



Spectrophotometric and Chromatographic Estimation of Linagliptin in Bulk and Tablet Dosage Form

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Abstract: Objective: An accurate, precise, rapid & economical Zero order derivative spectrophotometric and RP-HPLC method have been developed for the estimation of Linagliptin as per International Conference on Harmonization (ICH) guideline in pharmaceutical dosage form using ultraviolet detector (UV).

Methods: The zero order derivative spectrophotometric method was used for the determination of LNG in the range of 1-11 µg/ml by measuring the absorbance at 227 nm. Besides, a reversed-phase liquid chromatographic (RP-LC) method is described for the simultaneous determination of LIN. Chromatographic separation was achieved on a Pronto SIL-C8 column (250 mm × 4.6 mm, 5 µm). Gradient elution was carried out using a mobile phase consisting of Phosphate Buffer (pH 3) and Acetonitrile (35:65 v/v) and the flow rate was set 1 ml/min at 227 nm, retention time for Linagliptin was found to be 2.41 min.

Results: The zero order derivative spectrophotometric method was found to be linear in the concentration range of 1-11 µg/ml, in the linearity study regression equation was found to be $y = 0.1213x - 0.0572$ and correlation coefficient was found to be 0.9982. Whereas, chromatographic method was found to be linear in the concentration range of 5-100 µg/ml, in the linearity study regression equation was found to be $y = 448404x + 10568$ and correlation coefficient was found to be 0.9998. This method was rugged and robust in different testing criteria, LOD and LOQ were found to be 2.6×10^{-07} and 7.9×10^{-07} respectively. Accuracy study was done in 3 different concentration levels i.e. 80%, 100%, 120% and % recovery of the method was found to be 103%, 101% and 104% respectively in 3 different levels and mean recovery was 103%-105%, so method was accurate.

Conclusion: Results of all validation parameters were within the limits as per ICH guidelines.

Keywords: UV, HPLC, Validation, Method Development, Linagliptin, Accuracy, Precision.