Stability Testing of Drug Eluting Stents

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Abstract

Stability testing of drug eluting stents (DES) is performed to provide evidence on how the quality of the product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light, and to support the establishment of product shelf life or expiration dating period and recommended storage conditions. Stability studies are critical for ensuring the maintenance of product quality, safety and efficacy throughout the shelf life, and together with testing performed to demonstrate that the functionality of the stent and delivery system (i.e., mechanical performance), coating integrity and package integrity have not degraded over the requested shelf life are considered as pre-requisite for the acceptance and approval of any DES product. FDA draft guidance recommends that the stability studies of DES be conducted in a planned way following the guidelines issued for stability testing by ICH, WHO and/or other agencies. However, these regulatory guidelines are mainly designed to address stability studies that need to be conducted to determine the shelf life of pharmaceutical products. There is currently no clearly established regulatory basis or information in the scientific literature on how to conduct the stability testing of DES. This presentation attempts to discuss key points to consider when designing the stability studies to be performed during the DES lifecycle, as well as some other important aspects related to the stability testing of DES.

Key Words: Drug eluting stent, combination products, shelf life, stability, stability testing, stability studies, guidelines.