Sanjay Sharma, J Anal Bioanal Tech 2014, 5:4
http://dx.doi.org/10.4172/2155-9872.S1.019

OMICS Group Conferences
Accelerating Scientific Discovery

5th International Conference and Exhibition on
Analytical & Bioanalytical Techniques
August 18-20, 2014 DoubleTree by Hilton Beijing, China

Degradation and characterization of impurities of new active pharmaceutical ingredient using advance analytical techniques

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One of the most important considerations in the drug discovery process is safety, not only of the drug itself, but also impurities and degradation products. Impurities present in the API have to be identified to make sure no mutagenic or toxic substances will be administered to patients. Drug product degradation profiles need to be established to guide stable formulation and provide suitable drug shelf life assessment. Drug regulatory agencies also have requirements for characterization of the impurity profile of a pharmaceutical. Structural characterization of impurities and degradation products in bulk drug substances is an integral part of pharmaceutical product development. The analysis of these low level unknown impurities and degradants can be very challenging. 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). Impurity and degradant structure elucidation is a collaborative effort involving the analytical chemist, and /or formulation as well as experts in degradation, mass spectrometry, and nuclear magnetic resonance. Identification of the degradation sample set leads to understating of degradation mechanism. In present scenario, there is advancement in the conventional instrumental techniques that aid in fast characterization of impurities and related substances/degradation products spectral analysis and isolation, using new analytical techniques, like UPLC, LC-MS, GC-MS, SFC-MS, LC-NMR, CE-MS etc. The conventional technique included separation and identification of impurities or related substances (RS) by suitable method. Eventually they are isolated and followed by characterization using various spectroscopic techniques. The new advance concept is their characterization by the use of advanced analytical techniques.

Biography

Sanjay Sharma has doctorate in Pharmaceutical Sciences and working as Associate Professor, Head of Department of Quality Assurance and Central Instrumtal Lab-In Charge. He has 12 years professional experience of research, teaching and industrial. He has filed 3 patents and more than 30 international / national research publications to his credit. He has been serving as a reviewer in many of reputed journals. He has been the guide for several PhD and PG students. His current areas of research are analytical and bioanalytical method development, validation Degradation and Characterization of Impurities and handling conventional and modern sophisticated instruments.

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