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Review Article

Isolation and Characterization of Impurity

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ABSTRACT

Impurity profiling is the common name of a 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 impurities present in the drug are adversely affecting the quality of the drug product. There are various types of impurities like starting materials, intermediates, penultimate impurity, by product and degradation product. Various regulatory authorities like ICH, USFDA, Canadian Drug and Health Agency are emphasizing on the purity requirements and the identification of impurities in Active Pharmaceutical Ingredient's (API's). Qualification of the impurities is the process of acquiring and evaluating data that establishes biological safety of an individual impurity; thus, revealing the need and scope of impurity profiling of drugs in pharmaceutical research. Identification of impurities is done by variety of Chromatographic and Spectroscopic techniques, either alone or in combination with other techniques. There are different methods for detecting and characterizing impurities with TLC, HPLC, HPTLC, AAS *etc*. Among all hyphenated techniques, the most exploited techniques, for impurity profiling of drugs are LC-MS-MS, LC-NMR, LCNMR- MS, GC-MS, and LC-MS.

Keywords: Impurity, Analytical method development, Spectrophotometry, Chromatography.

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