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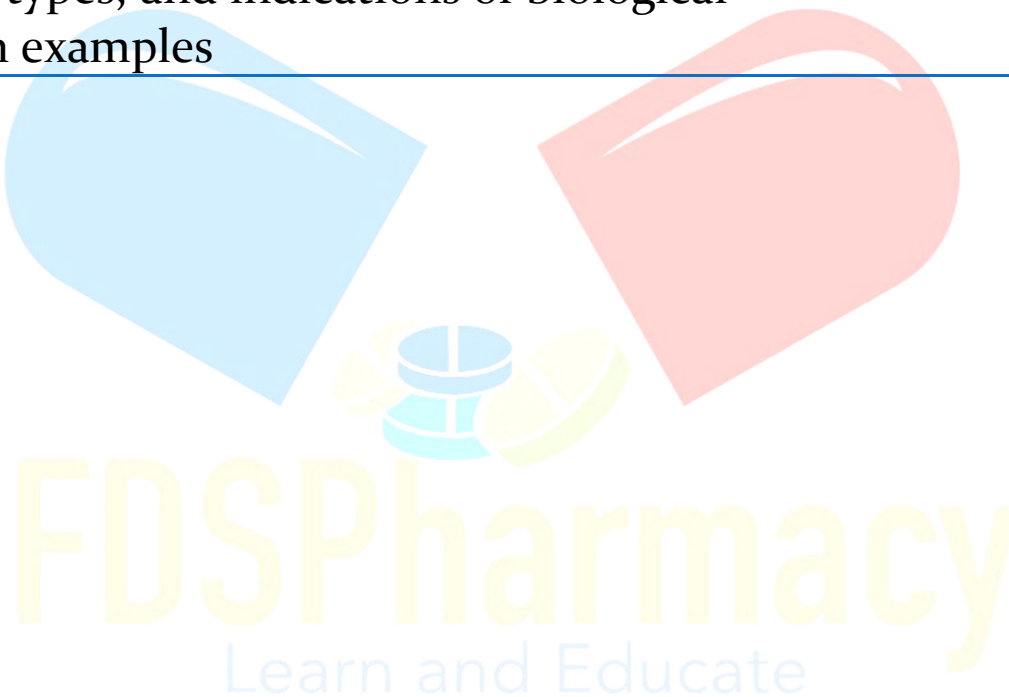
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**Diploma in Pharmacy 2<sup>nd</sup> Year**  
**Pharmacology**  
**Chapter 13 : Biologicals**

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# PHARMACOLOGY

## Chapter 13

### Biologicals

- Biological , biopharmaceuticals or biologics are substances (medicinal products) made from a living organism or contain components of living organism . e.g. Vaccines , blood , hormones etc.
- Biologicals include a wide variety of products derived from human , animal or microorganism by using biotechnology.
- Biological products may contain proteins that control the function of other proteins , cellular process and gene which regulate the production of vital proteins.
- Biologics may content modified human hormones or cells which produce the substances that suppress or activate the immune system.

### Sources of Biologicals

- Mammalian cell culture
- Humans
- Avian cell culture
- Mice
- Transgenics
- Insect cell culture

### Steps Involved In Production

- **Develop Host** : A host cell is developed by isolating the DNA sequence that codes for the desired protein,
- **Establish a Cell Bank** : A cell bank is then established using elaborate cell screening and selection process
- **Protein Production System** : The “engineered” cells are then cultured on a large scale under growth conditions to optimize cellular production
- **Purification** : Fractions containing the desired protein are harvested and isolated, and the undesired proteins and impurities are separate
- **Analysis** : Protein molecules are analyzed for uniformity in terms of structure, character, and potency;
- **Formulation** : Therapeutic protein is then formulated

# Types of Biologicals

- ◆ **Proteins** : Examples include insulin for diabetes and erythropoietin for anemia.
- ◆ **Vaccines** : These are used to prevent the spread of infectious diseases.
- ◆ **Gene therapies** : These involve the introduction of a functional gene into a patient's cells to treat genetic disorders.
- ◆ **Monoclonal antibodies** : These are laboratory-made molecules that mimic the immune system's ability to fight off harmful substances.
- ◆ **Cell therapies** : These involve the transplantation of living cells into a patient's body to treat diseases or conditions.
- ◆ **Toxoids** : These are toxins that have been made harmless and used as vaccines against certain bacterial diseases.
- ◆ **Fusion proteins** : These are made by combining two different proteins to treat diseases such as arthritis and cancer.
- ◆ **Recombinant DNA products** : These are produced using genetic engineering techniques and used to treat a range of conditions, including hemophilia and growth hormone deficiencies.

## Indications of biological agents with examples:

### 1. Cancer:

- Monoclonal antibodies such as trastuzumab (Herceptin) are used to treat breast cancer.
- Cell therapies such as chimeric antigen receptor T cell (CAR-T) therapy are used to treat certain types of blood cancers.

### 2. Autoimmune disorders :

- Monoclonal antibodies such as adalimumab (Humira) are used to treat rheumatoid arthritis.
- Fusion proteins such as etanercept (Enbrel) are used to treat psoriatic arthritis and ankylosing spondylitis

### 3. Infectious diseases :

- Vaccines such as HPV vaccine and influenza vaccine are used to prevent the spread of the respective diseases.
- Monoclonal antibodies such as infliximab (Remicade) are used to treat viral infections such as hepatitis B and C

### 4. Hormonal deficiencies :

- Recombinant DNA products such as human growth hormone (HGH) are used to treat growth hormone deficiency.
- Insulin is used to treat diabetes.

## 5. Genetic disorders:

- Gene therapies such as lentiviral vector gene therapy are used to treat severe combined immunodeficiency.
- Stem cell transplantation is used to treat genetic blood disorders such as sickle cell anemia.

## 6. Neurological disorders :

- Monoclonal antibodies such as ocrelizumab (Ocrevus) are used to treat multiple sclerosis.

## 7. Inflammatory disorders :

- Fusion proteins such as infliximab (Remicade) are used to treat inflammatory bowel diseases such as Crohn's disease and ulcerative colitis.

## 8. Allergic conditions :

- Monoclonal antibodies such as omalizumab (Xolair) are used to treat severe asthma and allergic rhinitis.



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