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IMPURITY PROFILING FOR PHARMACEUTICAL PRODUCT BY USING DIFFERENT ANALYTICAL TECHNIQUES - AN OVERVIEW

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Abstract

Impurity profiling brings tremendous efforts in the group of analytical activities, the aim of which is the detection, identification/structure elucidation and quantitative determination of organic and inorganic impurities, as well as residual solvents in bulk drugs and pharmaceutical formulations. The control of impurities is currently a critical issue to the healthcare manufacturing. Various regulatory authorities like ICH, USFDA, UK-MHRA, CDSCO are emphasizing on the requirements and the identification of impurities in Active Pharmaceutical Ingredient`s (API`s) and as well as finished products. International Conference on Harmonization (ICH) formulated guidelines concerning the control and limit of impurities. To isolate and characterize impurities in pharmaceuticals diverse methods are used such as, capillary electrophoresis, gas–liquid chromatography, high performance liquid chromatography, solid-phase extraction methods, Ultraviolet Spectrometry, infrared spectroscopy, supercritical fluid extraction chromatography, mass spectroscopy, Nuclear magnetic resonance (NMR) spectroscopy etc. On the beginning of hyphenated techniques, the most browbeaten techniques for impurity profiling are Liquid Chromatography (LC)-Mass Spectroscopy (MS), LCNMR, LC-NMR-MS, GC-MS and fully automated Comprehensive Orthogonal Method Evaluation Technology (COMET). That is why it has plentiful claim in the field of drug design, monitoring quality, stability and as well as safety of the product.

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