

# 3<sup>rd</sup> International Conference and Exhibition on **Biowaivers, Biologics & Biosimilars**

October 27-29, 2014 Hyderabad International Convention Centre, Hyderabad, India

## Development of forced degradation studies of drugs & pharmaceutical products

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Forced degradation is a powerful tool used routinely in pharmaceutical development in order to develop stability-indicating methods which has lead to quality stability data and to understand the degradation pathways of the drug substances and drug products. Forced degradation studies ensure appropriate stability of final pharmaceutical products in early stages of pharmaceutical development. Forced degradation studies show the chemical behavior of the molecule which in turn helps in the development of formulation and package.

A forced degradation study is an essential step in the design of a regulatory compliant stability program for both drug substances and products, and formalized as a regulatory requirement in ICH Guideline. Forced degradation is a degradation of new drug substance and drug product at conditions more severe than accelerated conditions. It is required to demonstrate specificity of stability indicating methods and also provides an insight into degradation pathways and degradation products of the drug substance and helps in elucidation of the structure of the degradation products.