

Antiulcer activity of pantoprazole from multiple-unit tablet dosage form

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Abstract : Pantoprazole is a proton pump inhibitor prodrug used in the treatment of gastric ulcers and gastroesophageal disease. The proton pump inhibitors pantoprazole inhibits gastric acid by blocking the H^+/K^+ - adenosine triphosphatase enzyme system (the proton pump) of the gastric parietal cell. It is used to short term treatment of ulceration and erosion of the esophagus. The present study was carried out to determine the special effects of multiple-unit multiparticulate pantoprazole tablet dosage form for anti-ulcer activity. The multiple unit tablet of pantoprazole showed antiulcer effects as indicated by a decrease in ulcer index.

Keywords: Pantoprazole, gastric ulcer, omeprazole

Introduction

Peptic ulcer diseases are one of the widespread diseases. The causes of peptic ulcer diseases are increases gastric acid secretion and / or abridged gastric cytoprotection. The diseases is generally due to use of NSAID's, infection by *H.pylori*, stress or due to pathological conditions such as Zollinger-Ellison syndrome. The treatment of the peptic ulcer diseases is mostly intended at reducing the gastric acid secretion, increasing gastric cytoprotection, eradication of *H.pylori* or curing the underlying causes such as Zollinger-Ellison syndrome. Pantoprazole is also the third proton pump inhibitor to be marketed in the UK; it is mainly used to treat too much acid secretions in the stomach, duodenal ulcer, benign gastric ulcer and gastro-esophageal reflux diseases (GERD) and reflux oesophagitis. Pantoprazole has a number of reward compared to its analogus (e.g., omeprazole and lansoprazole) such as specific binding site, superior stability in neutral pH environment and longer extent of action. It is more selective inhibitor of acid secretion than other proton pump inhibitors. In case of oral administration pantoprazole drug is traumatized in acid medium (stomach), due to prerequisite to pass intact through the stomach for reaching to duodenum for absorption, the pantoprazole is formulated as controlled release multiple-unit tablet dosage forms^{1,2,3}.

Materials and methods

Animals

Healthy wister albino rats of either sex weighing between (150-200 gm) were used for present study. These animals were used for anti-ulcer activity. The animals were kept in polypropylene cages in a room maintained under controlled atmospheric conditions in department of pharmacology at B.R. Nahata College of pharmacy, Mandsaur (M.P.). The animals were stabilized for a week. They were maintained in standard conditions at room temperature and relative humidity at 60 ± 5 % for 12 hours light dark cycle. They have been given standard pellet diet supplied by hindustan lever limited company, Mumbai and water ad-libitum throughout the course of study. Food was withheld overnight prior to experiment^{4,5}. The experimental protocol, was approved by the institutional animal ethics committee (IAEC) of B.R. Nahata College of pharmacy, Mandsaur (M.P) India, vide approval number-80/FAC/07/IAEC/BRNCP/07-08/Mandsaur

The anti-ulcer activity was evaluated in pylorus ligated rats with modification described by kulkarni. In the present study the animals were divided into three groups and kept six animals in each groups. Each group have received

GROUP I - Control (0.1% sodium CMC suspension)

GROUP II - Omeprazole as standard drug in sodium CMC suspension at the

dose of 2 mg/kg body weight.

GROUP III - Pantoprazole multiple-unit tablet formulation in sodium

CMC suspension at the dose of 4 mg/kg body weight

The standard drug and multiple-unit tablet drug administered orally two hours before the administration of ethanol. After two hours of ethanol administration, under ketamine HCL (100 mg/kg, i.m.) and xalazine HCL (16 mg/kg, i.m.) anesthesia; the stomachs were removed, opened along with the greater curvature for lesion measurements. Put it on the glass slide and observed under 10 X magnification^{6,7,8}. Scored the ulcer as below-

- 0 = Normal colored stomach
- 0.5 = Red coloration
- 1 = Spot ulcers
- 1.5 = Haemorrhagic streaks
- 2 = Ulcer >3mm but <5mm
- 3 = Ulcer > 5 mm

Mean ulcer score for each animal was expressed as ulcer index (Kulkarni et al., 1999 with modification). The ulcer index was determined using the following formula

Ulcer index = $10/x$

Where x is the total mucosal area divided by total ulcerated area. The results/data is presented as mean $\pm$ SD. The statistical significance was determined using one way ANOVA followed by Dunnett's multiple comparison test⁹. The results are shown in table-1

Results and Discussion

In the present study, modification of the original method described by kulkarni was used.

The Anti-ulcer activity of alcohol induced ulcer rat model with 4 mg / kg b.w. of pantoprazole multiple-unit tablet showed that the tablets are able to protect ulcer formation by alcohol.

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Table- 1

S.No	Treatment	Mean ulcer index	% Protection
1.	Control	5	
2.	Omeprazole as standard drug (2 mg/kg b.w.)	$0.5 \pm 0.3161^*$	90.00
3.	Pantoprazole multiple unit tablet (4mg/kg b.w.)	$1 \pm 0.8333^*$	80

Statistical analysis was done by one-way ANOVA followed by Dunnett's multiple comparison tests. Significant at * $P < 0.05$ as compared to control. Values are expressed in mean $\pm$ SD for six observations.

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