Development and Validation of Analytical Method For Simultaneous Estimation of Metformin Hydrochloride And Saxagliptin In Bulk And Its Formulation

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ABSTRACT

A novel, simple, accurate, sensitive, reproducible, economical HPLC method was developed and validated for the determination of Saxagliptin and Metformin Hydrochloride in combined dosage form. The method obeys Beer's Law in concentration ranges of 50-150 ppm for Metformin Hydrochloride and 10-30 ppm Saxagliptin. The method was validated for linearity, accuracy and precision as per ICH guidelines. The Chromatographic conditions were Wavelength 228 nm, Temperature 25^0C, Flow Rate 1 ml/min, Phenomenex C_{18} Column, Mobile Phase –50mM Potassium Dihydrogen Phosphate: Methanol: Acetonitrile (pH 4). The LOD and LOQ value were found to be 0.2592 and 0.7845 ppm for Metformin Hydrochloride and 0.07932 and 0.24038 ppm for Saxaglipitn respectively. The developed and validated method was successfully used for the quantitative analysis of commercially available dosage form. Proposed methods were validated as per ICH guidelines for linearity, accuracy, precision, specificity and robustness for estimation of Metformin Hydrochloride and Saxagliptin in commercially available tablet dosage form and results were found to be

satisfactory. Thus the developed and validated RP-HPLC method can be used successfully for marketed formulations.

Key words: Metformin hydrochloride, Saxagliptin, RP-HPLC method