



RP-HPLC METHOD DEVELOPMENT AND VALIDATION OF TENELIGLIPTIN AND METFORMIN IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT:

RP-HPLC method was studied to develop and validate a simple, rapid and reproducible gradient high performance reverse phase liquid chromatography method for the estimation of Teneligliptin and Metformin in bulk drug sample and pharmaceutical dosage forms using Cosmosil (C18, 250X4.6mm, 5 μ m) column with mobile phase composition of methanol and water (pH 3.5) 50:50 v/v. Flow rate of 0.7ml/min and UV detection at 242nm was maintain during the entire study. Teneligliptin (TEN) is a novel drug, used for the treatment of type 2 diabetes mellites. The retention time for Metformin and Teneligliptin was found to be 2.45 min and 6.21 min respectively. Linearity was observed over concentration range of 2-10 μ g/ml and 50-250 μ g/ml for Teneligliptin and Metformin respectively. The accuracy of the proposed method was determined by recovery studies and found to be 98-101%. The proposed method was validated and results conformed to ICH parameters.

KEYWORD: RP- HPLC Methods, Validation, Teneligliptin, Metfomin.

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