"Stability Indicating Method for Simultaneous Estimation of Linagliptin and Metformin hydrochloride in their Combine Dosage form"

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Abstract

The simple, specific, accurate, precise and reproducible methods have been developed and validated for the simultaneous estimation of both drugs in their combined dosage form.In RP-HPLC, analysis is carried out using Buffer(KH_2PO_4 50mM 4.5 pH): Methanol (55:45 %v/v) pH 4.5 adjusted by Orthophosphoric acid) mobile phase and BDS hypersil C_{18}, 250mm × 4.6mm, 5µ(particle size), Thermo scientific as stationary phase with detection wavelength of 232 nm.Linearity was obtained in the concentration range of 5-15µg/ml and50-150 µg/ml for Linagliptin and Metformin Hydrochloride respectively.The % recoveries of the both the drugs were found to be 99.81-100.21% and 99.74-100.15%respectively. LOD were found to be 0.18 µg/ml and 6.24µg/ml at 232 nm for Linagliptin and Metformin Hydrochloride respectively.Methods were statistically validated for accuracy, precision, specificity, LOQ, robustness and ruggedness according to ICH guidelines and can be used for analysis of combined dosage form.

Key Words: RP-HPLC, Force degradation study, Linagliptin and Metformin Hydrochloride