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RESEARCH ARTICLE

RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ESOMEPRAZOLE MAGNESIUM AND DOMPERIDONE IN A TABLET DOSAGE FORM

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A simple, sensitive and validated isocratic reverse phase high performance liquid chromatographic (RP-HPLC) method has been developed for the simultaneous determination of esomeprazole and domperidone in tablet dosage form. The chromatographic separation was achieved on a hyperchrome C-18 (4.6×150 mm, 5*μ* particle size) analytical column using a mixture of acetonitrile: phosphate buffer (pH 5.0) in the ratio of 60:40 (*v/v*) used as the mobile phase, at a flow rate of 1.0 ml/min and detector wavelength at 290 nm. The validation of the proposed method was carried out for specificity, linearity, accuracy, precision, limit of detection, limit of quantitation and robustness. Linearity of method was found to be in concentration range 10-50 *μ*g/ml for esomeprazole and 5-25 *μ*g/ml for domperidone with correlation coefficient greater than 0.9999. The retention time of domperidone and esomeprazole was found to be 2.92 and 3.91 min respectively. The method is suitable for the estimation of both the components simultaneously in pharmaceutical tablet formulations.

Key words: Esomeprazole, Domperidone, RP-HPLC, Validation, Simultaneous estimation.

INTRODUCTION

Domperidone (DOM), which is chemically 5-chloro-1-[1-[3-(2-oxo-2,3-dihydro-1*H*-benzimidazol-1-yl)propyl]piperidin-4-yl]-1, 3-dihydro-2*H*-benzimidazol-2-one (**Figure 1**), is used as an anti-emetic and to suppress nausea and vomiting.

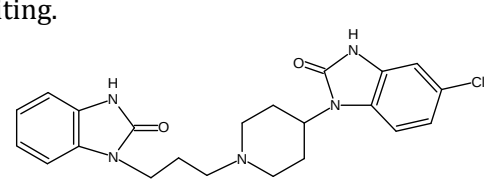

Fig. 1. Chemical structure of Domperidone

DOM is indicated for treating symptoms associated with upper gastrointestinal motility disorders caused by chronic and sub-acute gastritis. It is a gastrointestinal emptying (delayed) adjuvant, a peristaltic stimulant and exhibits anti-emetic properties. It can be used in patients with Parkinson's disease (Shindler *et al* 1984) and also found to be effective in the treatment of gastroparesis (Silvers *et al* 1998). It is official in BP which recommends non-aqueous titration with perchloric acid as titrant and naphthol benzein as indicator (British Pharmacopoeia, 2009). Several chromatographic methods have been reported for determination of Domperidone in pharmaceutical dosage form by differential pulse voltammetry (El-Shahawi *et al* 2007), planar chromatography (Gosavi *et al* 2006), high-performance liquid chromatography