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Research article

Analytical method development and validation of Erlotinib hydrochloride in bulk and pharmaceutical dosage form by RP-HPLC

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Abstract

A simple, precise and accurate method for the estimation of Erlotinib in bulk and pharmaceutical dosage forms by reverse phase high performance liquid chromatography method was developed. A reverse phase Grace C18 column (250 cm · 4.6 mm · 5 µm) with mobile phase consisting of potassium dihydrogen orthophosphate, acetonitrile and methanol (50:30:20 V/V) having pH 4.0 which was adjusted by using orthophosphoric acid. The flow rate was 1 mL min^{-1} and the effluents were monitored at 247 nm. The retention time was found to be 5.83 min. The drug shows good linearity within the range of 10–60 µg mL^{-1}. The inter-day and intra-day variation was found to be less the 2%. The mean recovery of drug from solution was 101.10%. The results of analysis have been validated according to ICH guideline requirements. The method can be applied for the estimation of Erlotinib in pharmaceutical dosage form.