Introduction:

Analytical chemistry is an important part in monitoring the quality of pharmaceutical products for safety and efficacy. With the advancement in synthetic organic chemistry and other branches of chemistry including bio analytical sciences and biotechnology, The scope of analytical chemistry has enhanced to, much higher levels. The emphasis in current use of analytical methods particularly involving advance analytical technology has made it possible not only to evaluate the potency of active ingredients in dosage forms and APIs but also to characterize, elucidate, identify and quantify important constituents like active moiety, impurities, metabolites, isomers, chiral components and prediction of the degradations likely impurities being generated.

Impurities in pharmaceuticals are the unwanted chemicals that remain with the active pharmaceutical ingredients (APIs), or develop during formulation, or upon aging of both API and formulated APIs to medicines. The presence of these unwanted chemicals even in small amounts may influence the efficacy and safety of the pharmaceutical products. Impurity profiling (i.e., the identity as well as the quantity of impurity in the pharmaceuticals), is now important critical attention from regulatory authorities. The different pharmacopoeias, such as the British Pharmacopoeia (BP) and the United States Pharmacopoeia (USP), are incorporating limits to allowable levels of impurities present in the drug substance or drug products.

The control of pharmaceutical impurities is currently a critical issue to the pharmaceutical industry. The International Conference on Harmonization (ICH) has formulated a workable guideline regarding the control of impurities.

The International Conference on Harmonization (ICH) has published guidelines on impurities in new drug substances [1], products [2], and residual solvents [3]. In addition, Ahuja [4] and Gorog [5] have published books covering different aspects of impurities, including the governmental regulations and guidelines and the identification and monitoring of impurities found in drug products.
The pharmaceutical analysis plays a vital role in order to monitor and control the “Quality” and the “Safety” of the drugs. As far as the quality and safety of the any pharmaceutical product the most critical part is to control the impurities formed during the process or formed during the stability. Out of these impurities some of the impurities are toxic and causes adverse effect and demolish the quality as well as safety of the drug product. So it’s become very important to identify and quantify these impurities to maintain the acceptable quality and safety. For the purpose of identification and quantification of the impurities present in the pharmaceuticals, various analytical techniques were employed. There is a great need for development of analytical methods for new emerging drugs. In earlier days the quantification of impurities were employed by qualitative and comparative study and is become very difficult to find out the exact level of the impurities. By using the current advancement in the pharmaceutical testing it’s become possible to exact and more accurate quantification of the impurities present in the pharmaceuticals.