Euro analytica 2020: Pharmaceutical Impurity Analysis of Raw Materials and Final Product by using analytical techniques - Muhammad Jehangir - Novamed Pharmaceuticals

ABSTRACT:

"Isolation and identification of unknown components and impurities" 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.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 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

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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. Pharmaceutical impurity testing and quantification is vital to address the purity, safety and quality of drug substances or finished drug products. Pharmaceutical impurities can arise from many sources and include starting materials and their contaminants, reagents, catalysts, solvents, intermediates, excipients and their contaminants, leachables and degradation products. They can be organic impurities, both process and drug-related, inorganic or elemental impurities. These impurities are often present at very low levels highly complex sample matrices, and consequently, sensitive and specific assay methods are required to determine the levels of the impurity to collect the data requiNDMA-related impurities potentially found in ranitidinered to complete relevant risk assessments or to support submission requirements. A recent example is or some angiotensin II receptor blocker (ARB) medicines that have been highlighted by the US FDA as a concern and are thought to be a result of the manufacturing process.

Our GMP compliant laboratories provide pharmaceutical impurity testing for new drug substances (ICH Q3A(R2)) and new drug products (ICH Q3B(R2)) which can support your product development from an early stage and across the lifecycle of your drug product.

With scientists who are adept at method development and validation of suitable analytical procedures, we can overcome the challenges of low detection levels and difficult matrices. As part of our comprehensive stability study capability, we examine degradation products under stressed conditions to help establish degradation pathways. Additionally, we offer highly sensitive and specific method development and validation expertise which is required to address the issues of genotoxic impurities.

With many years of experience in toxicological risk assessments, our consultants conduct risk assessments to address the issues associated with exposure toresidual solvents, process impurities, extractables & leachables, elemental impurities (ICH Q3D)and other substances that may find their way into a pharmaceutical product.

Pharmaceutical impurity testing is one aspect of our global GMP and CMC laboratory services solutions which

include pharmaceutical analysis, stability testing,quality control (QC)and batch release testing. Bringing quality and safety to life, we offer Total Quality Assurance expertise to help you to meet and exceed quality, safety and regulatory standards

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