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RP-HPLC Method for Estimation and Stability Study of Drotaverine HCl as per ICH Guidelines

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***SUMMARY*. A validated stability indicating assay method was developed for the estimation of drotaverine HCl in the presence of its degradation products. The best separation of analyte was achieved in the C8 analytical column at ambient temperature using a mobile phase composition of methanol and ammonium acetate (75:25) in isocratic mode. The flow rate and the detection wavelength were set at 0.9 ml/min and 308 nm, respectively. The drug gives peak at R_T 7.483 min and the forced degradation studies gave three degradation products peaks in which two degradation products (R_T 4.202 and 5.010 min) were obtained from alkaline hydrolysis and the third product from neutral hydrolysis of the drug and was eluted at R_T 5.842 min. The limit of detection (LOD) and limit of quantitation (LOQ) of the developed method was found to be 0.4 μg /ml and 1.4 μg/ml respectively. The validation results obtained from the analysis reveals that the developed method is simple, accurate, precise, specific and selective.**

KEY WORDS: Drotaverine. HCl, ICH, Smooth-muscle relaxant, Stability indicating assay.

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