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A Review on HPLC Method Development and Validation in Forced Degradation Studies

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Abstract: In the pharmaceutical sector, High-Performance Liquid Chromatography (HPLC) has emerged as a vital analytical method for both qualitative and quantitative assessment of medicinal ingredients and products. Because they shed light on the intrinsic stability of molecules and their degradation processes, forced degradation investigations are crucial to the development of stabilityindicating methods. The methods used in HPLC method development and validation, as well as the importance of forced degradation studies in accordance with ICH principles, are the main topics of this paper. Crucial elements such mobile phase selection, column type, detection wavelength, system suitability, and robustness are highlighted, as are the difficulties and regulatory viewpoints associated with carrying out degradation studies..

Keywords: Forced degradation study, Method Development, Validation, HPLC



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1