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Perspective

Preformulation Studies of Pharmaceuticals and Pharmaceutical Formulations

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DESCRIPTION

During the development phase, drug ingredients and drug formulations are exposed to stress testing under a variety of stress conditions such as temperature, humidity, acidity, basicity, oxidation, light, and so on. The same allows for the development of proven analytical methods and gives extrapolative data for future formulation and packaging research. Practical approaches to structural elucidation of degradation products using modern Liquid Chromatography Mass Spectrometry (LC-MS) techniques and information collected from them, such as retention duration, molecular weight, and fragmentation pattern, have become critical in these investigations. The technique for identifying degradation products during early development necessitates the use of quick and sensitive LC-MS analytical tools. Clinical Trial Materials (CTMs) undergo stability assessments to monitor their Critical Quality Attributes (CQAs) and help identify which formulation will result in a successful candidate for regulatory submission.

The team is in charge of activities referred to in regulatory papers as "Chemistry, Manufacturing, and Control" (CMC), hence it is also known as the CMC team. As a result, a structural database may be created from the results, which can be used to distinguish unstable structures within the drug structure as well as for the quick identification of degradation products generated during these investigations. These procedures are also used later in the analysis of long-term and accelerated stability samples to obtain useful and relevant information. Determining product shelf life is a regulatory requirement for medications and many other regulated consumer products. The shelf life of medications is determined by tight rules; thus, effective application of stability science is crucial. The shelf life of pharmaceutical items is displayed on their labels to assure the product's integrity, purity, and efficacy when used within specified time period. Shelf life is determined using data generated to verify the label claim and approved by regulatory organisations. Regional regulations need an expiration date to assure the safety, efficacy, and quality of drug products, and that these criteria are maintained throughout the pharmaceutical product's labelled shelf life.

Process chemistry, synthetic organic chemistry, formulation or pharmaceutics, analytical chemistry analytical development and Quality Control [QC], Pharmacokinetics and Drug Metabolism (PKDM), outsourcing, regulatory affairs, supply chain, and project management are typical members of the CMC team. The development phase determines the level of participation. For example, the analytical development chemist is increasingly involved in the discovery and early stages of development to assist Drug Substances (DS) and Drug Products (DP) processes. In contrast, quality control chemists and regulatory staff are increasingly active in the final clinical phases of CTM manufacture and regulatory filings.

The activities undertaken by the analytical development and QC scientists within the CMC team are the topic of this series of white papers on stability testing. The analytical chemist assigned to the CMC team's initial responsibility is to create a viable stability-indicating method for assessing the quality of CTMs. This is a "composite" analytical approach that determines both the potency of the API and the chemical impurities of the DS. Ideally, it can also be used to evaluate DP samples. Once a feasible analytical process has been created, forced degradation tests are carried out to evaluate the analytical procedure's specificity. This procedure is employed in early clinical batch release testing as well as sample testing from initial stability. A gradient reversed-phase High-Performance Liquid Chromatography (HPLC) method with Ultra Violet (UV) detection that can separate the API and all known impurities and degradation products is often used for the stability-indicating assay and contaminants method.

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