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Forced degradation studies and analytical method validation

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Stability of pharmaceuticals is very important in terms of patient safety. These drug molecules are monitored frequently for its potency, strength and purity. The analytical methods used for stability testing should be stability indicative. Other wise the degradants or any other kind of impurities arises can not be identified and controlled properly. Then, we need stability indicative methods for stability samples analysis. The stability indicative method can detect any impurity or the degradant is merged or mixed with the active ingredient or any other identified impurities. The stability indicative method can separate all the impurities from the active material so that of the strength will be exactly determined. This activity of assessing stability indicative nature of the method is called stress testing or forced degradation study. During the study, the analytical method will be optimized to be perfect. Once the methodology is confirmed as stabilility indicative, the method is verified for its fitness. The performance verification of analytical procedure is called analytical method validation.

Biography

Bujji Reddy Kanchi completed B.Sc. in Chemistry from Nagarjuna University, India at the age of 22 years. He is working with Hetero Group of Companies as a trainer and speaker on Quality and published presentations to public websites like www.askaboutvlidation.com and www.phdig.gropsite.com.

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