DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULTANEOUS ESTIMATION OF LORNOXICAM AND EPERISONE AS API AND ITS FORMULATION

Submitted by

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ABSTRACT

Present work describes a precise, accurate and reproducible absorbance ratio, first order derivative spectroscopy and Reverse Phase High Performance Liquid Chromatographic (RP-HPLC) methods for simultaneous estimation of Lornoxicam and Eperisone. The absorbance ratio (Q-analysis) method was based on the measurement of absorbances at two wavelengths, one being the iso-absorptive point at 291.5 nm (λ_1) and other being λ_{max}, 254.5 nm (λ_2) of one of the sample components. The second method was based on the use of first order derivative spectroscopy, in which derivative amplitudes were measured at selected wavelengths 254 nm (ZCP of EPE) for LXM and 264.5 nm (ZCP of LXM) for EPE in 0.1N methanolic NaoH, without mutual interference. Linearity was found in the concentration range of 0.16 – 0.96µg mL and 2 - 12µg/mL, respectively for Lornoxicam and Eperisone in API mixture for both methods. In the RP-HPLC method, the drugs were resolved in a synthetic mixture, using Enable C18H column (250 mm x 4.6 mm, i.d. 5µm particle

size) with acetonitrile:water (70:30 v/v) mixture as a mobile phase of pH 2.8 adjusted with triethylamine and orthophosphoric acid. The detection of the synthetic mixture was carried out at 291 nm with a flow rate of 0.8 mL/min. The retention times were 3.345±0.00665 and 4.729 ± 0.01105 min for Eperisone and Lornoxicam, respectively. Linearity was found in the concentration range of 4 – 24µg/mL and 50 - 300µg/mL, respectively for Lornoxicam and Eperisone in API mixture. The correlation coefficient was 0.9987 and 0.9975 for Lornoxicam and Eperisone, respectively. The % RSD values for repeatability, intraday and interday precision studies were less than 2%, and % recovery was between 98 - 102% for both drugs. The proposed method was found to be suitable for the routine estimation of EPE and LXM in tablet dosage form. As per ICH guidelines the developed method were validated in terms of linearity, precision, accuracy, limit of detection and limit of quantification, and the results were found to be satisfactory.

Key Words: Absorbance Ratio Method, Derivative Spectroscopy Method, Eperisone, Lornoxicam, RP-HPLC, Validation.