

Stability-Indicating High-Performance Thin-Layer Chromatography Method for Estimation of Naftopidil

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Abstract : A simple, selective, precise and Stability-indicating High-performance thin-layer chromatographic method for analysis of Naftopidil both in a bulk and in pharmaceutical formulation has been developed and validated. The method employed, HPTLC aluminium plates precoated with silica gel as the stationary phase. The solvent system consisted of hexane: ethyl acetate: glacial acetic acid (4:4:2 v/v). The system was found to give compact spot for Naftopidil (R_f value of 0.43 ± 0.02). Densitometric analysis of Naftopidil was carried out in the absorbance mode at 253 nm. The linear regression analysis data for the calibration plots showed good linear relationship with $r^2 = 0.999 \pm 0.0001$ with respect to peak area in the concentration range 200-1200 ng per spot. The method was validated for precision, recovery and robustness. The limits of detection and quantification were 20.35 and 61.68 ng per spot, respectively. Naftopidil was subjected to acid and alkali hydrolysis, oxidation and thermal degradation. The drug undergoes degradation under acidic, basic, oxidation and thermal conditions. This indicates that the drug is susceptible to acid, base, oxidation and thermal conditions. The degraded product was well resolved from the pure drug with significantly different R_f value. Statistical analysis proves that the method is repeatable, selective and accurate for the estimation of investigated drug. The proposed developed HPTLC method can be applied for identification and quantitative determination of Naftopidil in bulk drug and pharmaceutical formulation.

Keywords : naftopidil, HPTLC, validation, stability, degradation

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