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Development and Validation of a Stability Indicating HPLC Method for Determination of Erlotinib Hydrochloride in Bulk

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Abstract : Determination of Erlotinib hydrochloride in the presence of its degradation products was studied and validated by a RP-HPLC method. The RP-HPLC method was developed for the chromatographic separation of Erlotinib and its impurities by using Hibar C_{18} (250x4.6 mm, 5 µm) column with a mobile phase combination of 10 mM ammonium formate with pH-4.0 and acetonitrile in isocratic elusion with an injection volume of 20 µl and flow rate was 1.0 ml/min and detection was carried a wavelength of 290 nm. Further, stress studies for acidic, basic, neutral, oxidative, and thermal degradations studies were carried out as per ICH guidelines An MS/MS study has been performed on the degradation products to predict the degradation of Erlotinib. The method provided linear responses over the concentration range of 100–1500 ng/ml and regression analysis showed a correlation coefficient value (r^2) of 0.995. The LOD and LOQ were found to be 1 ng/ml and 3 ng/ml, respectively. The developed LC method was validated as per ICH guidelines with respect to accuracy, selectivity, precision, linearity, and robustness.

Key words : Erlotinib, Degradation, RP-HPLC, ICH.

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