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Degradation kinetics and stability indicating RP-HPLC method for the estimation of flavoxate hydrochloride in bulk and pharmaceutical dosage forms

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A simple, rapid, economic stability indicating reversed-phase HPLC method was developed, validated and subsequently degradation kinetics in acidic, alkaline, oxidative, thermal, photolytic media are assessed for Flavoxate Hydrochloride (FVH) present in pharmaceutical dosage forms. The proposed RP-HPLC method utilizes a LiChroCART-Lichrosphere100, C18 RP column Hibar (250 x 4 mm, 5µm) in an isocratic separation mode with mobile phase consisting of methanol and water in the proportion of 50:50 % (v/v), at a flow rate of 0.8 ml/min and the effluent was monitored at 315 nm. The retention time of FVH was found to be 2.92 min. Stability of FVH was investigated as per ICH-prescribed stress conditions. Significant degradation of FVH was observed under all studied stress conditions. A kinetic study was conducted to investigate the degradation kinetics of FVH at different temperatures; reaction rate constants, half-life times and activation energy were calculated in all the media. The described method was linear over a range of 1-300µg/ml. The percentage recovery was 99.46. F-test and t-test at 95% confidence level were used to check the intermediate precision data obtained under different experimental setups; the calculated value was found to less than the critical value. The proposed method can thus be used for routine analysis, quality control and for studies of the stability of pharmaceutical tablets containing these drugs.

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