Single RP-HPLC Method for Simultaneous Estimation of Pioglitazone, Glibenclamide and Glibenclamide Impurities from a Combination Drug Product

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SUMMARY. A simple reversed phase HPLC method was developed for simultaneous estimation of pioglitazone, glibenclamide, and glibenclamide impurities A and B from a combination drug product. The drugs and impurities are well separated using a reverse phase liquid chromatography with C-8 column. The isocratic mobile phase comprising phosphate buffer (pH 5.0): acetonitrile in the ratio of 75:25 (v/v) at 1.0 mL/min flow rate, UV detection at 250 nm, column temperature was maintained at 30 °C and the injection volume was used 150 μL. The proposed method was validated according to the ICH guidelines and proved suitable for routine analysis and quality control testing of these drugs in pharmaceutical preparations.