

Shrestha DM, Srinivasa Rao T, Sreedhar C, Akkamma HG, Bharadwaja Reddy G, Yadav PK. Development and validation of new analytical method for the simultaneous estimation of naproxen and esomeprazole in bulk and pharmaceutical formulation. *Bull. Pharm. Res.* 2016;6(1):28-35.

Abstract: A new, simple, rapid, sensitive and inexpensive RP-HPLC method has been developed for the simultaneous estimation of naproxen and esomeprazole in bulk drug and pharmaceutical formulations. The method was validated for linearity, precision, accuracy, LOD and LOQ according to ICH guidelines. Chromatographic separation was achieved on Waters XBridge C18 column (250 × 4.6 mm, 5 μ) using isocratic mobile phase 20 mM ammonium acetate (pH 3.8), acetonitrile and methanol (45:44:11 v/v) at 228 nm. The flow rate was 1 ml/min. The retention time was observed at 3.69 min for esomeprazole and 6.6 min for naproxen. The standard curve was linear over the range of 2-12 μ g/ml with the correlation coefficient of 0.9988 for esomeprazole and 0.995 for naproxen. The mean recoveries obtained for esomeprazole and naproxen were 100.06% and 99.8 to 100.01% respectively and RSD was less than 2%. Developed method was highly precise and convenient for routine analysis of naproxen and esomeprazole in bulk and tablet dosage forms.

Key words: Naproxen, Esomeprazole, RP-HPLC, Simultaneous estimation, ICH guidelines.

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