Biologicals & Herbals, and Food & Nutraceuticals

Biologicals

- Biologicals are medicinal products that are prepared from living organisms or their biological materials.
- They are used to prevent, diagnose, or treat diseases.
- Biological medicines are more complex than ordinary chemical medicines because they are produced using biotechnology.

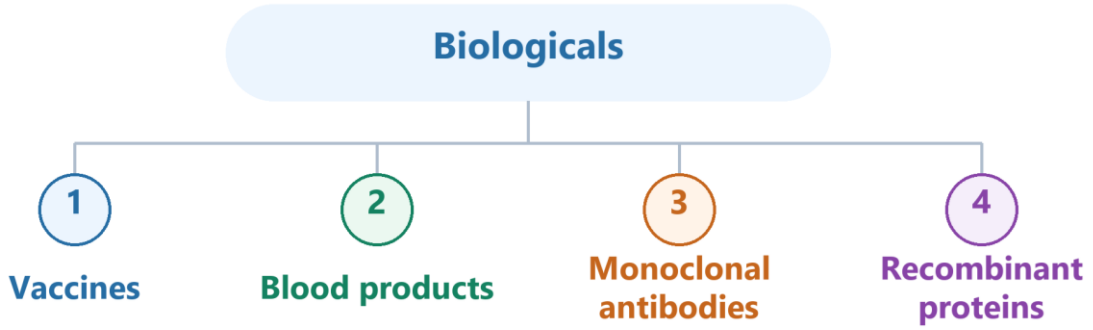
Examples

- Vaccines.
- Monoclonal antibodies.
- Blood products.
- Insulin produced by recombinant DNA technology.
- Gene therapy products.

Characteristics

- Biologicals are produced from living cells or microorganisms.
- They have a complex molecular structure.
- They require strict quality control during manufacturing.
- They are sensitive to heat, light, and contamination.

Types of Biologicals



Biological products include vaccines, blood products, monoclonal antibodies and recombinant proteins

1. **Vaccines**
   - Vaccines help the body's immune system develop protection against infectious diseases.
   - They contain weakened, killed, or purified parts of microorganisms.
2. **Blood Products**
   - Blood products are prepared from human blood or plasma.

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- They are used to treat bleeding disorders, immune deficiencies, and other medical conditions.

3. Monoclonal Antibodies

- Monoclonal antibodies are laboratory-produced proteins that specifically target certain cells or substances in the body.
- They are used to treat cancer, autoimmune diseases, and infectious diseases.

4. Recombinant Proteins

- Recombinant proteins are produced using genetic engineering techniques.
- Examples include insulin, growth hormone, and erythropoietin.

Uses

1. Disease Prevention

- Vaccines help prevent infectious diseases.

2. Disease Treatment

- Biological medicines are used to treat cancer, autoimmune diseases, and hormonal disorders.

3. Diagnosis

- Some biological products help diagnose diseases through laboratory testing.

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Approval of Biologicals

A. Preclinical Studies

- Biological products are tested in laboratories and animals to evaluate their safety and biological activity.

B. Clinical Trials

- Human studies are conducted to determine safety, effectiveness, and appropriate dosage.

C. Manufacturing Approval

- Manufacturing facilities must comply with Good Manufacturing Practices (GMP).

D. Regulatory Approval

- Regulatory authorities review all scientific data before granting permission to market the product.

Advantages

- Biologicals are highly specific in their action.
- They can treat diseases that cannot be managed effectively with conventional medicines.

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- They improve the quality of life for many patients.

Limitations

- Biologicals are expensive to manufacture.
- They usually require refrigeration during storage.
- They may produce immune reactions in some patients.
- Most biologicals are given by injection because they are destroyed in the digestive system.

Herbals

- Herbal medicines are products prepared from plants or plant parts that are used for the prevention or treatment of diseases.
- Herbal medicines have been used in traditional systems of medicine for many centuries.

Sources

- Leaves.
- Roots.
- Flowers.
- Seeds.
- Bark.
- Fruits.

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Common Examples

- Turmeric.
- Ginger.
- Aloe vera.
- Neem.
- Ashwagandha.
- Tulsi.

Characteristics

- Herbal medicines contain natural plant constituents.
- They may contain one or more active ingredients.
- Their composition may vary depending on the source and method of preparation.
- Proper quality control is necessary to ensure safety and effectiveness.

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Types of Herbal Medicines

A. Single Herbal Products

- These products contain one medicinal plant as the active ingredient.
- They are used for specific therapeutic purposes.

B. Polyherbal Products

- These products contain two or more medicinal plants.
- The combination is intended to improve therapeutic effectiveness.

C. Herbal Extracts

- Herbal extracts are concentrated preparations obtained from medicinal plants.
- They contain active plant constituents in a purified form.

D. Traditional Herbal Preparations

- These products are prepared according to traditional systems such as Ayurveda, Siddha, and Unani.
- They have been used for many years based on traditional knowledge.

Regulation of Herbal Medicines

1. Quality Control

- Herbal medicines are tested for identity, purity, strength, and contamination.

2. Safety Evaluation

- Products are evaluated for possible toxicity and adverse effects.

3. Manufacturing Standards

- Herbal products must be manufactured according to approved quality standards.

4. Labeling Requirements

- Labels must provide accurate information about ingredients, dosage, storage, and precautions.

Uses

A. Health Promotion

- Herbal medicines are used to maintain general health.

B. Disease Treatment

- Some herbal products help relieve symptoms of various diseases.

C. Traditional Medicine

- Herbal medicines are widely used in Ayurveda, Siddha, and Unani systems.

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Advantages

- Herbal medicines are obtained from natural sources.
- Many herbal medicines have a long history of traditional use.
- Some herbal medicines produce fewer side effects when used properly.

Limitations

- Scientific evidence is not available for all herbal medicines.
- Quality may vary between manufacturers.
- Some herbal medicines may interact with prescription medicines.
- Incorrect use may lead to harmful effects.

Food and Nutraceuticals

- Nutraceuticals are food products or food components that provide health benefits in addition to their nutritional value.
- They help maintain health and may reduce the risk of certain diseases.
- Nutraceuticals are not intended to replace medicines but may support overall health.

Types of Nutraceuticals

1. Dietary Supplements

- Dietary supplements contain vitamins, minerals, amino acids, or other nutrients.
- They are used to supplement the normal diet.

2. Functional Foods

- Functional foods are regular foods that provide additional health benefits.
- Examples include probiotic yogurt and fortified cereals.

3. Probiotics

- Probiotics are beneficial microorganisms that improve intestinal health.
- They help maintain a healthy balance of gut bacteria.

4. Prebiotics

- Prebiotics are substances that promote the growth of beneficial bacteria in the intestine.
- They improve digestive health.

5. Medical Foods

- Medical foods are specially formulated products intended for dietary management of specific diseases under medical supervision.

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