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Stability Testing and its Role in Drug Development Process

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Commentary

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DESCRIPTION

Stability is a critical quality attribute of pharmaceutical products; therefore, Stability testing is used to determine how the quality of a drug substance or drug product changes over time as a result of various environmental factors such as temperature, humidity, and light, as well as to determine a retest period for the drug substance or a shelf-life for the drug product and recommended storage. As a result, it covers all stages of the drug development process. A testing program for stability samples requires a tremendous amount of resources and expertise. The drug development process is a time-consuming process. The drug development process generally consists of three periods namely discovery/toxicology, clinical development, and commercialization.

During the drug development process stability testing plays a significant role. Clinical trials are used to determine the safety and efficacy of drug products during development. If the drug product stability profile varies beyond predefined acceptable levels, defined safety and effectiveness are no longer applicable, and the drug product's safety and efficacy may need to be restored. This necessitates the conduct of additional stability tests. Changes in a drug product's life cycle are unavoidable, and these changes may have an impact on the drug's stability. As a result, additional studies and data will be required to support these changes. Stability explains several factors that affect the expiration dating of drug products, including the chemical and physical stability during the pre-clinical formulation stages, process development, packaging development, and post-marketing life.

For understanding the physical and chemical properties of the drug material, it is required to assess the product's physico-chemical stability. The purity, efficacy, and safety of a drug product may be degraded by a lack of drug

substance or drug product stability. Pharmaceutical stability can be used in a variety of ways; therefore the effectiveness of a drug will be determined by whether it is evaluating a drug substance, a formulation, a drug product, or a packed product. The safety and efficacy of a drug product are established during the development process *via* pre-clinical animal and human clinical studies. Identity, concentration, and purity are specified as quality attributes, and testing is developed. Because the dosage delivered to the patient may be lower than intended due to changes in medication stability, patient safety may be impacted. Instability can also lead to hazardous degradants forming. If a drug's instability causes these undesirable side effects in patients, it might cost makers a lot of money as they try to figure out what's causing the instability and how to fix it. An unstable product would reveal an uncontrolled process, necessitating a thorough investigation of the product and process, as well as possible product recalls. As a result of stability testing, suggested storage settings, retest intervals, and, eventually, product shelf-life and expiry dates can be determined.

The environment for drug substance manufacturing and storage, packaging options, and the final drug product's permissible shelf life will be determined by stability factors. When planning the production, storage, and final packaging of a drug product, environmental elements such as temperature, humidity, pH, light, and oxygen exposure must be taken into account and regulated. There are different types of stability studies during the drug development process; each phase of drug development requires addressing the time period that the drug product continues to maintain its specifications. This period is known as a drug's expiration dating period. Purpose of stability, testing of the final packaged drug product is to assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use.