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DEVELOPMENT AND EVALUATION OF PANTOPRAZOLE SODIUM FLOATING IN SITU GEL

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Abstract:

Objective: The objective of this study was to formulate, evaluate, and optimize a floating in situ gel of pantoprazole sodium.

Materials and Methods: In situ gel formulations were prepared using varying concentrations of sodium alginate, calcium carbonate, sodium citrate, and xanthan gum. The mechanism involved was pH-triggered ionic gelation. All formulations were subjected to various evaluation parameters.

Results: Formulation F8, containing 0.04 g of pantoprazole sodium, 2 g of sodium alginate, 1 g of $CaCO_3$, 1 g of xanthan gum, and 0.25 g of sodium citrate, was selected as the optimized batch. It had a floating time of 44.33 seconds and a drug content of 97.0%. FTIR studies revealed no incompatibility. The optimized batch passed accelerated stability studies with no significant change in drug content. An in-vivo study on albino Wistar rats demonstrated significant anti-ulcer effects of the optimized pantoprazole sodium formulation.

Conclusion: The study concluded that the hydrodynamically balanced oral in situ gel of pantoprazole sodium could be an effective dosage form, remaining buoyant and sustaining drug release for 8 hours.

Keywords: Pantoprazole Sodium, *In situ* gel, FTIR, Sodium alginate, Hydrodynamic.

Introduction:

Peptic ulcers are open sores that develop in the inner lining (mucosa) of the stomach or the duodenum (the first section of the small intestine). Normally, a coating of mucus and other chemicals protects the stomach and duodenum from digesting themselves. However, when these protective mechanisms are disrupted, powerful digestive acids can erode the lining of these organs, leading to peptic ulcers [1].

The term "in situ" is Latin for "in position." In situ gel formation in drug delivery systems refers to a liquid formulation that transitions into a solid or semisolid depot after administration. These systems, upon exposure to physiological conditions, shift to a gel phase. The concept of producing a gel in situ was first proposed in the early 1980s. Gelation occurs through the cross-linking of polymer chains, which can be achieved by covalent bond

formation (chemical cross-linking) or non-covalent bond formation (physical cross-linking) [2].

A floating drug delivery system is a key approach for achieving gastric retention to ensure sufficient drug bioavailability. These systems are ideal for drugs with an absorption window in the stomach or upper small intestine [3]. With a bulk density less than gastric fluids, they remain buoyant in the stomach without affecting the gastric emptying rate for a prolonged period, allowing the drug to be released slowly at a desired rate. Once the drug is released, the residual system is emptied from the stomach [4].

Pantoprazole is a proton pump inhibitor (PPI) that suppresses the final step in gastric acid production by covalently binding to the (H+, K+)-ATPase enzyme system at the secretory surface of the gastric parietal cell. This binding inhibits both basal and stimulated gastric acid secretion, regardless of the stimulus [5]. The binding to the (H+, K+)-ATPase results in an antisecretory effect that persists for more than 24 hours for all tested doses (20 mg to 120 mg) [6].

Materials and Methods:

Materials:

Pantoprazole Sodium was obtained as a generous gift sample from Pelltech Healthcare, Mumbai. Sodium Alginate, Calcium Carbonate, and Xanthan Gum were sourced from Meher Chemie, Mumbai. Sodium Citrate was obtained from Varsha Pharma, Mumbai [7].

Sr.No	Material	Property	Source
1.	Pantoprazole Sodium	API	Pelltech Healthcare, Mumbai.
2.	Sodium Alginate	Gelling Polymer	MeherChemie, Mumbai
3.	Calcium Carbonate	Cross Linking, Alkalizing Agent	MeherChemie, Mumbai
4.	Xanthan Gum	Rate Retarding Polymer	MeherChemie, Mumbai
5.	Sodium Citrate	Buffering, Neutralizing Agent	Varsha Pharma, Mumbai

Table No.01: Materials

Equipments:

Table No .02: Equipments

Sr.No	Equipment	Model No.	Make
1.	Magnetic Stirrer	Lms-28oe	Labtop
2.	Brookfield Viscometer	Model No. Cap-2000.	Middleboro Usa.
3.	UV-Spectrophotometer	UV-1800	Shimadzu Japan
4.	Digital Balance	Bl-22oh	Shimadzu Japan
5.	pH Meter	Pico+	Labindia
6.	Dissolution Apparatus	EDT – 08 LX	Electrolab
7.	FTIR	Specrum-2	Perkin Elmer

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RESULTS AND DISCUSSION

The UV spectrum of Pantoprazole sodium was scanned in 0.1 N HCl over the range of 400-200 nm[8]. The spectrum showed that the observed λmax of Pantoprazole sodium was 284 nm, consistent with the pharmacopeial value [9].

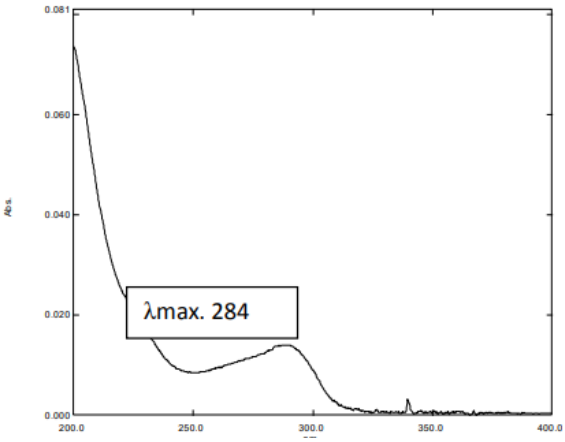

Fig. No. 01. UV Scan for Pantoprazole sodium at 284 nm in 0.1N HCl.

FTIR Spectroscopy

FTIR spectroscopy was used for identification studies. The characteristic absorption peaks of pantoprazole sodium were observed at various wave numbers [10]. The peaks identified in the spectra of the pure drug matched those in the official spectrum of the British Pharmacopeia, confirming the drug's purity [11].

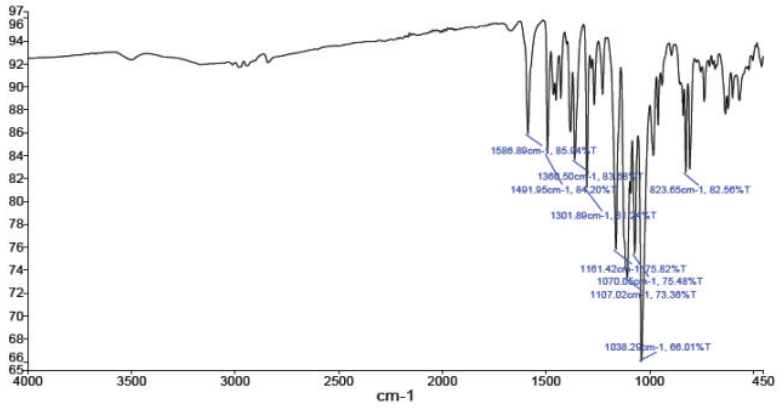

Fig. No. 03: FTIR spectra of Pantoprazole sodium

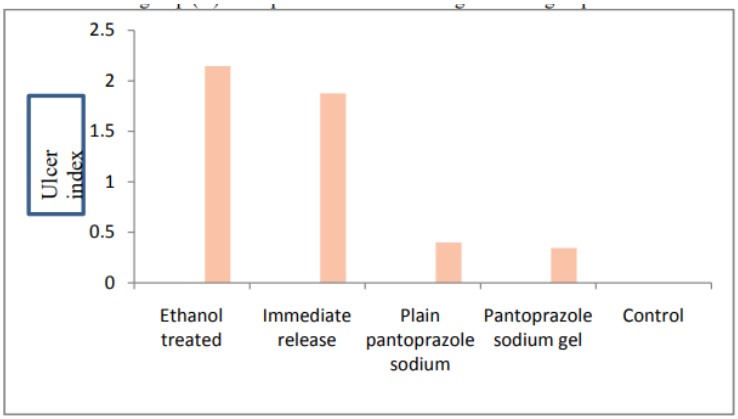

Fig. No.4: Ulcer index of alginate based in situ gel of pantoprazole sodium.

Conclusion:

The development of a floating in-situ gel for Pantoprazole sodium represents a promising drug delivery approach to enhance bioavailability and achieve prolonged release. FTIR studies confirmed that there was no interaction between the drug and excipients (sodium alginate, xanthan gum, calcium carbonate, sodium citrate). Xanthan gum was utilized for extended drug release, facilitating enhanced gastric retention times of the dosage form in the stomach. Sodium alginate, calcium carbonate, and sodium citrate served as gelling, gas-generating, and neutralizing agents, respectively. Evaluation of various formulations of floating in-situ gel of Pantoprazole sodium revealed that formulation F8 exhibited the most favorable characteristics, providing a slow release of Pantoprazole sodium over 8 hours with a dissolution rate of 96.082%. In vitro release rate studies demonstrated that maximum drug release was achieved with the F8 formulation over an 8-hour period. An in vivo study conducted using the optimized F8 formulation in Wistar rats assessed the ulcer index to further validate its efficacy.

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