**INTRODUCTION:**

Analysis is important in every product or service, but in drug it is very important as it involves life. As a matter of fact, quality is built in form the time of inception of the thought to make a product, to the time. It is finally made and sent out. The assurance of the quality together with their careful control are our moral obligation arising from humanism towards the seek human beings. Analytical chemistry is mainly concerned about determining the qualitative and quantitative composition of material under study. Analytical monitoring of a pharmaceutical product, is necessary to ensure its safety and efficacy throughout all phases of its shelf life, including storage, distribution, and use.

Analytical chemistry is the science that seeks ever improved means of measuring chemical composition of natural and artificial materials. Chemical composition is the entire composition of the material at the chemical scale induced geometric features such as molecular morphologies and distribution of species with in sample as well as single dimensional features such as percent composition and species identity.

Understanding the analytical toolbox requires a scientist to understand the basic principles of the analytical techniques. With a fundamental understanding of analytical methods, a scientist faced with a difficult analytical problem can apply the most appropriate technique(s). A fundamental understanding also makes it easier to identify when a particular problem cannot be solved by traditional methods, and gives an analyst the knowledge that is needed to develop creative approaches or new analytical methods.

Analytical chemistry requires broad background knowledge of chemical and physical concepts. Major steps of analytical process cycle involves, sample preparation, sample analysis, data handling, report generation, archiving and information to customer.
Analytical chemistry based on two aspects **Qualitative analysis** and **Quantitative analysis**.

- **Qualitative analysis** seeks to establish the presence of a given element or functional group in a sample (inorganic/organic).
- **Quantitative analysis** seeks to establish the amount of the given element or compound in given sample.

**Methods of Detecting Analysts**

- Physical means
  - Mass
  - Color
  - Refractive index
  - Thermal conductivity

- With electromagnetic radiation (Spectroscopy)
  - Absorption
  - Emission
  - Scattering

- By an electric charge
  - Electrochemistry
  - Mass spectrometry

The patterns of absorption (wavelengths absorbed and to what extent) and/or emission (wavelengths emitted and their respective intensities) are called ‘**spectra**’. The field of **Spectroscopy** is concerned with the interpretation of **spectra** in terms of atomic and molecular structure. Spectroscopy consists of many different applications such as atomic absorption spectroscopy, atomic emission spectroscopy, UV-Visible spectroscopy, Infrared spectroscopy, Raman spectroscopy, NMR spectroscopy, Mass spectroscopy, Photo-emission spectroscopy etc.
Separation processes are used to describe the complexity of material mixture. Chromatography and electrophoresis is representative of this field.

Method for separating the constituents of a solution (gas or liquid) by exploiting the different bonding properties of different molecules. Used in qualitative and quantitative analysis of biological and chemical substances, this technique employs two immiscible substances. One substance (a gas or liquid, called the mobile phase) transports the solution being analysed through the other substances (a liquid or solid, called the stationary phase). The stationary phase absorb or impedes different components of the solution to different degrees and thus, causes their separation as different layers.

Commonly used methods of chromatography are adsorption chromatography, partition chromatography, ion exchange chromatography, molecular exclusion chromatography, affinity chromatography.

There are various advanced chromatographic techniques which are more reliable and widely used for the estimation of multi component drug in their formulation namely gas chromatography, High Performance Liquid Chromatography (HPLC), High Performance Thin Layer Chromatography (HPTLC).

Commonly used methods of chromatography are divided into following groups’ namely chiral, iron exchange, normal phase, reverse phase, when compared to classical column chromatography this technique preferred because of its improved performance in terms of rapidity, specificity, sensitivity, accuracy, convinincy, ease of automation and cost of analysis. Advance in column technology, high pressure pumping system and sensitive detectors have transformed liquid column chromatography into high speed, efficient, accurate and highly resolved method of separating.

Combination of the above techniques produces ‘hybrid’ or ‘hyphenated’ techniques. Several examples are in popular use today and new hybrid techniques are under development namely, GC-MS, LC-MS, HPLC/ESI-MS, and LC-DAD etc.
Method of data analysis is based on standard curve and internal standard. A standard method for analysis of concentration involves the creation of a calibration curve. This allows for determination of the amount of a chemical in a material by comparing the result of unknown sample to those of a series unknown standards. Some time an internal standard added at known concentration directly to an analytical sample to aid in quantitation. The amount of analyte present is then determine relative to the internal standard as a calibrant.

The number of drugs introduced into the market has been increasing at an alarming rate. Newer analytical methods are developed for this drugs or drug combinations because of following reasons.

- The drug or combination may not be official in any Pharmacopoeia.
- A literature survey may not reveal an analytical procedure for a drug or its combination.
- Analytical methods may not be available for the drug combination due to the interference caused by excipients.
- Analytical method for the quantification of the drug or drug combination with other drug may not be available.
- The newly developed analytical method find their importance in various fields such as research institutions, quality control department in industries, approved testing laboratories, bio-pharmaceutical and bio-equivalence studies, clinical pharmacokinetic studies.
- The existing analytical procedures may require expensive reagents and solvents. It may also involve cumbersome extraction and separation procedures and these may not be reliable.
What is validation?\textsuperscript{10,12,13,22}

Validation is a process, which is required in industry to counter check the reproducibility of results of manufacturing process, equipment and method. It is an integral part of quality assurance. It involves the systematic study of systems, facilities and processes aimed at determining whether they perform their intended functions adequately and consistently as specified. A validated process is one which has been demonstrated to provide a high degree of assurance that uniform batches will be produced that meet the required specifications and has therefore been formally approved. Validation in itself does not improve processes but confirms that the processes have been properly developed and are under control.

Beneficial aspects of validation

- It deepens the understanding of processes, decreases the risk of preventing problems and thus assures the smooth running of the process.
- It decreases the risk of defect costs.
- It decreases the risk of regulatory noncompliance.
- A fully validated process may require less in-process controls and end product testing.

Validation is required in the following situations:

- Totally new process;
- New equipment;
- Process and equipment which have been altered to suit changing priorities
- Process where the end-product test is poor and an unreliable indicator of product quality.