Development and Validation of Analytical Method for Simultaneous Estimation of Cefixime Trihydrate and Levofloxacin Hemihydrate in Bulk and tablet dosage form

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ABSTRACT

Present work describes a precise, accurate and reproducible absorption ratio, first order derivative spectroscopy and Reverse Phase High Performance Liquid Chromatographic (RP-HPLC) methods for simultaneous estimation of Levofloxacin Hemihydrate (LFX) and Cefixime Trihydrate (CEF) from their tablet dosage form. Method-I is the first order derivative spectroscopy for the simultaneous estimation of LFX and CEF. The absorbance of the standard solutions have been taken at two wavelengths 280.6 nm (ZCP of CEF) for LFX and 263.4 nm (ZCP of LFX) for CEF. Method-II involves formation of Q-absorbance equation at 255.20 nm (iso-absorptive point) and 291.6 nm (λ_{max} of LFX). Dilutions were prepared in 0.1N methanolic NaOH. Linearity was found to be 2-20 µg/mL and 2-12 µg/mL for CEF and LFX respectively. In the RP-HPLC method, the drugs were resolved in a tablet dosage form, using a 250 mm x 4.6 mm, 5 µm particle size, Enable C18H column using acetonitrile:water (20:80 v/v) mixture as a mobile phase of pH 2.8 adjusted with tri ethyl amine and ortho-phosphoric acid. The detection of the tablet mixture was carried out at 291 nm with a flow rate of 1.0 mL/min. The retention times were 7.167 and 8.970 minutes for

LFX and CEF respectively. Linearity was found to be 8-48 µg/mL and 10-60 µg/mL for CEF and LFX respectively. The relative standard deviation values for repeatability and intermediate precision studies were in the range of 0.3479 – 1.9138, and % recovery was in the range of 98.25 – 101.96 for both drugs. The developed method was found to be suitable for the routine estimation of LFX and CEF in tablet dosage form. The developed methods were validated as per ICH in terms of linearity, precision, accuracy, limit of detection and limit of quantification, and the results were found to be within acceptance limit.

Key Words: Absorbance ratio method, derivative spectroscopy method, RP-HPLC, Validation, Cefixime Trihydrate, Levofloxacin Hemihydrate.