Development and Validation of Stability Indicating HPLC Method for Gefitinib and Its Related Compounds and Characterisation of Degradation Impurities

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1. Abstract

A validated stability indicating RP-HPLC was developed for the estimation of Gefitinib related compounds as well as degradants on Inertsil C_8 (250 × 4.6 mm, 5 µ) column using 50mM aqueous ammonium acetate: acetonitrile as the mobile phase in a gradient mode of elution at a flow rate of 1.0 mL/min at 50°C. The column effluents were monitored by a photo diode array detector set at 300 nm. The method was validated in terms of accuracy, precision and linearity as per the ICH guidelines. The limits of quantification of Gefitinib and impurities were obtained in the range of 0.015–0.05%. The forced degradation of Gefitinib was carried out under acidic, basic, thermal, reduction and oxidation conditions. The degradation products were characterized by MS-MS and ^{1}H NMR spectroscopy. The method was successfully applied to quantify the related substances and degradation products of Gefitinib in bulk drugs. The recoveries of Gefitinib and impurities were well within the range.

2. Keywords: Anti-cancer; Gefitinib; Forced degradation; Related compounds