Bringing medicinal drugs for our healthy living

July 2022

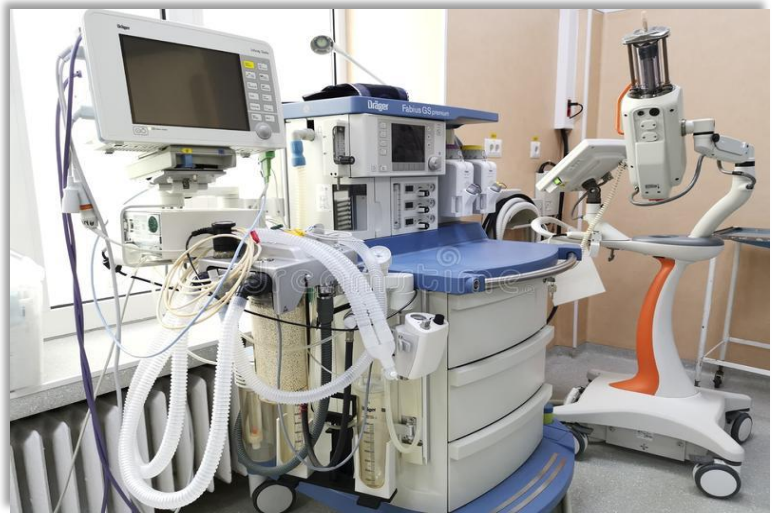
1. Pharmaceutical products for our medical care

Medicinal Drugs

Medicinal drugs are used to diagnose, cure, treat, or prevent diseases. Drug therapy relies on the science of pharmacology for continual advancement and on pharmacy for appropriate management.

Medical Devices

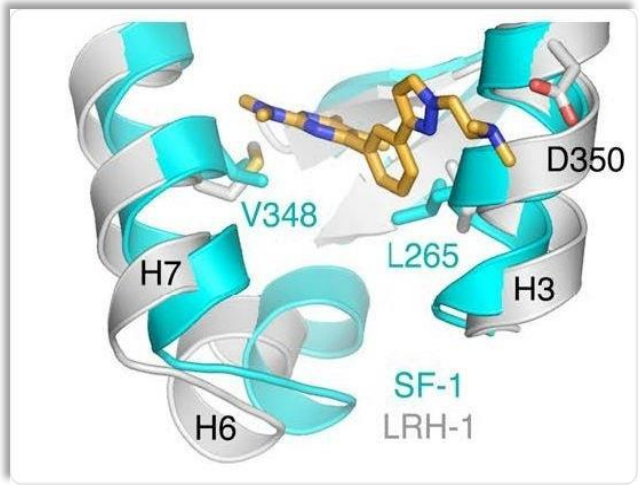
A Medical device is an instrument, tool, machine, test kit, or implant that is used to prevent, diagnose, or treat a disease or other medical conditions



Medical Equipment

Medical equipment is used in a patient care environment to support patient treatment and diagnosis

2. Categorization of Medicinal Drugs



Small Molecules

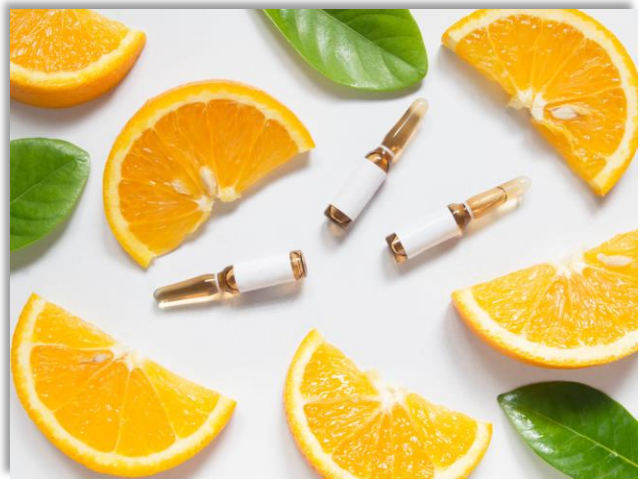
Small molecule or micro-molecule is a low molecular weight organic compound that may regulate a biological process, with a size of the order of 1 nm

Natural Products

A medicinal product containing one or more herbal substances, one or more herbal preparations, or a combination of the two as active ingredients

Biologics

Biologics are isolated from a variety of natural sources and may be produced by biotechnology methods and other technologies



Nature Derived

A medicinal product that has a substance taken from a natural source and chemically processed to create a drug

3. Classification of Medicinal Drugs

ATC Classification System

Anatomical Therapeutic Chemical Classification System classifies medicinal drugs among 5 levels

Levels	Classification Criteria
Level 1	Describes the organ system treated
Level 2	Describes the therapeutic effect
Level 3	Describes the mechanism of action
Level 4	Describes general chemical properties
Level 5	Describes chemical components

USP Classification System

United States Pharmacopeia Classification System classifies medicinal drugs by their Therapeutic use, Mechanism of action & method of formulation

Analgesics	Antiparkinson agents	Hormonal agents (pituitary)
Anesthetics	Antipsychotics	Hormonal agents (prostaglandins)
Anti-addiction agents	Antispasticity agents	Hormonal agents (sex hormones)
Antibacterials	Antivirals	Hormonal agents (thyroid)
Anticonvulsants	Anxiolytics	Hormone suppressant (adrenal)
Antidementia agents	Bipolar agents	Hormone suppressant (pituitary)
Antidepressants	Blood glucose regulators	Hormone suppressant (thyroid)
Antiemetics	Blood products	Immunological agents
Antifungals	Cardiovascular agents	Infertility agents
Antigout agents	Central nervous system agents	Inflammatory bowel disease agents
Anti-inflammatories	Contraceptives	Metabolic bone disease agents
Antimigraine agents	Dental and oral agents	Ophthalmic agents
Antimyasthenic agents	Dermatological agents	Otic agents
Antimycobacterials	Electrolytes, minerals, metals	Respiratory tract agents
Antineoplastics	Gastrointestinal agents	Sexual disorder agents
Anti-obesity agents	Genitourinary agents	Skeletal muscle relaxants

4. Type of Medicinal Drugs

Innovator Drug

- *It is the first drug created containing its specific active ingredient to receive approval for use*
- *It is the product for which efficacy, safety & quality have been fully established*
- *When a new drug is first made, drug patent is typically acquired by the founding company*
- *Most drug patents are protected up to 20 years. During the patent period, other companies cannot make or sell the same drug until the patent expires*

Generics Drug

- *A generic drug is made of the same active ingredient as its innovator drug*
- *An active ingredient is the chemical contained inside a drug that makes it work*
- *In other words, the pharmacological effect of a generic drug is exactly-the-same as those of its innovator counterpart*
- *Other companies can manufacture the generic drugs when the patent expires*

5. Process for Medicinal Drug development

1

Discovery & Development

2

Pre-clinical Research

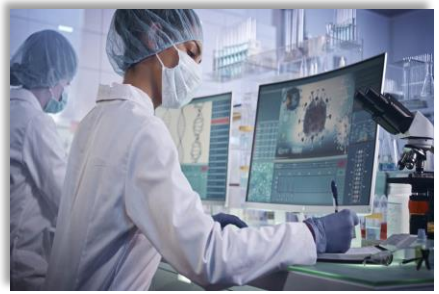
3

Clinical Research

4

Regulatory Review

5



Post-approval market safety monitoring

6. Medicinal Drug development - Discovery & Development

Discovery

Typically, researchers discover new drugs through:

- New insights into a disease process that allow researchers to design a product to stop or reverse the effects of the disease
- Many tests of molecular compounds to find possible beneficial effects against any among a large-number of diseases
- Existing treatments that have unanticipated effects
- New technologies, such as those that provide new ways to target medical products to specific sites within the body or to manipulate genetic material

Development

Once researchers identify a promising compound for development, they conduct further experiments to gather information on:

- How it is absorbed, distributed, metabolized, and excreted by the body
- Its potential benefits, mechanisms of action and the best dosage
- The best way to give the drug (such as by mouth or injection)
- Side effects or adverse events that can often be referred to as toxicity
- How it affects different groups of people (by gender, ethnicity) differently
- How it interacts with other drugs & its effectiveness as compared with similar drugs

7. Medicinal Drug development - Pre-Clinical Research

In Vitro research

- Research is conducted outside the living organism
- Study cell targets & how the drug behaves with individual cells

In Vivo research

- Research is conducted inside the living organism
- Study how the drug behaves with different organs & metabolic pathways

Good Laboratory Practices (GLP)

These regulations set minimum basic requirements for:

- Conduct of the study
- Personnel
- Facilities
- Equipment
- Written protocols
- Operating procedures
- Study reports
- Quality assurance oversight for each study to assure the safety of regulated product

Results from Pre-clinical research guide the safety threshold for dosing & toxicity

8a. Medicinal Drug development - Clinical Research

Clinical research refers to studies, or trials, of the effect of the new drug on people

The protocol for conduct of the research or trial includes:

- Who qualifies to participate (selection criteria) ?
- How many people will be part of the study ?
- How long the study will last ?
- Whether there will be a control group and other ways to limit research bias ?
- How the drug will be given to patients and at what dosage ?
- What assessments will be conducted, when, and what data will be collected ?
- How the data will be reviewed and analyzed ?

8b. Medicinal Drug development - Clinical Research - Study phases




Phases	Phase 1	Phase 2	Phase 3	Phase 4
Participants	20 to 100 healthy volunteers or people with the disease or condition	Up to several hundred people with the disease or condition	300 to 3000 volunteers with the disease or condition	Several thousand volunteers with the disease or condition
Study duration	Several months	Up to 2 years	Up to 4 years	Up to 8 years
Purpose	Assess the safety and dosage of the drug	Assess the efficacy and side effects of the drug	Assess the efficacy and monitor any adverse reactions to the drug	Assess the safety and efficacy of the drug across a wider population
Success rate	Approximately 70% of the drugs progress to the next phase	Approximately 33% of the drugs progress to the next phase	Approximately 25% of the drugs progress to the next phase	Approximately 15% of the drugs progress to the next stage

9. Medicinal Drug development - Regulatory reviews

If a drug developer has evidence from its tests & preclinical & clinical research that a drug is safe & effective for its intended use, the company can file an application to market the drug

The new drug application must include reports on all studies, data, and analyses. Along with clinical results, the developers must include:

- Proposed labelling for the drug
- Safety updates
- Drug abuse information
- Patent information
- Any data from studies conducted outside the United States
- Institutional review board compliance information
- Directions for use

The FDA/ EMA/ MHRA review team thoroughly examines all submitted data on the drug and decides to approve or not to approve it

10. Medicinal Drug development - Post approval market safety monitoring

- Even though clinical trials provide important information on a drug's efficacy and safety, it is impossible to have complete information about the safety of a drug at the time of approval
- Despite the rigorous steps in the process of drug development, limitations exist
- Therefore, the true picture of a product's safety actually evolves over the months and even years that make up a product's lifetime in the marketplace

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of marketed medicines or those under trial

The drug regulatory agencies have the responsibility of having a well-established pharmacovigilance system to monitor adverse reactions of drugs during the drug development phase and later during the life-time of a marketed drug

11. Medicinal Drug development - Patent protection for the Innovator

Data Exclusivity	Marketing Exclusivity	Special protection certificate
Valid up to 8 years	Valid up to 2 years	Valid up to 1 year
○ Clinical and scientific data for drug composition is confidential ○ No other company can manufacture the same drug and apply for approval	○ Clinical and scientific data for drug composition is made public ○ Other company can manufacture the same drug and apply for approval but cannot market the product	○ If innovator drug is approved for additional indications, the protection for the drug is extended by 1 year and no generic can be marketed (SPC) ○ If innovator drug is approved for use in paediatric patients, the protection for the drug is extended by 6 months and no generic can be marketed (PPC)

12. Medicinal Drug development - Generics development post patent expiry

Once the patent expires, other drug manufacturers can develop the drug, which will be known as a generic version of the drug

Generic drugs are comparable to brand name drugs and must have the same:

- Dosage form
- Strength
- Safety
- Quality
- Performance characteristics
- Intended use

Because generic drugs are comparable to drugs already in the market, **generic drug manufacturers are not required to conduct clinical trials to demonstrate that their product is safe and effective**. Instead, they conduct **bio-equivalence studies** and file an Abbreviated New Drug Application

The Navikenz difference....

- Experienced and dedicated **team** that fights for engagement success
- Solution building focus with the right **partner eco-system**
- Ability to attract and retain the right **techno-domain expertise**
- High quality delivery, enabled by **mature management systems** and **right culture**

info@Navikenz.com

www.navikenz.com