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Development and Validation of New Analytical Rp-hplc Method for the Estimation of Antidiabetic Drug Ertugliflozin and Metformin Hcl in Combined Pharmaceutical Dosage Form.

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Abstract

A simple, rapid, accurate, precise and robust reverse phase high performance liquid chromatography (RP-HPLC) method was developed for the estimation of Ertugliflozin and Metformin HCl in combined pharmaceutical dosage form. Reverse phase Kromasil C18 column (250 cm × 4.6 mm, 5µm) at 25°C with mobile phase consisting of 0.1 % v/v Phosphoric acid buffer: acetonitrile (60:40 % v/v) was used. The flow rate was 1.0 mL/min and the effluents were monitored at 235 nm and run time 20 min. The retention time was found to be 1.82 min for Metformin HCl and 3.81 min for Ertugliflozin. The response was linear over the concentration range of 350 - 600 µg mL-1 Metformin HCl and 3.75 - 11.66 µg mL-1 Ertugliflozin. The validation of HPLC method was carried out in accordance with the ICH guidelines. This is newly approved Antidiabetic drug combination consisting of the Ertugliflozin and Metformin HCl in tablet dosage form and this method is suitable for further application in routine Quality Control testing and in addition, the main features of the developed method is low run time.

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