

Quantitative analysis and dissolution of mebeverine and its related substances in dosage forms by HPLC

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Background and Aims: A simple and rapid, High performance liquid chromatography procedure for determination of mebeverine and its related substances (veratric acid) in dosage forms (tablet and liquid) is described.

Methods: Reversed phase chromatography was carried out using a mobile phase containing 0.07 M Disodium hydrogen phosphate buffer and acetonitril(65:45% v/v),pH 5.7 with UV detection 263 nm and chromatographic separation was accomplished using XOB- C18 ,Eclipse ,150 mm with 5 μ m packing. Column equilibrium with the fluent was established by pumping the mobile phase at a rate of 0.4 ml/min for overnight. The flow rate was set at 0.5 ml/min during analysis. The chromatogram was recorded and integrated at a speed of 0.25 cm/min. All analysis was done at room temperature. Also dissolution method was set up with H₂O+SLS 1% as media and 100 RPM.

Results: Replicate regression analyses of three standard plots in the concentration range of 0.2-10 mcg /ml obtained on three different days gave a correlation coefficient >0.9997 and the coefficient of variation of the slopes <2.5%.the recoveries from 10 replicate tablets of commercial mebeverine brand and liquid were in order 98.9 and 100.4 of the label amount and their coefficient of variations were 0.88 and 0.72%, respectively.

Conclusions: The investigated HPLC and dissolution procedure indicated excellent resolution and peak symmetry of mebeverin and its related substances. The applicability of the method for routine drug analysis revealed that the proposed proposed procedure is simple, time consuming and precise enough for the determination of mebeverine in dosage forms.

Keywords: Column liquid chromatography; Dissolution; Related substances; Mebeverin; Pharmaceutical forms