

Roadmap of stability studies for biosimilar product development

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The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity, and light, and to establish a re-test period for the drug substance or a shelf life for the drug product and recommended storage conditions. For the biosimilar product development stability data is very important to show the biosimilarity as well as comparability study. In this presentation it will cover the following aspects:

Stability studies with respect to different stage of biosimilar product development

1. Critical product development stages in which stability is required and where the study will be done how many batches and how long all these aspects will be discussed

Regulatory expectations of stability studies at different stages

1. Prerequisites for initiation of stability studies
2. Points to consider in designing the exploratory stability study

Requirement of stability data in case of any change

1. Evaluation of need for a change
2. Changes and their implications on subsequent stages
3. Impact assessment on product quality & stability studies
4. Post approval requirements as per regulatory guidelines

Biography

Rashbehari Tunga joined Agila Biotech with over 13 years of experience in the field and industry primarily in the biosimilar product development. He holds a Ph.D. in Biotechnology from IIT, Kharagpur. He has post-doctoral experience in fermentation technology from the Osaka University, Japan. He also has extensive industry experience for biosimilar/biotherapeutic product development and has published extensively in peer reviewed journals including *PDA Journal of Pharmaceutical Science and Technology*, *Fermentation Technology*, *Bioprocess International* etc. He has four process patents to his credit. His skills sets include process development (fermentation & purification technology) including high cell density cultivation, scale-up, process characterization, QbD etc. He has the credit of developing 4 products (from clone to market) for Indian market and one product for regulated market.

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