J Pharma Care Health Sys 2017, 4:4 (Suppl)
DOI: 10.4172/2376-0419-C1-024

Stability indicating analytical method development and validation for Tolterodine tartrate in pharmaceutical dosage form

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A specific stability indicating high-performance thin-layer chromatographic method for analysis of Tolterodine tartrate both as a bulk drug and in formulations was developed and validated. The method employed HPTLC aluminum plates precoated with silica gel GF254 (aluminium sheet) as the stationary phase. The optimized mobile phase system consisted of Ethyl acetate:Methanol:TEA (5:5:0.2 v/v/v) which gave compact spots for Tolterodine tartrate at R_f of 0.65. Tolterodine tartrate was subjected to forced degradation studies in order to check the specificity of the method. Analysis of the drug was carried out at 280 nm. The calibration plots showed linear relationship in the concentration range of 800-1200 mg per band. Moreover, linearity was also confirmed by verification of homoscedasticity of variance. According to validation studies, the developed method was repeatable and specific as revealed by % RSD less than 2 and hence can be used for routine analysis of pharmaceutical formulation. The percentage recovery was found to be 99.23% to 101.00%. Stress studies were conducted on the drug substance and product under the ICH prescribed stress condition viz., hydrolysis, oxidation, photolysis and thermal stress. The drugs showed sufficient decomposition under acidic and alkaline hydrolysis and oxidation. The forced degradation study data represented that the degradation pattern for Tolterodine tartrate was in Sunlight>UV light>Acid>H_2O_2>Base. The developed stability indicating HPTLC method was found to be sensitive, precise, accurate, economical and reproducible for analysis of pharmaceutical formulation containing Tolterodine tartrate. Statistical analysis proves that this method can be successfully employed for quantitative analysis of Tolterodine tartrate in pharmaceutical dosage form.

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