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Research article

Method development and validation of Prucalopride succinate in bulk and tablet dosage form by RP-HPLC method

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Abstract

A new selective and sensitive High-performance Liquid Chromatography (HPLC) method was developed for the Quantification of Prucalopride succinate in bulk and tablet dosage form. Estimation was achieved by C_{18} column (KROMASIL 150) using Potassium dihydrogen orthophosphate and Methanol in the ratio (60:40% v/v) at ambient temperature, flow rate was 1 ml/min, injection volume 20 µl. The run time for Prucalopride succinate was 3.24 minutes and monitored at 225 nm.

The method was validated to fulfill the International Conference on Harmonization (ICH) requirements and this validation included specificity, linearity, limit of detection (LOD), limit of quantification (LOQ), accuracy, precision and robustness. The linearity of the proposed method was at the range of 50-150 µg/ml of Prucalopride succinate with a Correlation coefficient of 0.999 the precision (relative standard deviation – RSD) of six samples was 0.3068. The accuracy (recovery) was 100.90%, 100.05% and 100.80%.

All results were acceptable and this confirmed that the method is suitable for its intended use in routine Quality control and assay of drugs.