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Development and validation of a hydrophilic interaction liquid chromatography method for the quantitation of impurities in fixed-dose combination tablets containing rosuvastatin and metformin

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Abstract

A hydrophilic interaction liquid chromatography method with diode array detection (HILIC-DAD) was developed and validated for the simultaneous determination of impurities in extended-release fixed-dose combination tablets containing rosuvastatin and metformin in a ratio 1:100. The analytes were separated by hydrophilic interaction liquid chromatography using an XBridge®-HILIC analytical column under isocratic elution. The mobile phase was composed of ammonium formate at 150 mM containing 0.05% diethylamine (pH 8.5)/acetonitrile, 4/96 (v/v) and pumped at a flow rate of 0.5 mL min^{-1}. Method validation was performed according to ICH guidelines. The calibration curves for rosuvastatin, metformin and their seven impurities showed good linearity ($r > 0.994$) within the calibration ranges tested. The intra- and inter-day R.S.D. values were less than 4.5 %, while the relative percentage error Er was less than 2.7 % for all compounds. Accelerated stability studies performed under various stress conditions including hydrolysis, oxidation and heat