Stability Indicating Methods for the Determination of Sildenafil Citrate in the Presence of its Degradation Product

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Abstract

Three stability-indicating methods were developed for the determination of Sildenafil Citrate (SLDC) in the presence of its degradation product. The First method depends on the quantitative densitometric evaluation of thin layer chromatogram of sildenafil citrate in the presence of its degradation product without any interference. Chloroform : methanol : ammonia (9: 1: 0.01 by volume) was used as a mobile phase and the chromatogram was scanned at 292 nm. This method determines SLDC in the concentration range 1.2-3.6 µg/spot with mean percentage recovery 99.80±0.928%. The second method is based on the high performance liquid chromatographic separation on Phenomenex10µ ODS (150 mm ×3.9 mm I.D), particle size (10µm), with a mobile phase consisting of acetonitrile: methanol: 0.05 M potassium dihydrogen phosphate (pH: 5.8) (50: 20: 30 v/v/v) followed by UV detection at 290nm. Calibration graph is linear in the concentration range 8-40µg/ml with mean percentage recovery of 100.23±1.188 %. The third method depends on application of bivariate calibration algorithm to the spectrophotometric determination of SLDC in the concentration range 10-60 µg/ml with mean percentage recovery 100.05±1.181%. The suggested procedures were checked using laboratory-prepared mixtures and were successfully applied for the analysis of pharmaceutical preparations. The methods retained their accuracy and precision when the standard addition technique was applied. The results obtained by applying the proposed methods were statistically analyzed and compared with those obtained by the reference method.

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