ISSN 2181-3187

USE OF DUSPATALIN (MEBEVERINE HYDROCHLORIDE) IN GASTROINTESTINAL DISEASES

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Abstract. Abdominal pain and spasms are common symptoms in organic gastrointestinal diseases, yet are associated with significant unmet need in terms of recognition and treatment. There was an examination of 20 patients who had cholecystectomy and have dysfunctional disorders of the Oddi's sphincter. All of the patients underwent the monotherapy with Mebeverine Retard in the dosage of 200 mg twice a day. The treatment efficiency was evaluated by the dynamics of clinical symptoms, results of the study of biochemical blood indices, data of the ultrasonic examination, and intragastric pH measurement. The aim of this review was to help physicians to understand the pathophysiology and impact to patients of abdominal pain and spasms in inflammatory bowel disease (IBD) and biliary diseases. This may in turn help in the selection of the most appropriate treatment to improve patients' overall daily functioning and quality of life in addition to reducing health resource utilization. Relative to the healthy colon, the mechanisms of pain generation in IBD include peripheral sensitization, including visceral hypersensitivity, central processing and modulation, and associated features or modifiers. Calcitonin gene related peptide, substance P, transient receptor potential vanilloid type, and serotonin biosynthesis in the colon are implicated in these processes.

Keywords: duspatalin, mebeverine hydrochloride, Oddi's sphincter, abdominal pain.

The release rate and mechanism of release of mebeverine hydrochloride were studied for commercial “Duspatalin” tablets and for different tablet formulations (F1, F2 & F3) containing 20, 40 and 65% polycarbophil, respectively. The formulated granules were obtained by freeze drying of polycarbophil granules loaded with aqueous solution of the drug at 25°C by swelling of the polymer. The release of mebeverine hydrochloride from prepared tablet formulations was faster than that of Duspatalin tablets. The release rate of the drug increased as the polycarbophil content of the tablets increased. To prolong the residence time of dosage forms within the gastrointestinal tract until all drug is released at the desired rate is one of the real challenges for oral controlled-release drug delivery systems. This study was designed to develop a controlled-release floating matrix tablet and floating raft system of Mebeverine HCl (MbH) and evaluate different excipients for their floating behavior and in vitro

controlled-release profiles. Oral pharmacokinetics of the optimum matrix tablet, raft system formula, and marketed Duspatalin® 200 mg retard as reference were studied in beagle dogs. The optimized tablet formula (FT-10) and raft system formula (FRS-11) were found to float within 34±5 sec and 15±7 sec, respectively, and both remain buoyant over a period of 12 h in simulated gastric fluid. MbH is a musculotropic antispasmodic drug without atropic side effect, whose major therapeutic role is in the treatment of irritable bowel syndrome. It has a short biological half-life of 2.5 h, plasma protein binding of 75%, and is rapidly absorbed after oral administration from the upper part of gastrointestinal tract with peak plasma concentration occurring in 1–3 h. Hence, MbH has been selected as a model drug as it fulfills the required pharmacokinetic and physicochemical properties for controlled delivery. Mebeverine hydrochloride is a potent direct antispasmodic drug which is acting mainly on the smooth muscles of the gastrointestinal tract and it is particularly effective against colonic spasms. There are several analytical methods have been reported in literatures for the determination of mebeverine hydrochloride in its different forms and preparations, some of these methods are spectrophotometric methods Spectrofluorometric electrochemical, chromatographic and flow injection analysis (FIA) method Erythrosin B (Erth-B); tetra-iodofluorescein, also known as Spiro [isobenzofuran-1(3H), 90-[9H] xanthen]-3-one, 30, 60-dihydroxy-20, 40, 50, 70-tetraiodo-, sodium salt. Its molecular formula C20H6I4Na2O5 and molecular weight of 876.86 g/mol red to brown powder that's soluble in water and ethanol It is an organoiodine compound and it is cherry-pink synthetic, primarily used for food coloring Mebeverine HCl was obtained as pure powder and filmcoated tablets (Mebagen 135 mg) from Riyadh Pharma Medical and Cosmetic Products Co. Ltd. (Riyadh, Saudi Arabia), as sugar-coated tablets (Colospasmin forte 135 mg) from Egyptian International Pharmaceuticals Industries Co. (10th of Ramadan City, Egypt), and as retardcapsules (Duspatalin 200 mg) from Abbott Healthcare SAS (Lieu-Dit Maillard, France). Rialox antacid tablets and suspension (each tablet and 5 mL of suspension contained 225 mg aluminum hydroxide and 200 mg magnesium hydroxide) were obtained from Riyadh Pharma Medical and Cosmetic Products Co. Ltd. Moxal antacid tablets and suspension (each tablet and 5 mL of suspension contained 405 mg aluminum hydroxide and 100 mg magnesium hydroxide) were obtained from Julphar-Gulf Pharmaceutical Industries (Ras al-Khaimah, UAE).

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