INTRODUCTION TO PHARMACEUTICAL TECHNOLOGY

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What is Pharmaceutical Technology?

"All of the technologies that involve the development and use of drugs"

- **Preparation, production, and quality control of dosage forms**
- **Properties of active substance, drug release, and interactions with human body**
- **Production and control of biotechnological, radiopharmaceutical, cosmetic and cosmeceutical (dermocosmetic) products**

Some historical steps in pharmacy

- Primitive tribes

*Treatment with plants

- China

*Opium, anise, sulfur, mercury, ephedra species
*Asthma, shortness of breath and cough treatment

- Indian (B.C. 3500)

*Ginger, sandalwood, aloe, mercury, gold
*Production of elixir, pomade, decoction, patch

- Mesopotamia

*Opium, benzoe, licorice
*Production of pomade, liniment, decoction, infusion

- Egypt

*Castor oil, aloe, opium, some minerals (Ar, Hg, S, Zn, Pb)
*Production of porridge, mouthwash, pat etc.
*Usage of mortar, sieve, mill, glass measuring cups

- Baghdad

*The first pharmacy was founded in 760

Some historical steps in pharmacy

- Hippocrates

*Father of medicine and pharmacy

- Dioscorides

*Author of Materia Medica

*Book includes pharmaceutical raw materials, preparations and uses

- Cladius Galenus

*Laid the foundation for pharmaceutical technology knowledge

*The name of «Galenic Pharmacy» comes from his name

*Drugs are grouped as specific drugs, poisons and antidotes according to their effects

*The first method of writing a prescription

Some historical steps in pharmacy

- Ibn-i Sina turned pharmacy into a profession
- 16th century

Paracelsus used mercury salts to treat syphilis

- 17th century

Homeopathy emerged

- 18th century

Licor de Hoffman and Dover Powder (T.K. 1954)

- 1806

Morphine production from opium

- 1827

*The foundation of the pharmaceutical industry was laid in pharmacy laboratories

*Emanuel Merck begins production of large quantities of alkaloid in his laboratory

Merck Pharmacy - Darmstadt

Riedel and Schering Pharmacy - Berlin

Pharmaceutical Technology

is a science that encompasses all the processes for turning an active pharmaceutical ingredient into a medicine that can be used safely and effectively by patients.

- Fenni İspençiyari
- Materia Medica
- Galenic Pharmacy
- Pharmaceutics

Ottoman

Rome

Europe

Anglo-Saxon

Scandinavia

«Pharmaceutics» definition covers the issues of

- General pharmaceutical technology
- Clinical pharmacology
- Biopharmaceutics and pharmacokinetics
- Pharmacy applications
- Cosmetics

Industrial Pharmaceutical Technology

involves the areas given below:

- Drug product preparation
- Methods of application of scientific bases to industry
- The scientific basis of the instruments and machines used in the operations
- Pharmaceutical engineering
- Effects of fabrication on drugs

Codex and Pharmacopoeia

Codex

Codex is a manuscript, official and antique book containing a list of chemical and medical items

Pharmacopoeia

They are official books containing the pharmaceutical active substances and the necessary properties for the preparation of medicinal forms prepared therefore for the protection of life and for therapeutic purposes.

Pharmakon + Poiein = Pharmacopoeia

Pharmacopoeias

The therapeutically effective amount of the active ingredients, the excipients used and the dosage forms prepared therefrom are given in pharmacopoeias.

They contain;

- Physical, chemical and physicochemical properties
- Control methods and identification reactions
- Quantity assignments
- Storage conditions
- Some formulations

- They are prepared and printed by the authorities assigned by each country. This ensures a legal standard.

History of Pharmacopoeias

50-70 Materia Medica (Dioscorides)
1498 First pharmacopoeia in Florence
1820 First pharmacopoeia in USA (USP)
1969 First pharmacopoeia in Europe (EP)

1930 First Turkish Codex (T.K.1930) in Republic of Turkey
1948 T.K. 1948 is the extended version of T.K.1930
1974 First Pharmacopoeia of Turkey (T.F. 1974)
1994 European Pharmacopeia Commission membership acceptance
2004 Adaptation of the European Pharmacopoeia Volume 1 was published

Formulary

Formulary includes the active substances and dosage forms which are not important enough to be involved in the pharmacopoeia.

National Formulary (N.F.)
British National Formulary (B.N.F.)

Examples

- **Turkish Pharmacopoeia 2004 (TF 2004)**
  (The newest one is (TF 2018)
- **European Pharmacopoeia 6.0 (EP 6.0)**
  (The newest one is EP 9.0)
- **American Pharmacopoeia 27 (USP 27)**
  (The newest one is USP 34)

- ✓ **Turkish Codex 1954 (T.K.)**
- ✓ **American National Formulary (N.F.)**
- ✓ **British Pharmaceutical Codex (B.P.C.)**

Drug
or
Pharmaceutical Product
?

Drug can be defined as the medicine or other substance which has a physiological effect when ingested or otherwise introduced into the body.

Under the «Health Topics» title, WHO

(World Health Organization) defines drugs under two different subtitles;

- Essential medicines
- Pharmaceutical products

which the latter is commonly called as drug or medicine.

Drug is the pharmacologically active ingredient in a medicine.

Drug = Medicinal agent = Active substance

Drug = Active pharmaceutical ingredient (API)

Drugs are rarely administered as pure chemical substances alone and are almost always given as "formulated preparations" or "pharmaceutical products" or "dosage forms" or "medicines".

Medicines (Pharmaceutical Products)

- They are protecting the living from disease
- They are used in different ways
- They are used with the aim of diagnosing and treating the diseases
- They contain one (or more) active ingredient
- They are designed to be easily received by the patient
- They are prepared in the form of a formula (auxiliary substances) which will be effected according to the desired purpose and duration.

It is essential that the pharmaceutical products are safe, effective and of good quality and are prescribed and used rationally.

Pharmaceutical products can be categorized as:

- **Magistral**

This is the common name of medicines prepared by a pharmacist according to a prescription written by a doctor, veterinary doctor or a dentist.

- **Officinal**

Pharmacist usually prepares this kind of medicines according to the formulations given in codex or pharmacopoeia. They are prepared as stock formulations.

- **Pharmaceutical preparations**

These are the pharmaceutical products prepared in a factory after licenced by the health authority of the country. TURKISH MEDICINES AND MEDICAL DEVICES AGENCY (TMMDA; TİTCK) is the authority in our country. These medicines can be over the counter (OTC) products or they can be given with a prescription.

Pharmaceutical products can be classified as human products and veterinary products according to the organism applied to.

Pharmaceutical products can also be classified as;

- Simple products

Pharmaceutical product contains only one drug

- Composed products

Pharmaceutical product contains more than one drug

Structure of the pharmaceutical product

They contain - Active substance
- Auxiliary substances / vehicles

Active substance (drug) is an organic / inorganic substance that provides the therapeutic and diagnostic effect of the pharmaceutical product.

According to their structure they can be classified as

- *Natural*
- *Semisynthetic*
- *Synthetic*

Excipient (vehicle) is the inert substance used in the formulation according to the type of dosage form to be formulated.

Excipient (Vehicle)

Excipient term is used for semisolid dosage forms while vehicle term is generally used for solid dosage forms.

When the active ingredient is formulated with a suitable excipient in a pharmaceutical product:

- It can be easily taken by the patient
- Dose is precisely adjusted
- It is well absorbed
- Its stays long-lasting