Pharmaceutical impurity analysis of raw materials and final product by using analytical techniques

Muhammad Jehangir

Senior Manager Quality Control and Validation

Novamed Group, Lahore-54600, Pakistan

Abstract

The evaluation of pharmaceutical raw materials and finished products for impurities and degradation products is an essential part of the drug development and manufacturing testing process. Additionally, toxicological information must be obtained on any drug-related impurity that is present at a concentration of greater than 0.1% of that of the active pharmaceutical ingredient (API). In pharmaceutical QC and manufacturing, impurity analysis has traditionally been performed by HPLC with UV, PDA, or MS detection. As it is essential to detect and measure all of the impurities in the sample, it is necessary to have a high resolution separation process. This usually involves long analysis times resulting in low throughput. As candidate pharmaceutical compounds become more potent and are dosed at lower and lower levels, ever more sensitive assays are needed to detect and measure impurities. The low throughput of HPLC can become the rate-limiting step in product release testing or process evaluation. Since much of the process of impurity identification involves the coupling of LC to sophisticated MS, any reduction in analysis time will result in a more efficient use of these significant investments. Analytical technology advances such as UPLC and UPC offer significant improvements in throughput and sensitivity, with benefits to the process of product release and identification of drug-related impurities. The most characteristic feature of the development in the methodology of pharmaceutical and biomedical analysis during the past 25 years is that HPLC became undoubtedly the most important analytical method for identification and quantification of drugs, either in their active pharmaceutical ingredient or in their formulations during the process of their discovery, development and manufacturing.

Biography

Muhammad Jehangir has 13 years diversified experience of Quality Control, Quality Assurance, Registration Affairs, Product development and Pharmaceutical manufacturing, Process Planning, Method development, Method validation, Statistical Methodology, Process & Cleaning Validation, and Equipment Validation. Certificate Courses on cGMP, cGLP, Process Validation, CTD Documents, ISO 9001:2015, 13485-2016, and 14001-2004, has strong scientific, analytical, statistical, managerial and training skills. Currently he is working as a Senior Manager Quality Control and validation for Novamed Pharmaceuticals. It is toll manufacturing oriented company, manufacturing of companies like Getz Pharma, ICI, SEARLE, Macter, Ray, and for Sanofi-Aventis. He is also looking after the Quality of Novamed Healthcare, the nutraceutical and cosmeceutical manufacturing plant.



Email ID: m.jehangir@novamed.com.pk,

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