



Dr. Kailas Thakker

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Title: Development of Topical Drugs Using Quality by Design Approach

Abstract : To develop a topical drug using QBD approach, one must consider the development strategy with end in mind. It is important to know the desired target product profile and quality parameters that need to be established. Tergus approach is to first determine the type of formulation to be developed. Generally, it is disease specific, often based on delivery kinetics and sometimes for some unmet needs. Type of dossier that needs to be filed the regulatory agency often determines the development strategy. Is it an NCE with full fledged NDA or a 505 (b)1, is it 505(b)2, or is it an ANDA? General development path is to first determine proof of concept with early skin biology and candidate molecule selection followed by early formulation development and concurrent analytical method development. Early prototypes are assessed for their suitability as a clinical candidate using analytical stability testing, skin permeation and in vitro testing. Other studies to aid in additional proof of concept and understanding physico-chemical character of the dosage form would be performed also. As a result of these, formulation optimization to develop a more suitable candidate takes place and one or two prototypes are developed. Formulation optimization includes developing a manufacturing process and any parameters affecting scaling up the product. Analytical development includes finalization of analytical method, validation and characterization of impurities and degradation products, assessment of stability of product and characterization of product with key necessary physical tests, assessment of release characteristics with in vitro release testing and confirmation of skin/tissue permeation profile. Assessment of appropriate container closure is also carried out.

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Professional Biography

Kailas Thakker graduated from Institute of Chemical Technology in Mumbai with a degree in Pharmacy and then went on to earn Masters in Pharmaceutical Sciences from Columbia University in New York and Doctor of Philosophy in Pharmaceutical Sciences from University of Kansas. She worked at United States Pharmacopeia for 12 years and then went on to head Analytical Department at small, virtual, venture backed biotech company in RTP Area. In 1994, she founded Analytical Solutions with a vision to provide high quality analytical services to Pharmaceutical Industry. Working with regulatory, compendial and industry leaders, she worked towards developing and improving In Vitro Release Test (IVRT) for topical dosage forms emerging as a premier service provider for developing IVRT. In 2012, Analytical Solutions was rebranded to Tergus Pharma with a vision to expand the service base by partnering with Dr. Vijendra Nalamothu. Today Tergus Pharma is a world known service provider for topical product development. After retiring from active duty at Tergus Pharma in 2018, Kailas still continues to advise and assist in developing In Vitro Sciences at Tergus Pharma as Confounder Emeritus. Kailas's interests are in developing and standardizing in vitro sciences for topical as well as other novel dosage forms where same principles are applicable.