




# DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR SIMULTANEOUS DETERMINATION OF EMPAGLIFLOZIN AND LINAGLIPTIN IN BULK & ITS FORMULATION

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**ABSTRACT:**

A new simple, accurate, precise, reproducible Reverse Phase-High Performance Liquid Chromatography method was developed for the simultaneous estimation of Empagliflozin and Linagliptin in bulk as well as in pharmaceutical dosage form by using Youglin C18 column (250 mm x 4.6 mm) 5 µm particle sizes. The mobile phase consists of Methanol: Water (80:20). The detection was carried out at 233 nm at a flow rate of 1.00 ml/min. The retention time of Empagliflozin and Linagliptin were found to be 2.773 min and 5.583 min respectively. Linearity was $R^2$ = 0.906 for Empagliflozin and $R^2$ = 0.909 for Linagliptin and the percentage recoveries of Empagliflozin and Linagliptin were found to be 98.54 to 101.58 % and 101.51 to 101.58 % respectively. The drug content formulations were quantified by using the proposed analytical method. The proposed method can be successfully applied in the quality control of bulk and pharmaceutical dosage forms. The validation of method was carried out utilizing International Conference on Harmonization (ICH) guidelines. The developed method is also found to be precise, accurate, specific, robust and rapid for the simultaneous determination of Empagliflozin and Linagliptin in tablet dosage forms.

**KEYWORDS:** Empagliflozin, Linagliptin, Acetonitrile, Methanol.

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