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Development and Validation of a Bioanalytical Method for determination of Teneligliptin in Human Plasma by RP-HPLC

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Abstract: A simple, reliable, precise, accurate, sensitive and selective RP-HPLC method was developed and validated for estimation of Teneligliptin in Human plasma using protein precipitation extraction method. Teneligliptin is an antidiabetic drug from the class called Dipeptidyl peptidase-4 (DPP-4) inhibitor. The chromatographic separation was carry out using AGILENT C18 column (250mm x 4.6ID) as stationary phase and mobile phase of Methanol and 0.05% orthophosphoric acid solution in ratio of 70:30 v/v with pH of 2.7 at flow rate of 0.7 ml/min. Detection was carry out at 245nm using DAD detector. The injection volume was 20µl. The run time was 8min. The retention time of Teneligliptin was shorter i.e. 3.5 min. The overall recovery of teneligliptin was 97.83%. The calibration curve was linear over the concentration range of 5-25 µg /ml. Accuracy ranges from 98.82% to103.28 % with the precision 1.41% to 3.06% in intra-day method. In inter-day method the accuracy ranges from 99.80% to 103.33% with the precision 2.12% to 5.29%. The Lower limit of quantification (LLOQ) and the Limit of Detection (LOD) for Teneligliptin were found to be 2.09µg/ml and 0.69µg/ml respectively. The method developed can be used in therapeutic drug monitoring units, bioequivalence and bioavailability studies, pharmacokinetic and toxicology studies of Teneligliptin.

Keywords : Teneligliptin, Bioanalytical method, Bioanalytical validation, RP-HPLC, Human Plasma.

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