# Immunological Products

## Introduction to Immunological products

### Definition:

- Immunological products are biological preparations used to induce, enhance, or provide passive or active immunity against infectious diseases.
- They are derived from biological sources such as microorganisms, human or animal blood, or purified toxins.

### Classification of Immunological Products:

| Type | Description |
|---|---|
| **Sera** | Provide **passive immunity**; contain preformed antibodies. |
| **Vaccines** | Provide **active immunity** by stimulating the body to produce antibodies. |
| **Toxoids** | Detoxified toxins that induce immunity against the toxins themselves. |

### Classification of Immunological Products

| Type | Function | Examples |
|---|---|---|
| **Sera** | Passive immunity through preformed antibodies | Anti-tetanus serum, anti-snake venom |
| **Vaccines** | Active immunity by stimulating antibody production | Polio vaccine, measles vaccine |
| **Toxoids** | Detoxified bacterial toxins used as vaccines | Tetanus toxoid, diphtheria toxoid |

## Sera (Antisera)

### Definition:

- Sera (plural of serum) are immunological products containing specific antibodies obtained from the blood of humans or animals that have been immunized against a specific pathogen or toxin.
- Sera provide passive immunity.

### Types of Sera:

1. **Antibacterial sera** – Against bacterial infections (e.g., anti-diphtheria serum).

2. **Antiviral sera** – Against viral infections (e.g., rabies immune globulin).
3. **Antitoxic sera** – Neutralize toxins (e.g., anti-tetanus serum).
4. **Antivenom sera** – Neutralize venoms (e.g., anti-snake venom serum).

## Composition:

- **Gamma globulins (immunoglobulins)**: Active components.
- **Stabilizers**: e.g., sucrose.
- **Preservatives**: e.g., phenol or thimerosal.

## Characteristics:

- Provide immediate but short-term protection.
- Used in post-exposure prophylaxis or treatment.
- Mostly derived from horses, rabbits, or humans (e.g., hyperimmune globulins).

## Method of Manufacturing (Horse-Derived Sera):

### A. Selection of Healthy Animals:

- Typically, horses or large animals.
- Screened for zoonotic diseases (e.g., tuberculosis).

### B. Immunization:

- Animal is injected with inactivated antigen or toxin in increasing doses over weeks.
- Boosters are given to ensure high antibody levels.

### C. Bleeding:

- Once adequate antibody titers are reached, blood is drawn aseptically.

### D. Serum Separation:

- Coagulated blood is centrifuged to separate serum from clot.

### E. Purification:

- Removal of unwanted proteins and contaminants.
- Precipitation (e.g., with ammonium sulfate) or chromatography may be used.

### F. Inactivation (if needed):

- To remove infectious agents without damaging antibodies.

### G. Sterilization:

- Sterile filtration (not heat sterilized as antibodies are heat-sensitive).

### H. Standardization and Testing:

- Potency, sterility, pyrogenicity, and safety are tested.

### I. Packaging:

- Filled into ampoules or vials under aseptic conditions.

### J. Labeling:

- Includes antigen specificity, potency (e.g., IU/mL), expiration date, and storage instructions.

## Advantages:

- Immediate effect.
- Life-saving in acute infections or envenomation.

## Disadvantages:

- Short duration of protection.
- Risk of hypersensitivity (serum sickness, anaphylaxis).
- Usually animal-derived (except human immunoglobulins).

# Vaccines

## Definition:

- Vaccines are biological preparations that stimulate the body's immune system to recognize and fight specific pathogens, thereby inducing active immunity.

## Types of Vaccines:

| Type | Description | Examples |
|---|---|---|
| **Live attenuated** | Weakened pathogens; stimulate strong, long-lasting immunity | MMR, BCG, oral polio vaccine |
| **Inactivated (killed)** | Pathogens killed by heat or chemicals | Inactivated polio vaccine (IPV) |
| **Subunit or acellular** | Specific antigens extracted from pathogen | Hepatitis B, acellular pertussis |
| **Conjugate** | Antigens linked to carrier proteins for better response | Haemophilus influenzae type b (Hib) |

| | | |
|---|---|---|
| **Recombinant** | Produced via genetic engineering | HPV vaccine |
| **mRNA or DNA vaccines** | Nucleic acids encoding antigens | COVID-19 mRNA vaccines |
| **Vector vaccines** | Use viral vectors to deliver genetic material | Adenovirus-based COVID-19 vaccines |

## Composition:

- **Antigen**: Whole organism or its part.
- **Adjuvant**: Enhances immune response (e.g., aluminum hydroxide).
- **Stabilizers**: Protect active components (e.g., sugars, gelatin).
- **Preservatives**: Prevent contamination in multidose vials (e.g., thiomersal).
- **Diluent**: Sterile water or buffer (used for reconstitution).

## Characteristics:

- Induce long-term immunity.
- Can be prophylactic or therapeutic.
- Require **cold-chain storage** (especially live vaccines).

## General Method of Manufacturing (Live Attenuated/Inactivated):

### 1. Strain Selection

- Select a suitable microorganism strain: either a naturally attenuated strain or a virulent strain intended for attenuation through laboratory methods.

### 2. Cultivation

- Grow the selected microorganism in controlled environments such as bioreactors, using suitable media (e.g., chicken embryos, tissue cultures).

### 3. Inactivation (for inactivated vaccines only)

- Apply heat or chemical agents (e.g., formalin) to kill the pathogen while preserving its antigenic properties.

### 4. Purification

- Remove impurities, cell debris, and toxins using techniques like centrifugation, filtration, and chromatography.

### 5. Formulation

- Combine the purified antigen with:

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