Development And Validation Of HPLC Method-A Review

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Many different strategies of high performance liquid chromatographic method development are used today.This review describes a strategy for the systematic development of High performance liquid chromatographic (HPLC) methods. HPLC is an analytical tool which is able to detect, separate and quantify the drug, its various impurities and drug related degradants that can form on synthesis or storage. It involves the understanding of chemistry of drug substance and facilitates the development of analytical method. A number of chromatographic parameters were evaluated in order to optimize the method. An appropriate mobile phase,column, column temperature, wavelength and gradient must be found that affords suitable compatibility and stability of drug as well as degradants and impurities. Forced degradation or alternatively referred as stress testing and it demonstrates specificity when developing stability indicating methods, especially when little is known about potential degradation products. Force degradation studies are helpful in development and validation of stability-indicating methodology, determination of degradation pathways of drug substances and drug products, discernment of degradation products in formulations that are related to drug substances versus those that are related to non–drug substances (e.g. excipients).

Biography

Muhammad Jehangir has 15 years diversified experience of Quality Control, Quality Assurance, Registration Affairs, Product development and Pharmaceutical manufacturing, Process Planning, Method development, Method validation, Statistical Methodology, Process & Cleaning Validation, and Equipment Validation etc. Certificate Courses on cGMP, cGLP, Process Validation, CTD Documents, ISO 9001:2008, 13485-2003, 14001-2004 and 17025:2017 have strong scientific, analytical, statistical, managerial and training skills. Currently he is working as a Senior Manager Quality Control and validation for Novamed Pharmaceuticals. It is toll manufacturing oriented company, manufacturing of companies like Getz Pharma, ICI, SEARLE, Macter, Ray, and for Sanofi-Aventis. He is also looking after the Quality of Novamed Healthcare, the nutraceutical and cosmeceutical manufacturing plant.

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