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RP-HPLC METHOD DEVELOPMENT AND VALIDATION FOR THE SIMULTANEOUS ESTIMATION OF TENELIGLIPTINE HYDROBROMIDE HYDRATE (TEN) AND METFORMIN HYDROCHLORIDE (MET) IN TABLET DOSAGE FORM

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Abstract:

A simple, accurate, precise, reproducible and economic method developed and validated for the simultaneous estimation of teneligliptine hydrobromide hydrate (TENE) and metformin hydrochloride (MET HCl) in pharmaceutical dosage form. TENE and MET HCl were estimated on Thermoscientific C18 column using mobile phase 0.01M PDP: methanol (45:55 % v/v) (pH 3.5 adjusted with 5% acetic acid) at flow rate 1.0 mL/min. Detection was carried out at 254 nm. The retention time of teneligliptine hydrobromide hydrate and metformin hydrochloride were 7.77 min and 2.64 min, respectively. The linearity was found to be 4-12 µg/mL and 100-300 µg/mL for TENE and MET HCl respectively. R2 value was found to be 0.998 and 0.995. For the assay method % recovery was found in the range of 98.16 – 101 for TENE and MET HCl. The LOD and LOQ were found to be 0.3527 and 1.0690 for TENE and 0.5077 and 1.538 for MET HCl respectively. Method was validated as per ICH guidelines.

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