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Kung Tien Liu
Everlight Chemical Industrial Corporation, Taiwan

Elucidation of unknown pharmaceutical degradation products: Structures and pathways

Algorithm for the elucidation of several unknown degradation products shown in the stability studies of Active Pharmaceutical Ingredients (APIs) and drug products, including structures and degradation pathways has been proposed. Collision Activated Dissociation (CID) fragments of APIs and their related intermediates, received using high-performance Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS) were achieved firstly. Accordingly, Multiple Reaction Monitoring (MRM) ion pairs and fragmentation pathways can be developed secondly. Meanwhile, considering the feasibility of secondary degradation products, core chemical structures that might occur in common in the degradation products were deduced. MRM ion pairs together with related biotransformation scanning (i.e. oxidation (+O, +2O), dehydration ($-H_2O$, $-(H_2O)_2$), carbon dioxide removal and HOAc removal) and Information-Dependent Acquisition (IDA) in the target HPLC retention regions were evaluated and compared thoroughly. Finally, unknown degradation products needed to be verified by the stability test samples. Countermeasures, such as pattern of stable isotopic peaks, kinetics studies and interference factors existed in reagents, manufacturing process raw materials and environment such as plasticizer and catalysts were investigated. Unexpected products and interaction between excipients were also identified.

Biography

Kung Tien Liu has completed his PhD from Department of Chemistry, National Taiwan University, Taiwan and has worked in Institute of Nuclear Energy Research (INER) more than 29 years. He also concentrates his major activities on the GxP related compliance issues for the development and applications of pharmaceuticals. Currently, he is the Deputy Director of Administration Office, Pharmaceutical B U, Everlight Chemical Industrial Co. (ECIC). He has been published more than 40 papers, patents and book chapters.

kungtien@ecic.com.tw

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