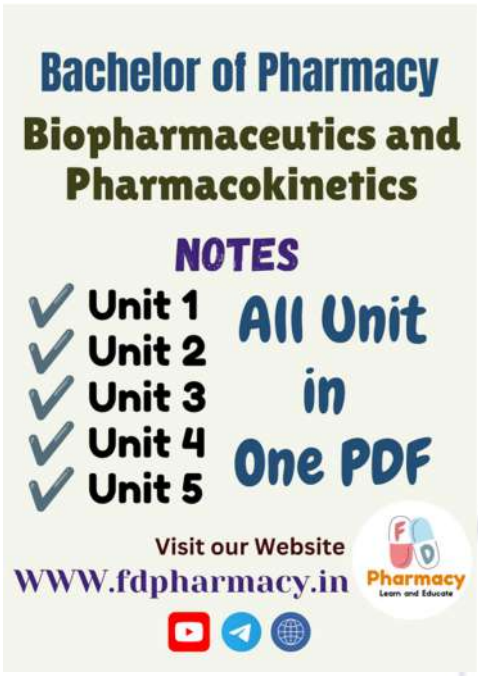
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PHARMACEUTICAL BIOTECHNOLOGY

UNIT 3

TOPIC :

- d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.

Vaccines

- A vaccine is a biological preparation that provides active immunity against a specific disease by stimulating the immune system.
- It contains antigens derived from pathogens in a safe form that do not cause disease but trigger an immune response.

Objectives of Vaccination

- Prevent infectious diseases
- Stimulate immune response
- Produce antibodies

Mechanism of Action of Vaccines

Step 1

Vaccine containing antigen enters the body.

Step 2

Antigen is recognized by immune cells.

Step 3

Activation of:

- B-lymphocytes
- T-lymphocytes

Step 4

Production of antibodies.

Step 5

Formation of memory B-cells and memory T-cells.

Step 6

Upon re-exposure to the pathogen, a rapid and strong immune response occurs.

Result

Long-term protection against disease.

Types of Vaccines

1. Live Attenuated Vaccines
2. Inactivated (Killed) Vaccines
3. Toxoid Vaccines
4. Subunit Vaccines
5. Recombinant Vaccines
6. mRNA Vaccines

1. Live Attenuated Vaccines

- These vaccines contain live microorganisms that have been weakened (attenuated) so they cannot cause disease in healthy individuals.

Characteristics

- Mimic natural infection
- Produce strong immune response
- Provide long-term immunity
- Usually require fewer booster doses

Advantages

- Strong cellular and humoral immunity
- Long-lasting protection

Disadvantages

- Not suitable for immunocompromised individuals
- Require careful storage

Examples

- BCG Vaccine
- Measles Vaccine
- MMR Vaccine (Measles, Mumps, Rubella)

2. Inactivated (Killed) Vaccines

- These vaccines contain pathogens that have been killed by heat, chemicals, or radiation.

Characteristics

- Cannot cause disease
- Safer than live vaccines
- Produce weaker immune response

Advantages

- Safe in immunocompromised patients
- Stable during storage

Disadvantages

- Require booster doses
- Lower immune response

Examples

- Rabies Vaccine
- Inactivated Polio Vaccine (IPV)

3. Toxoid Vaccines

- These vaccines contain inactivated bacterial toxins (toxoids) rather than the microorganism itself.

Characteristics

- Protect against toxin-mediated diseases
- Stimulate antibody formation against toxins

Examples

- Tetanus Vaccine, Diphtheria Vaccine

4. Subunit Vaccines

- Subunit vaccines contain only specific antigenic parts of the pathogen, such as proteins or polysaccharides.

Characteristics

- Highly safe
- Cause fewer side effects
- Often require adjuvants

Advantages

- No live organism present
- Reduced adverse reactions

Examples

- Hepatitis B Vaccine, Acellular Pertussis Vaccine, HPV Vaccine

5. Recombinant Vaccines

- Recombinant vaccines are produced using genetic engineering techniques.
- Genes encoding antigenic proteins are inserted into host cells, which then produce the antigen used in the vaccine.

Characteristics

- Contain only required antigen
- Do not contain whole pathogen
- Highly specific and safe

Advantages

- High purity
- Reduced risk of infection

Examples

- Recombinant Hepatitis B Vaccine, Recombinant HPV Vaccine

6. mRNA Vaccines

- mRNA vaccines contain messenger RNA (mRNA) that instructs host cells to produce a specific antigen.
- The produced antigen stimulates an immune response.

Characteristics

- Rapidly developed
- Strong immune response
- No live pathogen used

Advantages

- High efficacy
- Flexible production
- Safe and effective

Examples

- COVID-19 mRNA Vaccines

General Method of Vaccine Preparation

Step 1: Antigen Generation

Production of:

- Antigen
- mRNA
- DNA
- Viral vector

depending on vaccine type.

Step 2: Isolation

Desired antigen or genetic material is isolated.

Step 3: Purification

Impurities are removed to obtain pure antigen.

Step 4: Formulation

Addition of:

- Adjuvants
- Stabilizers
- Preservatives
- Buffer systems

Step 5: Filling, Packaging and Labeling

Vaccine is filled into sterile containers and labeled appropriately.

Step 6: Quality Control Testing

Testing for:

- Sterility
- Safety
- Potency
- Stability

Step 7: Final Vaccine Product

Approved vaccine is released for use.

Preparation of Bacterial Vaccines

Bacterial vaccines are prepared from:

- Whole bacteria
- Bacterial toxins
- Bacterial antigenic components

Types

1. Live Attenuated Bacterial Vaccines

Example:

- BCG Vaccine

2. Inactivated Bacterial Vaccines

Example:

- Cholera Vaccine
- Typhoid Vaccine

Steps in Preparation of Bacterial Vaccines

1. Selection and Cultivation

- Suitable bacterial strain is selected.
- Organisms are grown on culture media.
- Growth usually continues for 1–2 days.
- Culture is washed with sterile normal saline.

2. Preparation of Suspension

- Bacterial cells are suspended in sterile medium.
- Thorough mixing ensures uniform distribution.

3. Removal of Unwanted Material

Impurities are removed by:

- Centrifugation

- Sedimentation

This helps obtain purified bacterial suspension.

4. Sterilization / Inactivation

Bacteria are killed using:

- Heat
- Alcohol
- Other bactericidal agents

For Non-Spore Forming Bacteria

Heating at:

56–60°C for approximately 1 hour

Important:

- Bacteria must be killed.
- Antigenic properties must remain intact.

5. Standardization and Dilution

After sterilization:

- Bacterial concentration is measured.
- Required dilution is prepared.
- Preservatives may be added.

Common Preservatives

- Phenol
- Thiomersal

6. Filling and Packaging

Final vaccine is:

- Filled into sterile vials or ampoules
- Sealed under aseptic conditions
- Properly labeled and stored

Advantages of Vaccines

- Prevent infectious diseases
- Reduce mortality and morbidity
- Create herd immunity
- Provide long-term protection
- Cost-effective disease prevention

Preparation of Viral Vaccines

- Viral vaccines are biological preparations made from whole viruses or their components in a form that is safe but still capable of inducing an immune response.
- The main objective is to retain antigenicity (ability to stimulate immunity) while reducing or eliminating pathogenicity (ability to cause disease).

Objectives of Viral Vaccine Preparation

- Provide protection against viral diseases
- Induce active immunity
- Generate antibodies and memory cells
- Prevent viral infection and transmission
- Ensure vaccine safety and efficacy

Principle of Viral Vaccine Preparation

Viral antigens are introduced into the body in a safe form.

The immune system recognizes these antigens and produces:

- Antibodies
- Memory B-cells
- Memory T-cells

These provide long-term protection against future infection.

Steps in Preparation of Viral Vaccines

1. Selection of Virus and Antigen

- The first step is identifying the virus and selecting the antigen responsible for producing protective immunity.
- Usually, surface proteins of the virus are selected because they are recognized by the immune system.

Importance

- Ensures specific immune response
- Targets the most immunogenic part of the virus
- Improves vaccine effectiveness

2. Cultivation (Propagation) of Virus

- The selected virus is grown in a suitable host system to obtain large quantities of viral particles.

Methods of Cultivation

A. Embryonated Chicken Eggs

Commonly used for:

- Influenza vaccines
- Yellow fever vaccines

B. Cell Culture Systems

Examples:

- Vero cells
- Human diploid cells

C. Animal Tissue Culture

Used for some specialized vaccines.

Purpose

- Mass production of virus
- Collection of viral antigens

3. Attenuation or Inactivation

After cultivation, the virus is modified according to the type of vaccine.

A. Live Attenuated Vaccines

- The virus is weakened so that it cannot cause disease but can still stimulate immunity.

Advantages

- Strong immune response
- Long-lasting immunity

Examples

- Measles vaccine
- Mumps vaccine
- Rubella vaccine

B. Inactivated Vaccines

- The virus is killed using physical or chemical methods.

Methods

- Formaldehyde treatment
- Heat treatment
- Radiation

Advantages

- Cannot cause disease
- Safer for immunocompromised individuals

Examples

- Rabies vaccine
- Inactivated Polio Vaccine (IPV)

C. Recombinant Vaccines

- Only specific viral proteins are produced through genetic engineering and used as antigens.

Advantages

- Highly safe
- No whole virus present

Example

- Hepatitis B vaccine

4. Purification

- The viral material is separated from host cells, culture media, and impurities.

Methods

- Filtration
- Centrifugation
- Chromatography

Importance

- Removes contaminants, Improves vaccine quality

5. Formulation

- The purified antigen is mixed with additional substances to improve stability and effectiveness.

Components Added

Stabilizers

- Protect vaccine during storage.

Preservatives

- Prevent microbial contamination.

Adjuvants

- Enhance immune response.

Importance

- Maintains vaccine potency, Improves shelf life

6. Quality Control and Testing

- Before approval, vaccines undergo extensive testing to ensure safety and effectiveness.

Parameters Evaluated

Safety

- Ensures vaccine does not cause harmful effects.

Potency

- Measures ability to produce immunity.

Sterility

- Confirms absence of microbial contamination.

Preparation of Toxoid

- A toxoid is a chemically modified toxin obtained from pathogenic microorganisms.
- It is non-toxic but remains antigenic, therefore it can safely be used as a vaccine.

Examples

- Tetanus toxoid
- Diphtheria toxoid

Method of Preparation of Toxoid

1. Formal Toxoid

Step 1: Selection of Organism

A suitable toxin-producing bacterial strain is selected.

Step 2: Cultivation

The organism is grown in a liquid culture medium under optimum conditions for maximum toxin production.

Step 3: Filtration

Bacterial cells are removed by filtration.

The filtrate containing toxin is collected.

Step 4: Sterilization

The toxin solution is sterilized to remove contamination.

Step 5: Formaldehyde Treatment

Formaldehyde (Formalin) is added to the toxin solution.

The mixture is incubated at:

37°C for several weeks

Step 6: Conversion into Toxoid

Formaldehyde converts the toxin into toxoid.

Result:

- Toxicity is lost.
- Antigenicity is retained.

2. Alum Precipitated Toxoid (APT)

➢ APT is a toxoid preparation adsorbed onto aluminium salts to enhance the immune response.

Method of Preparation

Step 1

- The toxoid solution is purified by filtration.

Step 2

- Alum (aluminium salts) is added.

Step 3

- Alum reacts with impurities and forms a precipitate.

Step 4

- The toxoid becomes adsorbed onto the precipitate.

Step 5

- The precipitate is washed.

Step 6

- It is suspended in saline containing a preservative.

Result

◈ A depot effect is produced, leading to prolonged antigen release and stronger immunity.

3. Purified Toxoid Aluminium Phosphate (PTAP)

➢ PTAP is a highly purified toxoid preparation adsorbed onto aluminium phosphate gel.

Preparation

Step 1

- Toxin is produced in a semi-synthetic medium free from unwanted proteins.

Step 2

The toxoid is purified using agents such as:

- Magnesium hydroxide

Step 3

✪ The purified toxoid is combined with aluminium phosphate gel.

Advantages

- High purity
- Prolonged immune response

Preparation of Antitoxin

- Antitoxins are antibodies produced against bacterial toxins.
- They provide passive immunity and immediate protection.

Examples

- Tetanus antitoxin, Diphtheria antitoxin

Method of Preparation of Antitoxin

1. Selection of Animal

Large animals, usually horses, are selected because:

- They produce large amounts of antibodies.
- They can tolerate repeated toxin exposure.

2. Immunization of Animal

- The animal is injected with small doses of toxin or toxoid.
- The dose is gradually increased over time.
- This stimulates production of large quantities of specific antibodies.

3. Collection of Blood

After sufficient antibody formation:

- Blood is collected under sterile conditions.

4. Separation and Purification

Serum Separation

- Blood is processed to obtain serum.
- The serum contains antitoxin antibodies.

Purification

Unwanted substances are removed:

- Proteins
- Impurities
- Contaminants

5. Standardization

- Antitoxin potency is measured and adjusted to the required therapeutic strength.

Purpose

- Ensures correct dosage, Maintains uniform quality

6. Filling and Storage

The final product is:

- Filled into sterile vials, Sealed aseptically
- Stored under recommended conditions

Preparation of Serum

Serum is the clear fluid obtained after blood clotting.

It contains:

- Antibodies
- Proteins
- Electrolytes

But lacks:

- Fibrinogen
- Other clotting factors

Uses

- Passive immunization, Treatment of infections
- Antitoxin preparation, Diagnostic purposes

Method of Preparation of Serum

1. Selection of Donor

A healthy donor is selected.

The donor may be: Human, Horse, Other suitable animals

2. Immunization

The donor is immunized with:

- Antigen, Toxin, Toxoid

Booster doses are administered to increase antibody production.

3. Blood Collection

- After adequate antibody formation:
- Blood is collected under sterile conditions.

4. Clot Formation

- The blood is allowed to clot naturally.

5. Serum Separation

Serum is separated by:

- Centrifugation, Decantation

6. Purification and Testing

The serum is tested for:

- Safety, Sterility, Potency

7. Preservation and Storage

- Preservatives may be added.
- The serum is stored under suitable conditions until use.