Development and Validation of UV Spectrophotometric and RP-HPLC Methods for Estimation of Esomeprazole Magnesium Trihydrate and Naproxen in bulk & tablet dosage form

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ABSTRACT

Naproxen and Esomeprazole Magnesium Trihydrate are used in combination for treatment of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis. The present work deals with two simple, precise and economical spectrophotometric methods and one RP-HPLC method for simultaneous estimation of Naproxen and Esomeprazole Magnesium Trihydrate in combination. In spectrophotometric method Simultaneous equation method was used. 271 nm and 302 nm were used as analytical wavelengths. Correlation coefficient was obtained as 0.998 and 0.999 for Naproxen and Esomeprazole Magnesium Trihydrate, respectively. Second method was first order derivative method. 269nm (ZCP of Esomeprazole Magnesium Trihydrate and 317 nm (ZCP of Naproxen) as detection wavelength were used for the estimation of Naproxen and Esomeprazole Magnesium Trihydrate, respectively. Correlation coefficients obtained were 0.9985 and 0.999 for Naproxen and Esomeprazole

Magnesium Trihydrate, respectively. For both the spectrophotometric methods Beer's law was obeyed in the concentration range of 5-50µg/ml and 2-12µg/ml for Naproxen and Esomeprazole Magnesium Trihydrate, respectively. In RP-HPLC method efficient chromatographic separation was achieved on Phenomenex luna ODS C_{18} stationary phase (250mm X 4.6 mm i.d., 5 µm particle size) with simple mobile phase combination of methanol: water 65:35 (%V/V) in an isocratic mode at a flow rate of 1.2 ml/min at 302 nm. The retention time for Naproxen and Esomeprazole Magnesium Trihydrate was 3.78±0.06 min and 5.72±0.04 min, respectively. The calibration curve of Naproxen and Esomeprazole Magnesium Trihydrate was linear in the range of 5-30 µg/ml (r^2=0.9994) and 0.2-1.2 µg/ml (r^2=0.9991), respectively. Proposed methods were validated as per ICH guidelines for linearity, accuracy, precision and specificity for the estimation of Naproxen and Esomeprazole Magnesium Trihydrate in combination. All three methods were compared statistically using ANOVA test. The results were found to be satisfactory, shows the methods can be used successfully in marketed formulations.

Key words: Naproxen, Esomeprazole Magnesium Trihydrate, Simultaneous equation method, First order derivative method, RP-HPLC method, ANOVA