**Introduction**

A drug may be defined as a chemical substance used in the treatment, cure, prevention or diagnosis of disease or used to otherwise enhance physical or mental well-being.

The process of drug discovery and development is complex. Drug development in the pharmaceutical industry is a long-term process, from the start of research project to the appearance of drug in the market (1). This process of drug discovery and development involves the collective contributions of many scientists, such as organic chemist, biochemist, microbiologists, toxicologists, pharmaceutical scientists and analytical chemists. Analytical methods development & validation play important roles in the discovery, development & manufacture of pharmaceuticals. The official test methods that result from these processes are used by quality control laboratories to ensure identity, purity, potency & performance of drug products.

The results from such work lead to specifications that form the basis for the quality control of the product. In pharmaceutical analysis, the term “quality” applied to drug products is defined as the sum of all the factors, which contribute to the safety, effectiveness, and reliability of a product. To meet these demands of high quality drug products, modern pharmaceutical industry relies on analytical chemists for developing specific, accurate, sensitive and fast analytical methods (2).

Analytical chemistry is a scientific discipline that develops and applies methods, instruments and strategies to obtain information on the composition and nature of matter. Analytical chemistry deals with study of the separation, identification & quantification of the chemical components.

Analytical chemistry deals with old classical methods and modern instrumental techniques. The object of analytical chemistry is to obtain qualitative and quantitative information about the chemical composition and structure of materials (3). Two fundamental questions “What is present?” and “How much is present?” arises in case of identification and estimation of the components of a sample. “Qualitative analysis provides answer to ‘What’ and “quantitative analysis to how much is present”.

Pharmaceutical analysts play a major role in assuring the identity, safety, efficacy, and quality of a drug product. Safety and efficacy studies require that drug substance and drug product meet two critical requirements a) Established identity and purity

b) Established bioavailability/dissolution.
Concepts about purity change with time and are inseparable from developments in analytical chemistry. If a material previously considered being pure can be resolved into more than one component, that material can be redefined into new terms of purity and impurity (4). Testing of drug substances and drug products emphasizes that the testing of those features which are susceptible to change during storage and are likely to influence quality, safety and/or efficacy (5).

Dissolution testing has become an important component of the assessment of the quality of solid oral dosage forms and oral suspensions. The basic procedures for these oral dosage forms have been extended to transdermal delivery systems as well. The release rate for modified-release oral dosage forms adds a level of sophistication to the concept of dissolution testing, setting acceptance criteria at multiple time points. The dissolution procedure is a performance test applicable to many dosage forms. It is one test in a series of tests that constitute the dosage form’s public specification. Dissolution testing has emerged in the pharmaceutical field as a very important tool to characterize drug product performance. The significance of this test is based on the fact that the rate and extent of drug absorption depend on its dissolution from the dosage form. Therefore, dissolution test is used not only for quality control of the final dosage form, but also to assess several stages of formulation. The U.S. Food and Drug Administration (FDA) has recently encouraged pharmaceutical companies to explore the relationship between in vivo drug bioavailability and in vitro dissolution. The in vivo bioavailability study is to investigate the rate and extent of drug absorption in humans. On the other hand, drug absorption depends upon the dissolved state of the drug product. Lesson (1995) suggested that in vitro dissolution testing be used as a surrogate for in vivo bioequivalence studies to assess equivalence between the test and reference formulations, and for postapproval changes. (6). This test gains its significance from the fact that if a drug from a product is to produce its effect it must be released from the product and should generally be dissolved in the fluids of gastrointestinal (GI) tract. Therefore a dissolution test is often considered a surrogate for the assessment of availability of drugs in the body, generally termed as bioavailability (7). Dissolution testing historically has been a key tool during development stages of compound as well as for commercial manufacturing. For a development compound, dissolution testing is used primarily to help develop and evaluate new formulations by evaluating the rate of drug release from dosage forms, evaluating the stability of these formulations, monitoring product consistency, assessing formulation changes, and establishing IVIVRs or IVIVCs.

USP recognition of the need to control the in vitro dissolution performance of oral products by some level of compendia requirement was evidenced by the formation of a joint USP– NF panel on
physiological availability in 1967. The USP Compendial requirements of Dissolution Testing and NF separately introduced dissolution procedures to drug products in 1970 (8). The objectives of dissolution testing, in general, vary during the life cycle of a dosage form. The primary objective during Phases 0 and I is to develop a method to clearly establish the mechanism of in vitro drug release and solubilization. During Phases II and III, the objective shifts to identifying a test method that can provide an IVIVR, IVIVC, or other biorelevant information. At registration and beyond, the goal is to identify a quality control (QC) dissolution test method to verify process and product consistency (9).

The following methods are used to evaluate the stability and purity of drug substances and drug products: thin-layer chromatography (TLC), HPLC, gas chromatography (GC), capillary electrophoresis (CE), and ultraviolet (UV) spectroscopy. However, reversed-phase HPLC analysis is generally considered the most effective method of identifying most drug substance degradation or drug-excipient interactions. Hence, it is the typical choice for stability-indicating and stability-specific methods for small molecules (10).

Quantification of drug (assay) in pharmaceutical dosage form and impurity profiling of drug substance and in pharmaceutical dosage form (related substances) is necessary to evaluate their purity and quality. As per ICH ‘Impurity’ in drug substance is defined as “Any component of the new drug substance that is not the chemical entity defined as the new drug substance” (11) whereas in case of pharmaceutical dosage form (drug product) it is defined as “Any component of the new drug product that is not the drug substance or an excipient in the drug product.” Impurity profiling of drug substance / drug product is a description of the identified and unidentified impurities present in a drug substance / drug product. (12)