Bulletin of Pharmaceutical Research 2016;6(1):28-35
An Official Publication of Association of Pharmacy Professionals
ISSN: 2249-6041 (Print); ISSN: 2249-9245 (Online)

RESEARCH PAPER

DEVELOPMENT AND VALIDATION OF NEW ANALYTICAL METHOD FOR THE SIMULTANEOUS ESTIMATION OF NAPROXEN AND ESOMEPRAZOLE IN BULK AND PHARMACEUTICAL FORMULATION

Deepa Moye Shrestha*, T. Srinivasa Rao, C. Sreedhar, H.G. Akkamma, G. Bharadwaja Reddy and Purushotam Kumar Yadav

Dept. of Pharmaceutical Analysis, Karnataka College of Pharamacy, Bangalore-560064, Karnataka, India.

**E-mail*: moyedipa123@gmail.com
Tel.: +91 8553573851.

Received: Apr 15, 2016 / Revised: Apr 29, 2016 / Accepted: Apr 30, 2016

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 1ml/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.

INTRODUCTION

Naproxen [2-(6-methoxynaphthalen-2-yl) propanoic acid] (**Figure 1a**), is a widely used non-steroidal anti-inflammatory drug (NSAIDs) that belongs to aryl acetic acid group which is used in the treatment of rheumatoid arthritis, headache, muscle aches, dental pain, arthritis, bursitis, gout attacks and menstrual cramps. It has been used for a long time because of its efficacy and safety profile (Ahmed *et al* 2010; Manrique-Moreno *et al* 2010).

It works by inhibiting both the COX-1 and COX-2 enzymes (Vetrichelvan and Suresh, 2012). The constitutive cyclooxygenase, COX-1, synthesizes prostaglandins necessary for normal gastrointestinal (stomach mucus protection with regulation of gastric acid) and renal function (Dubois *et al* 1998). The inducible cyclo-oxygenase, COX-2, generates prostaglandins involved in signaling pain and inflammation (Turini and DuBois, 2002). So, inhibition of COX-1 is thought to be associated with gastrointestinal and renal toxicity while inhibition of COX-2 provides anti-inflammatory activity (Masferrer *et al* 1996). This drug is recognized to be highly effective and clinically safe, but some side-effects such as gastrointestinal toxicity, nephrotoxicity, jaundice and hepatotoxicity have been reported (Yokoyama *et al* 2006).

Esomeprazole (**Figure 1b**), the S-isomer of omeprazole (a racemic mixture), is the first proton pump inhibitor to be developed as a single optical isomer (Lind *et al* 2000).