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Formulation and Characterization of Pantoprazole Enteric Coated Multi Unit Pellet System

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ABSTRACT

Premise of the research: *GERD (Gastro-Esophageal Reflux Disease) disease is too most common problem and Pantoprazole to be an effective and well tolerated treatment of acid related disorder. Pantoprazole is not stable under acidic condition. Pellets are likely to be affected by gastric emptying due to their small size. MUPS (multi-unit pellet system) is the first PPIs (proton pump inhibitors) to be made available as an orally disintegrating tablet. Delayed release products are typically enteric coating or colon target system. Eudragit polymer is used as an enteric coating film former for solid dosage forms.*

Methodology: *Eudragit L 30 D 55 is used as an enteric coating film former for solid dosage forms. Eudragit L 100-55 is an alternative to Eudragit L 30 D-55. It is commercially available as a redispersible powder. Eudragit L 100-55 (prepared by spray-drying Eudragit L 30 D-55) is a white, free-flowing powder that is redispersible in water to form latex that has properties similar to those of Eudragit L 30 D-55.*

Results: *Use of Eudragit L 30 D 55 in the preparation to delaying the release of Pantoprazole to the colon system. In trial VI, solvent based Eudragit L 30 D 55 coating was most suitable when used 60% with respect to pellets weighs 0.1 N HCl is formed to be 6% in 1 hrs.*

Keywords: *MUPS (multi-unit pellet system), GERD (Gastro esophageal reflux disease), PPIs (proton pump inhibitors).*

INTRODUCTION

Pantoprazole is a proton pump inhibitor (PPI) which inactivates the final step in the gastric acid secretion pathway in gastric parietal cells in a dose-dependent manner. Pantoprazole also exhibits antibacterial activity against Helicobacter pylori *in vitro*[1-5]. MUPS maintains the s

pharmacological properties as Pantoprazole capsules and can be taken by any patient who is currently prescribed Pantoprazole. The pellets are less likely to be affected by gastric emptying due to their small size. This formulation represents an improved alternative presentation for all patients requiring Pantoprazole offering the benefits of a choice of administration options. The main aim of this study is to delaying the drug (Pantoprazole) release to the colon system with the MUPS (multi-unit pellet system) formulation with use of Eudragit L 30 D 55.

MATERIALS AND METHODS

Chemical uses

Pantoprazole (Hetero Drugs Limited), HPMC (Hydroxy propyl methyl cellulose) (Shin-Etsu Chemical co. Ltd.), MCC (methyl cellulose) (Asahi Kasei Chemicals Co.), Eudragit L 100 (95%) (DEGUSSA), Eudragit L 30 D 55 (30%) (DEGUSSA), Acryl EZE (95%).

Method

Pellet evaluation, friability, bulk density, Seal coating, Enteric coating, Acid resistance test, Loss on drying, Compressibility index, Hausner ratio, Sieve analysis, Hardness.

Bulk density

A weighed amount (50 g) is introduced into a 100 ml graduated cylinder. The cylinder is fixed on the Bulk Density Apparatus and the timber knob is set (regulator) for 100 tapings [6-8]. The volume occupied by the pellets is noted. After tapping, the final volume is noted. Bulk density is calculated by using formula.

Bulk Density=Mass of pellets/Bulk volume.

Friability

Weighed 50 g of pellets were placed in the friabilator which was then operated for 100 revolutions at 25 rpm. The pellets were weighed and friability is calculated by using the formula-

$$\% \text{ Friability} = \frac{\text{Initial weight - Final weight}}{\text{Final weight}} \text{ x } 100$$

Compressibility index

The simplest way for measurement of free flow of powder is compressibility, a indication of the case with which a material can be induced to how is given by compressibility index (I) which is calculated as follows

$$. I = \frac{V_b - V_t}{V_b} x100$$

Where V_b is the bulk volume and V_t is tapped volume.

Hausner ratio

Hausner ratio is an indirect index of ease of powder flow. It is calculated by the following formula

$$\text{Hausner ratio} = \frac{\rho_t}{\rho_b}$$

Where ρ_t s tapped density and ρ_b is bulk density lower Hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25)

Loss on drying

Finely powder 10 tablets. Transfer about 1.0 g of the powder into the pan of the IR moisture balance which already set to O. Set the temperature to 105°C[9].. Close the lid of the IR balance and press start. After the temperature reaches to 105°C, check the % moisture displayed. Note down the constant value.

Hardness test

Select five tablets randomly. Place one tablet at a time in the hardness tester (Dr Schleuniger Model 5Y) which is already set to O. Apply pressure by pressing the start button of hardness tester apparatus, till the tablet breaks [10]. Note down the reading on the tester i.e. the hardness of the tablet in Newton's. Take the average of five such tablets and calculate the average hardness of the tablets.

Seal coating layer

Seal coating layer is done to guard the drug and for escalating the solidity of a drug. In order to avoid contact with functional groups limited in the enteric film coat, it is of advantage to combine enteric coatings with sealing coats made up of cellulose derivatives. Syloid 244 FP is used to avoid charging of pellets [11]. Lactose monohydrate acts as filler.

Enteric coating

An enteric coating escapes degradation or abolition in pancreatic press, but breaks down or disperses into fluids in the intestines. Many forms of pharmaceutical medication frustrate the stomach because of their chemical composition [12], while others perform changes in the body in stomach acid, and enzyme action. So becoming less efficient. To avoid the above conditions, enteric coating is used.

Instruments

UV Spectrophotometer (Shimadzu Europa products), IR Spectrophotometer (Lumex instruments), HPLC (Bischoff Chromatography).

RESULTS AND DISCUSSION

Pantoprazole is freely soluble in water, methanol and ethanol. Absorption maximum (λ max) was observed at 295 nm.

Film is cast into a glass petri dish by pouring some quantity of mixture into glass Petri dishes [13] with Teflon foil covered bottoms. The film is dried at room temperature for 24 hours and examined with regards to their appearance, flexibility, shrinkage, and stickiness.

Film from Petri dish no 03, 08, 14 show flexible film as shown in Table1.

Table 1: Effect of plasticizer film formation with methacrylate polymer.

Petri Dish No →	**01**	**02**	**03**	**04**	**05**	**06**	**07**	**08**	**09**	**10**	**11**	**12**
Eudragit L 30 D 55	30	30	30	30	30	30	30	30	30	30	30	30
Eudragit L 100 55	-	-	-	-	-	-	-	-	-	-	-	
Tri ethyl citrate	00	10	15	20	30	40	-	-	-	-	-	
PEG 6000	-	-	-	-	-	-	10	15	20	25	30	40
Petri Dish No →	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**-**	**-**
Eudragit L 30 D 55	-	-	-	-	-	-	-	-	-	-	-	-
Eudragit L 100 55	30	30	30	30	30	30	30	30	30	30	-	-
Tri ethyl citrate	10	15	20	30	40	-	-	-	-	-	-	-
PEG 6000	-	-	-	-	-	10	15	20	30	40	-	-

CONCLUSION

Pantoprazole drug delaying releasing in the forms of pellets coated with polymer Eudragit L 30 D 55 to reach the colon system by passing the acid resistance test and it is suitable for best GERD(Gastro esophageal reflux disease).

Pantoprazole sodium in 0.1 N NaOH is found to exhibit maximum absorption at 295 nm after scanning on the UV spectrophotometer. 295 nm has been reported as λ max.

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