

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:

- 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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