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Stability-indicating high performance thin layer chromatography determination of Paroxetine hydrochloride in bulk drug and pharmaceutical formulations

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Abstract

A simple selective precise and stability-indicating high performance thin layer chromatographic method of analysis of Paroxetine hydroc both as a bulk drug and in formulations was developed and validated. The method employed TLC (Thin Layer Chromatography) alu precoated with silica gel 60F-254 as the stationary phase. The solvent system consisted of butanol:acetic acid:water (8:2:0.5, v/v/v). This was found to give compact spots for Paroxetine HCl (Rf, retardation factor, value–0.48 ± 0.02). Paroxteine HCl was subjected to ac alkali hydrolysis, oxidation and photodegradation, where the degraded product was well separated from the pure drug. Densitometric anal Paroxetine hydrochloride was carried out in the absorbance mode at 295 nm. The linear regression analysis data for the calibration spots s good relationship with (regression) $r^2 = 0.9903$ in the amount range of 300–1500 ng (nanogram) per spot. The mean value of co-relati efficient, slope and intercept were 0.9903 ± 0.001, 5.38 ± 0.058 and 182.5 ± 2.16 respectively. The method was validated for precision, re and robustness. The limits of detection and quantitation were 50 and 150 ng, respectively. The drug doesnot undergo degradation with oxidati gets affected in acidic and alkaline conditions. The acid and alkali degradation showed extra peaks at 0.4 and 0.08 Rf, respectively. This in that the drug is susceptible to acidic and alkaline medium. As the method could effectively separate the drug from its degradation products be employed as a stability-indicating one.

Keywords: Pharmaceutical formulations; Paroxetine hydrochloride; High performance thin layer chromatography (HPTLC); Densitometry