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A Validated Stability indicating High Performance Thin Layer Chromatographic Method for Determination of Remogliflozin Etabonate in Tablet Dosage Form

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Abstract : The present work describes development and validation of a new simple, accurate and precise stability-indicating high performance thin layer chromatographic (HPTLC) method for determination of Remogliflozin etabonate as bulk drug andin tablet dosage form.As stability testing is major step in the development of new drug as well as formulation, stress degradation studies were carried out according to ICH guidelines. Remogliflozin etabonate was found susceptible to all the analyzed stress conditions. HPTLC plates precoated with silica gel 60 F_{254} were used as the stationary phase and chromatographic separation was achieved by using Toluene: Methanol (8.5:1.5,v/v) as mobile phase. Densitometric detection was carried out at 224 nm. The retention factor was found to be 0.35 ± 0.03. The developed method was validated with respect to linearity, accuracy, precision, limit of detection, limit of quantitation and robustness as per ICH guidelines. The developed method was found to be linear in the concentration range of 50-250 ng band^{-1}. The LOD and LOQ for Remogliflozin etabonate was found to be 13.04 ng band^{-1}and 35.04 ng band^{-1}, respectively. The developed method has been effectively applied for the drug estimation in tablet dosage form.

Keywords : Remogliflozin etabonate, Stability indicating method, HPTLC, Forced degradation studies.

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