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Validated stability indicating HPLC method for the determination of mebeverine in the presence of its degradation products: Kinetics study of its degradation in oxidative condition

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Background and Aims: An HPLC method for determination of mebeverine hydrochloride in the presence of its degradation products was developed.
Methods: The degradation of mebeverine hydrochloride was studied under hydrolysis, oxidative and photolysis stress conditions. Under alkaline, acidic and oxidative conditions, degradation of mebeverine hydrochloride was observed. The separation was performed using a Symmetry C18 column and a mixture of 50 mM KH2PO4, acetonitrile and THF (63:35:2; v/v/v) as mobile phase. No interference peaks from degradation products in acidic, alkaline and oxidative conditions was observed. The linearity, accuracy and precision of the method were studied.
Results: The method was linear over the range of 1-100 µg/ml mebeverine hydrochloride (r2>0.999) and the CV values for within-day and between-day variations were in the range of 1.0-1.8%. Determination of mebeverine hydrochloride in pharmaceutical dosage forms was performed using the developed method. Also the kinetics of degradation of mebeverine hydrochloride in the presence of hydrogen peroxide was investigated.
Conclusions: The proposed method could be a suitable method for routine quality control studies of mebeverine dosage forms.

Keywords: Mebeverine; HPLC; Stability indicating; Stress degradation