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Approaches to analyze genotoxic impurities in active pharmaceutical ingredients

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Controlling impurities in pharmaceuticals has always been a grave concern posing a question mark on its safe consumption by humans. In pharmaceutical industry, impurities are defined as not having any therapeutic benefits. It is very important to analyze genotoxic impurities in active pharmaceutical ingredients. Spectroscopy and Chromatography are some of the popular methods to analyze genotoxins in active pharmaceutical ingredients. Analyzing genotoxic impurities can be very challenging because they must be controlled at levels lower than 0.01-0.03%. The analytical procedures should allow detection limit in the range of 1-5 ppm. Approaches to analyze genotoxic impurities in active pharmaceutical ingredients should also take into consideration that genotoxins have different functional groups, different sources and some of them have really low molecular weight compound. Analytical and sampling procedures need to be defined based on these findings to make the method more effective. HPLC-UV detectors and GC-FID detectors are the most frequently used techniques for analyzing genotoxic impurities. Mass spectrometers are also being used as detectors in order to achieve higher sensitivity and selectivity in analyzing genotoxins. HPLC is used for non-volatile genotoxic impurities. Analysts usually prefer HPLC with smaller particle size columns reducing analysis time. Mass spectrometers work well to analyze confirmation of known impurities. LC/MS/MS systems also called triple quadrupole have become popular for quantitative analysis for organic impurities. Gas Chromatography is a preferred tool to analyze halides, sulfonates and epoxides. The scope of this research paper is to find the most effective analytical tool to study about genotoxic impurities which would lead to finding an approach to control them in pharmaceuticals

Biography

Zeel Shah has completed her Bachelor's degree of Pharmacy from India. Her interest is in knowing about analytical methods used in the pharmaceutical industry. She has conducted practical studies to carry out assays and determine impurities in active pharmaceutical ingredients. She further pursued her interest in the analytical field and did certificate course in Pharmaceutical and Food Science Technology in Canada. She has conducted practical studies using variety of instruments like HPLC, GC, IR, FTIR and UV-Spectroscopy

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