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Stability Indicating HPLC-UV Method for Simultaneous Estimation of Pantoprazole, Domperidone and Drotaverine

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Abstract: A stability indicating method for the simultaneous estimation of Pantoprazole (PPZ), Domperidone (DPD), and Drotaverine (DRT) using HPLC has been developed and validated. These drugs were separated through SD's Millenium C18 column (100x4.6 mm i.d., 5-µm particle size) with a mobile phase containing methanol, acetonitrile and 0.02M dipotassium hydrogen phosphate (pH 7.0), in the ratio of 20:33:47 (v/v/v) at a flow rate of 1mL/min for PPZ, 2.5mL/min for DPD and 1mL/min for DRT. Further, PPZ and DRT were detected at a wavelength of 290nm, and DPD at 240nm, based on the peak area. Parameters such as linearity, precision, accuracy, recovery and specificity were studied as per ICH guidelines. The retention time of PPZ, DPD and DRT were 2.5, 6.01 and 11.8 min. respectively. The limit of detection (LOD) was determined to be 0.01721µg/ml, 0.0115µg/ml, and 0.0212µg/ml for PPZ, DPD, and DRT, respectively. Lower limit of quantitation (LLOQ) was determined to be 0.0573µg/ml, 0.0385µg/ml, and 0.0706µg/ml for PPZ, DPD, and DRT, respectively. The linear ranges were found as 0.25-16 µg/ml for PPZ& DRT (n=7) and 0.125-8 µg/ml for DPD (n=7).The correlation coefficient for all components was found to be 1. In order to check the selectivity of the method for pharmaceutical preparations, forced degradation studies were also carried out.
Keywords : RP-HPLC, Pantoprazole, Domperidone, Drotaverine, Stability Studies, Degradation products.

Introduction

Multi-factorial origin is associated with Peptic ulcer disease; worldwide population is affected by it and it is a major source of morbidity and mortality [1]. Although cause of peptic ulcer is a very controversial subject but evidences suggest that stressful physical or mental situation, poor lifestyle including overindulging in rich and fatty foods, alcohol abuse, and consumption of tobacco [2], overuse of painkillers such as aspirin, ibuprofen, and naproxen are the major causes of peptic ulcer. Burning, aching, gnawing pain, back pain, bloating or nausea after eating and vomiting are the common symptoms of peptic ulcer [3]. In clinical practice, a combination of proton pump inhibitor, prokinetic agent (antiemetic) and antispasmodic drugs are prescribed for treatment of acid-peptic disorders including erosive gastro esophageal reflux disease (GERD) and non-erosive reflux disease (NERD) [4-7].

Pantoprazole (PPZ) is a proton pump inhibitor (PPI) and is the first line treatment for acid-peptic disorders. It, selectively and irreversibly, inhibits the proton pump (H^+/K^+-ATPase) that performs the final step in the acid secretary process [8, 9]. Domperidone (DPD) is a prokinetic drug which acts by selectively antagonizing the peripheral dopaminergic D2 receptors in the gastrointestinal wall, thereby enhancing gastrointestinal peristalsis and motility and increasing lower esophageal sphincter tone. The increased Gastro