Test Method Selection and Specification Setting in Stability Testing for Combination Medical Device Products

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Abstract

Stability testing for combination medical devices is relatively new in comparison to traditional pharmaceutical dosage products and has recently gained more attention for manufacturers and regulators. Test methods and specifications are integral parts of stability testing for combination products and play important roles in the success of a stability program. Combination medical devices have special considerations due to the complexity of the device design and integration of drug components. Additionally, with new regulations and less experience in industry this results in challenges for the developers of combination medical devices. This paper provides details and descriptions about how to select test methods and setting specification in stability testing for combination medical device products and also provides general practice guidelines about how to implement the changes of test methods and specification in the course of stability testing.

1. Introduction

Combination products are comprised of two or more regulated components such as drugs, devices, or biologicals that are physically, chemically, or otherwise combined or mixed and produced as a single entity to produce a therapeutic effect. They also may be comprised of two or more separate products packaged together in a single package or finally as products packaged separately that according to its labeling is for use only with another individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect (1,2). Single entity drug-device combination products are perhaps the most common and some examples include pre-filled insulin syringes, metered inhalers, catheters or contact lenses coated with antibiotics, transdermal patches, drug eluting stents, and steroid eluting pacemaker leads.

Tags:
Variation

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