

Pharmaceutical analysis- BP102T

UNIT : 1 (Pharmaceutical analysis ,Its definition and scope, methods expressing techniques)

CLASS:1

TOPIC: Definition of Pharmaceutical Analysis and its Scope

Pharmaceutical analysis is a branch of practical chemistry that involves a series of process for identification, determination, quantification and purification of a substance, separation of the components of a solution or mixture, or determination of structure of chemical compounds.

The substance may be a single compound or a mixture of compounds and it may be in any of the dosage form. The substance used as pharmaceuticals are animals, plants, microorganisms, minerals and various synthetic products.

The different pharmaceutical agents are as follows:

1. Plants
2. Microorganisms
3. Minerals
4. Synthetic compounds

Pharmaceutical analysis is traditionally defined as analytical chemistry dealing with drugs both as bulk drug substances and as pharmaceutical products (formulations). However, in academia, as well as in the pharmaceutical industry, other branches of analytical chemistry are also involved, viz. bioanalytical chemistry, drug metabolism studies and analytical biotechnology. The development of drugs in the pharmaceutical industry is a long-term process, often taking more than a decade from the start of a research project to the appearance of a drug on the market. That process involves several decision points, such as the choice of the candidate drug after the preclinical screening phase, the investigational new drug (IND) application before testing the compound for the first time in man, and finally the new drug application (NDA) which summarizes the data obtained from all the studies needed for marketing approval of the drug as a medicine. In all these steps, especially the IND and NDA, the amount of data generated is enormous. Analytical chemists take part in many of the

studies that constitute this documentation. Substance quality and its specifications are based on substance analysis, and that knowledge is later used for quality control during full-scale production. Product analysis involves dealing with the various formulations and starts after the IND has been approved. The results from such work lead to specifications that form the basis for the quality control of the product. For both substances and formulations there is an increasing interest in the introduction of process analytical chemistry.

The sample to be analysed is called as analyse.

- Quality control and quality assurance
- Chromatographic techniques
- Quantitative and qualitative analysis
- Validation methods
- Stoichiometry between reactants & products

Scope of Pharmaceutical Analysis

- Pharmaceutical Analysis is one of the most sort after specializations in masters of pharmacy. People specialised in pharmaceutical analysis are indispensable to the manufacturing, quality control and analytical manifestations of the industry.
- They can work in quality control department which oversees the purity, qualitative aspects and the matching of the stringent regulatory limits required by a finished product.
- Research and development has huge implications on the results of the analysis and detection of new compounds. More and more companies are stressing on a separate analytical R&D department.
- Pharmaceutical analysis students also find takers in the medical devices companies, equipment companies, regulatory agencies etc.
- Always remember, no matter what compounds you discover or formulation you make nothing is valid until it is evaluated, analysed and validated.
- Based upon the determination type, there are mainly two types of analytical methods. They are as follows:

Qualitative analysis:

Quantitative analysis:

1. Qualitative analysis

This method is used for the identification of the chemical compounds. Qualitative analysis is performed to establish composition of natural/synthetic substances. These tests are performed to indicate whether the substance or compound is present in the sample or not.

2. Quantitative analysis

This method is used for the determination of the amount of the sample. Quantitative analytical techniques are mainly used to quantify any compound or substance in the sample. There are various methods to find out the quantity of a substance in a product.

Various types of Qualitative analysis:

1. Chemical methods

a) volumetric or titrimetric methods

b) gravimetric methods

c) geometric analysis

2. Electrical methods

3. Instrumental methods

d) 4. Biological and

microbiological

Very Short Answer Questions:

1. Define the term pharmaceutical analysis
2. What is Quantitative analysis and describe its types

Short Answer Questions:

1. What is pharmaceutical analysis and its scope
2. Define Qualitative analysis and Quantitative analysis what is its importance in pharma industry