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FORCED DEGRADATION STUDY OF STATINS: A REVIEW

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Abstract

Forced degradation study is the degradation of new drug substances and drug products in more severe conditions than accelerated conditions. Forced degradation study were conducted to demonstrate the specificity of stability-indicating methods, providing insight into degradation pathways and drug degradation products, assisting in the elucidation of degradation product structures, identifying degradation products that could be spontaneously generated during storage and use of drugs and to facilitate improvement in manufacturing process and formulation corresponding with accelerated stability studies. Statins, a class of lipid-lowering medications, are the most widely prescribed drugs and an example of an unstable drug. Statins are susceptible to hydrolysis in the presence of high temperatures and humidity. Therefore, the review discusses various studies of forced degradation studies in six statins drug (atorvastatin, fluvastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin) to describe the drug's intrinsic stability thus it can assist the selection of formulations and packaging as well as proper storage conditions.

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Forced degradation study, Stress testing, Drugs stability, Statins

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