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

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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 ultraviolet (UV), photodiode array (PDA), or mass spectrometry (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 liquid chromatography (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 ultra-high pressure liquid chromatography (UPLC) and UPC^2 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.

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