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PREPARATION AND CHARACTERIZATION OF PANTOPRAZOLE SODIUM TABLETS USING CELLULOSE ACETATE PHTHALATE AND EUDRAGIT L100 COATINGS

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ABSTRACT

Pantoprazole is a proton pump inhibitor, belongs to group of benzimidazole, Pantoprazole sodium was prepared by direct compression method using different concentration of, microcrystalline cellulose as filler, mannitol and dicalcium phosphate as diluents, cross Carmel lose sodium as disintegrating agents, magnesium stearate and talc was used as a glidant and lubricant respectively. Direct compression is economic compare to wet granulation since it requires fewer unit operations. Direct compression is economic compare to wet granulation since it requires fewer unit operations. This means less equipment, lower power consumption, less space, less time and less labour leading to reduced production cost of tablets. The prepared tablets were evaluated for hardness, weight variation, friability and drug content uniformity and it was found that the results comply with official standards. The prepared tablets were coated using enteric coating polymer such as cellulose acetate phthalate, Eudragit L100 and by dip coating method. The in vitro release was studied using acidic buffer pH 1.2 and phosphate buffer pH 6.8. Prepared all batch's C2F9 was found best, with hardness 5.60 ± 0.24 (Kg/cm2), drug content 99.08 ± 0.35(%), disintegration time 7.02± 0.21(min), and percentage cumulative drug released which started after 120 min and reached 99.72 after 180 min. Stability studies indicated that the developed tablets were stable and retained their pharmaceutical properties at room temperature and 40 °C / 75% RH for a period of 3 month.

KEYWORDS: Pantoprazole, Direct compression, Proton pump inhibitor, Cellulose acetate phthalate, Eudragit L100.

INTRODUCTION

More than 50% of pharmaceutical products are orally administered for several reasons. This route of administration is considered as the most widely used route as it offers advantages like ease of administration, versatility, patient compliance and accurate dosing. Undesirable taste is one of the important formulation problems that are encountered with such oral product. The stomach is continuous with the oesophagus at the cardiac sphincter and with the duodenum at the pyloric sphincter. It has two curvatures. The stomach is divided into three regions: the fundus, the body and the antrum. At the distal end of the pyloric antrum is the pyloric sphincter, guarding the opening between the stomach and the duodenum. When the stomach is inactive the pyloric sphincter is relaxed and open and when the stomach contains food the sphincter is closed.

1.1. Structure and functions of the stomach

The stomach is continuous with the oesophagus at the cardiac sphincter and with the duodenum at the pyloric sphincter. It has two curvatures. The stomach is divided into three regions: the fundus, the body and the antrum. At the distal end of the pyloric antrum is the pyloric sphincter, guarding the opening between the stomach and the duodenum. When the stomach is inactive the pyloric sphincter is relaxed and open and when the stomach contains food the sphincter is closed. Temporary storage allowing time for the digestive, chemical digestion, preparation of iron for absorption, production of intrinsic factor needed for absorption of vitamin B12 in the terminal ileum regulation of the passage of gastric contents into the duodenum. When the chyme is sufficiently acidified and liquefied, the pyloric antrum forces small jets of gastric contents through the pyloric sphincter into the duodenum.[1]

1.2. Acid formation

The stomach secretes about 2.5 litres of gastric juice daily. The principal exocrine secretions are proenzymes such as prorennin and pepsinogen elaborated by the chief or peptic cells and hydrochloric acid (HCl) and intrinsic factor secreted by the parietal or oxyntic cells. Mucus-secreting cells abound among the surface cells of the gastric mucosa. Bicarbonate ions are also secreted and are trapped in the mucus, creating a gel-like protective barrier that maintains the mucosal surface at a pH of 6-7 in the face of a much more acidic environment (pH 1-2) in the lumen.[2]

1.3. Gastric Defenses Against Acid

The extremely high concentration of H+ in the gastric lumen requires robust defense mechanisms to protect the esophagus and the stomach. The primary esophageal defense is the lower esophageal sphincter, which prevents reflux of acidic gastric contents into the esophagus. The stomach protects itself from acid damage by a number of mechanisms that require adequate mucosal blood flow, perhaps because of the high metabolic activity and oxygen requirements of the gastric mucosa. One key defense is the secretion of a mucus layer that protects gastric epithelial cells. Gastric mucus is soluble when secreted but quickly forms an insoluble gel that coats the mucosal surface of the stomach, slows ion diffusion, and prevents mucosal damage by macromolecules such as pepsin. Mucus production is stimulated by prostaglandins E2 and I2, which also directly inhibit gastric acid secretion by parietal cells. Thus, alcohol, aspirin, and other drugs that inhibit prostaglandin formation decrease mucus secretion and predispose to the development of acid-peptic disease. A second important part of the normal mucosal defense is the secretion of bicarbonate ions by superficial gastric epithelial cells. Bicarbonate neutralizes the acid in the region of the mucosal cells, thereby raising pH and preventing acid-mediated damage.[3]

1.4. Tablet

Tablets are solid dosage forms containing medicinal substances with or without suitable diluents. They are the most widely preferred form of medication both by pharmaceutical manufacturer as well as physicians and patients. They offer safe and convenient ways of active pharmaceutical ingredients (API) administration with excellent physicochemical stability in comparison to some other dosage forms, and also provide means of accurate dosing. They can be mass produced with robust quality controls and offer different branding possibilities by means of colored film coating, different shapes, sizes or logos. The method for the preparation of tablet is shown in **Table 1**.

Table 1. Tablet manufacturing methods - advantages and limitations

Method	Advantages	Limitations
Direct compression	Simple, economical process. No heat or moisture, so good for unstable compounds	Not suitable for all API Generally limited to lower dose compounds Segregation potential Expensive excipients
Wet granulation	Robust process suitable for most compounds Imparts flowability to a formulation Can reduce elasticity problems Coating surface with hydrophilic polymer	Expensive: time and energy consuming process Specialized equipment required Stability issues for moisture sensitive and thermolabile API with aqueous granulation

	can improve wettability Binds API with excipient, thus reducing segregation potential.	
Wet granulation (non-aqueous)	Suitable for moisture sensitive API Vacuum drying techniques can remove/reduce need for heat.	Expensive equipment Needs organic facility Solvent recovery issues Health and environment issues
Dry granulation (slugging or roll compaction)	Eliminates exposure to moisture and drying	Dusty procedure Not suitable for all compounds Slow process

1.4.1. Types of tablets

The tablet dosage form is a versatile drug delivery system. Different types of tablet formulations are available, which could be broadly classified based on: (1) route of administration such as tablets for oral delivery, sublingual delivery, buccal delivery, rectal delivery or vaginal delivery, and (2) formulation characteristics such as immediate release tablets, effervescent tablets, melt-in mouth or fast dissolving tablets, delayed release or extended release tablets.[15]

1.4.2. Coated tablets:

Enteric coated dosage forms, such as coated tablets, sugar-coated tablets, soft and hard gelatin capsules, granulates or pellets, have their firm place in the medical arsenal. The preparations most commonly provided with enteric coatings contain pancreatin and other proteolytic enzymes, diclofenac, cardiac glycosides, electrolyte preparations with sodium, potassium and magnesium salts as well as calcium, iron and manganese preparations. Bisacodyl preparations, preparations containing valproic acid as well as formulations with plant extract or terpenes are also common. Nowadays, enteric coatings are particularly used to

- Protect active substances destroyed by the acidic gastric juice
- Improve tolerability of medicaments irritating the stomach by only releasing them in the small intestine
- Making active substances available after a time delay (sustained release),
- Achieving targeted release and concentration in the small intestine.[16]

MATERIALS AND METHODS

The following components are included in the formulation: magnesium stearate, microcrystalline cellulose, croscarmellose sodium, mannitol, dicalcium phosphate, and pantoprazole sodium. Talc, eudragit L-100, and cellulose acetate phthalate are some of the components that make up this product. Preparation of pantoprazole sodium tablets: In order

to immediately punch an appropriate mix of granules into 200 mg tablets that included 40 mg of pantoprazole sodium sesquihydrate, a rotating tablet compression machine was used. Furthermore, a concave punch with a diameter of 8 mm was utilized throughout the process. For the purpose of maintaining their freshness, we collected all of the pantoprazole tablet batches and placed them in containers that were sealed.

Table 2: Pantoprazole sodium enteric coated sodium tablet manufacturing process.

Composition	F1	F2	F3	F4	F5	F6	F7	F8	F9
Pantoprazole sodium (mg)	40	40	40	40	40	40	40	40	40
Croscarmellose sodium (mg)	2	4	6	2	4	6	2	4	6
Microcrystalline cellulose(mg)	27	25	23	27	25	43	80	50	23
Mannitol (mg)	50	75	100	40	85	80	43	50	75
Dicalcium phosphate (mg)	75	50	25	85	40	25	75	50	50
Talc (mg)	2	2	2	2	2	2	2	2	2
Magnesium stearate (mg)	4	4	4	4	4	4	4	4	4
Total weight (mg)	200	200	200	200	200	200	200	200	200

MATERIAL AND METHOD

Table 3: LIST OF CHEMICALS USED.

Sr. No.	Materials	Manufacturer / Supplier
1	Acetone	SD Pharma, Mumbai, India
2	Calcium phosphate	Fine Chem Industries, India
3	Disodium hydrogen phosphate	Fine Chem Industries, India
4	Potassium dihydrogen phosphate	Cipla Pharma, Mumbai, India
5	Cellulose acetate phthalate	SD Pharma, Mumbai, India
6	Micro crystalline cellulose	Cipla Pharma, Mumbai, India
7	Mannitol	Signet Chemical Corporation
8	Croscarmellose sodium	SD Chemical Corporation
9	Pantoprazole sodium sesquihydrate	Signet Chemical Corporation
10	Talc	Spectrochem Pvt. Ltd. Mumbai.
11	Magnesium stearate	Spectrochem Pvt. Ltd. Mumbai.
12	Eudragit L-100	Sd fine Chem. Ltd., Mumbai, India.
13	Potassium dihydrogen Phosphate	Spectrum reagent and chemicals Pvt. Ltd., India.
14	Hydrochloric acid	Swastik Pharmaceuticals, Mumbai,

Table 4: LIST OF EQUIPMENT USED.

Sr. No	Equipment	Manufacturer / Supplier
1	Rotary tablet punching machine	Ridhi Pharma machinery, Ahmedabad, India
2	UV Spectrophotometer	Shimadzu 1800, Japan
3	Digital Electronic Balance	Citizon, India.
4	Monsanto Hardness tester	Labtech, India
5	Friability apparatus	Ketan, Koshish Industries, India
6	Digital pH meter	Hanna, India
7	Vernier calipers	Mitutoyo. Japan

8	Disintegration test apparatus	Electrolab ED-2L,Servewell Industries, India
9	Dissolution test apparatus	Electrolab TDT-08L Servewell Industries, India
10	FTIR Spectrophotometer	Bruker,Japan.
11	Hot air oven	Servewell Industries, India

Coating of compressed pantoprazole sodium tablets

Preparation of enteric coating solution: The enteric coating solution was prepared by simple solution method. It was prepared by 6% w/w and 8% W/W of Eudragit L100 (E1 and E2) or cellulose acetate phthalate (C1 and C2) as an enteric polymer, PEG 1.5% w/w as plasticizer and acetone and isopropyl acetone was used as solvent. Diethyl phthalate was added and made up the volume with rest of the solvent mixture; this mixture was constantly stirred for 1h with paddle mechanical stirrer at the rate of 1000 rpm and the stirred coating solution was again filtered through muslin cloth, a coating solution was obtained (Neelam, 2011).

Table 5: Composition of Coating Solution.

Ingredients	Quantity (%)
Cellulose acetate phthalate/ Eudragit L100	6.0 / 8.0
PEG	1.5
Acetone	59.4

Enteric coating of pantoprazole sodium compressed tablets by dipping method:

The compressed tablets were coated with enteric coating polymer (Eudragit L100 or cellulose acetate phthalate) solution by dipping method. Desired tablet coating continued the dipping, and weight gain was achieved. The coated tablets were studied for its weight variation, thickness, uniformity of drug content and in vitro dissolution study (Senthil, 2010; Rupesh, 2010).

Physicochemical evaluation of coating films

The same polymer solution was used to prepare the polymeric films and was subjected for film thickness, film solubility. The polymeric films were prepared by casting the acetone with PEG the polymer solution was poured on the glass plate. The film was dried for 24 h at room temperature under a special cover with reduced solvent evaporation to obtained smooth homogenous films. The dried films were cut in to 1cm2 area the prepared polymeric film was studied for film thickness, and film solubility (Martin, 2001; Liberman, 1991; Saffar, 2007). The thickness of dried films was determined by thickness Digital micrometer. The film solubility was studied with pH 1.2 and pH 6.8. The 1×1 cm2 coating film was selected,

weighed and transferred in a beaker containing 20 mL of specified pH medium, which was mixed in a magnetic stirrer for 1 h at 37 ± 1°C and finally film solubility was examined.

In vitro drug release studies

USP dissolution apparatus type II (Electro lab TDT-08L, Mumbai, India) was employed to study the in vitro drug release from various formulations prepared. The dissolution medium used was 900 mL of acidic buffer of pH 1.2 for 2 h and phosphate buffer of pH 6.8 for 1 hrs. The tablet was kept in to the basket. The temperature was maintained at 37 ± 0.5°C and the stirring rate was 100 rpm. Samples were withdrawn at regular time intervals and the same volume was replaced with fresh dissolution medium. The samples were measured by UV spectrophotometer at 283 nm (pH 1.2) and at 288 nm (pH 6.8) against a blank. The release studies were conducted in triplicate and the mean values were plotted versus time (Bozdag, 1999).

Stability studies: Stability studies were performed as per the ICH guidelines. Selected formulations of Pantoprazole sodium tablet were sealed in aluminum foil cover and stored at (40 ± 2 °C / 75 ± 5 % R.H) for a period of 3 months. Samples from each formulation which are kept for examination were withdrawn at definite time intervals. The withdrawn samples were evaluated for physical appearance, hardness, drug content (Singh, 2009).

5. RESULTS AND DISCUSSION

The study was performed on enteric coating tablets with different formulation F1 to F9. Pantoprazole sodium sesquihydrate were prepared by direct compression method using different concentration of, microcrystalline cellulose, mannitol, dicalcium phosphate, croscarmellose sodium, magnesium stearate and talc, CAP and Eudragit L100 were used as enteric coating polymer, which prevent drug form gastric pH and release in intestinal pH.

Table 6: Calibration data of pantoprazole sodium in 0.1N HCl (pH 1.2).

Sl. No.	Concentration (mg /mL)	Absorbance* (nm)
1	0	0
2	2	0.082+0.0005
3	4	0.145+0.0015
4	6	0.231+0.0101
5	8	0.289+0.0023
6	10	0.361+0.0025
7	12	0.459+0.0047

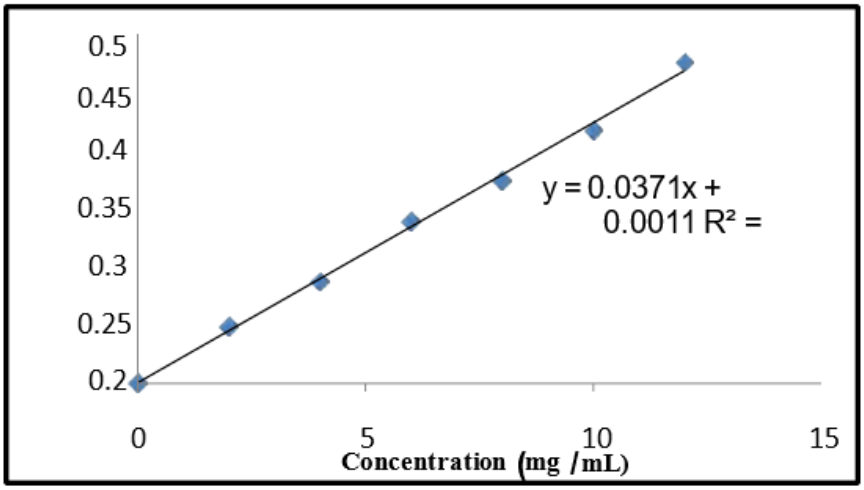

Figure 1: Standard graph of pantoprazole sodium in 0.1N HCl (pH 1.2).

Table 7: Calibration data of pantoprazole sodium in phosphate buffer (pH 6.8).

SL. NO.	Concentration (mg /mL)	Absorbance*(nm)
1	0	0
2	2	0.085±0.0040
3	4	0.149±0.0036
4	6	0.243±0.0015
5	8	0.305±0.0075
6	10	0.373±0.0051
7	12	0.468±0.0020

*Mean±SD, *n* = 3

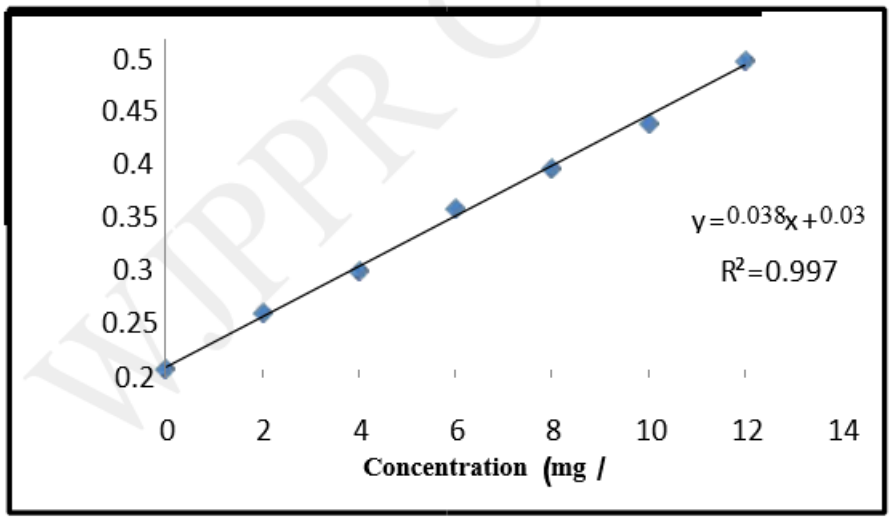

Figure 2: Standard graph of pantoprazole sodium in phosphate buffer (pH 6.8).

Formulation Code		Parameter			
	Bulk density (gm/mL) *	Tapped density (gm/mL) *	Carr's Index (%)*	Hausner's ratio*	Angle of repose (Ɵ)*
F1	0.357±0.03	0.384±0.05	7.03±0.09	1.075±0.04	28.31±0.26
F2	0.312±0.04	0.335±0.02	6.86±0.15	1.073±0.05	27.20±0.14
F3	0.306±0.03	0.326±0.03	6.13±0.12	1.065±0.02	29.13±0.34
F4	0.312±0.03	0.334±0.06	6.58±0.14	1.070±0.06	26.13±0.26
F5	0.306±0.03	0.334±0.05	8.38±0.17	1.091±0.08	26.78±0.18
F6	0.384±0.04	0.429±0.05	10.48±0.20	1.117±0.07	25.79±0.24
F7	0.358±0.05	0.385±0.04	7.01±0.13	1.075±0.03	29.52±0.14
F8	0.286±0.05	0.313±0.04	8.62±0.07	1.094±0.03	26.95 ±0.15
F9	0.348±0.08	0.328±0.05	5.74±0.13	1.06±0.08	26.13±0.26

Post compression parameters of pantoprazole sodium core tablet

The pantoprazole tablets were prepared by direct compression method and were evaluated for their hardness, weight variation, content uniformity, friability and *in vitro* drug release (Table 9). Hardness has to be controlled to ensure that the product is firm enough to withand handling without breaking or crumbling and not so hard that the disintegration time is unduly prolonged. The average hardness of the tablets to be in range was found within 4.93 ± 0.15 to 6.20 ± 0.35 Kg / cm2. Friability value which also affected by the hardness value of tablets should be in the range 1% limits, which is the usual friability range of tablets. The friability of the prepared tablets was found less than 1% w/w. The drug content uniformity of pantoprazole sodium present in tablets formulation ranged from 96.28 ± 0.15to 100.34 ± 0.13%. The average weight found 198 ± 0.15 to 206 ± 0.24 mg. Disintegration time varied between 11.48 ± 0.15 to 5.38 ± 0.23, hence all shows favourable result.

Table 9: Post compression parameters of pantoprazole sodium core tablets.

		Parameter			
Formulation Code	Hardness (Kg/cm2)*	Friability (%)*	Weight variation (mg) *	Drugcontent (%)*	Disintegration time (min) *
1	5.80 ± 0.12	0.69 ± 0.015	199 ± 0.12	96.28 ± 0.15	10.6± 0.62
F2	5.56 ± 0.24	0.51 ± 0.017	206 ± 0.24	97.62 ± 0.27	8.26± 0.56
F3	5.83 ± 0.08	0.48 ± 0.014	201 ± 0.17	99.51 ± 0.36	5.38± 0.23
F4	4.93 ± 0.15	0.64 ± 0.015	208 ± 0.20	98.17 ± 0.16	11.48± 0.15
F5	5.73 ± 0.25	0.71 ± 0.016	203 ± 0.16	98.92 ± 0.42	9.32± 0.18
F6	5.12 ± 0.34	0.68 ± 0.026	206 ± 0.14	100.34 ± 0.13	6.13± 0.25
F7	5.66 ± 0.17	0.54 ± 0.026	199 ± 0.22	98.50 ± 0.48	10.54± 0.43
F8	6.20 ± 0.35	0.49 ± 0.025	204 ± 0.18	98.41 ± 0.34	9.12± 0.71
F9	5.60 ± 0.24	0.42 ± 0.018	198 ± 0.15	99.08 ± 0.35	6.02± 0.21

Mean ± SD, n=3

Table 10: Physicochemical evaluation parameters of enteric coated tablets.

Polymer	Batch Code	Parameter		
		Weight Variation (mg)*	Hardness Kg/cm2*	Drug content (%)*
CAP	C1F3	211 ± 0.035	6.5 ± 0.15	96.75 ± 0.14
	C2F3	214 ± 0.016	5.9 ± 0.24	93.65 ± 0.35
	C1F9	212 ± 0.006	5.4 ± 0.09	94.45 ± 0.26
	C2F9	210 ± 0.024	6.3 ± 0.14	98.54 ± 0.12
Eudragit L 100	E1F3	214 ± 0.021	5.5 ± 0.16	93.47 ± 0.23
	E2F3	213 ± 0.012	6.0 ± 0.06	94.56 ± 0.14
	E1F9	215 ± 0.015	6.5 ± 0.31	98.27 ± 0.45
	E2F9	211 ± 0.024	5.7 ± 0.20	96.35 ± 0.12

*Mean±SD, *n* = 3

Table 11: *In vitro* drug release of pantoprazole sodium (C1F3).

Time (min)	Absorbance	Conc. (µg/mL)	Conc. in 900 mL (mg /mL)	Loss	Cumulative loss	Cumulative drug released	Cumulative percentage drug released *
0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0
105	0.024	0.6469	5.822	0	0	5.822	14.62±0.52
120	0.06	1.6172	14.555	0.0064	0.0064	14.561	36.58±0.40
135	0.091	2.3884	21.496	0.0161	0.0226	21.518	54.05±0.90
150	0.121	3.1758	28.582	0.0238	0.0465	28.629	71.91±0.39
165	0.142	3.7270	33.543	0.0317	0.0782	33.621	84.46±0.17
180	0.162	4.2519	38.267	0.0372	0.1155	38.383	96.42±0.40

*Mean±SD, *n* = 3

Table 12: Stability studies of cellulose acetate phthalate coated tablet formulation C2F9.

Evaluation parameters		Observation in month		
	Initial	1st month	2nd month	3rd month
Physical Appearance	white-collar tablets	No change	No change	No change
Hardness (Kg / cm2) *	6.3 ± 0.14	6.2 ± 0.56	6.2 ± 0.64	6.2 ± 0.26
Drug Content (%)*	98.54 ± 0.12	98.36 ± 0.52	98.16 ± 0.36	98.07 ± 0.28

Mean ± SD, n=3

CONCLUSION

During the course of this study, pantoprazole sodium enteric coated tablets were successfully manufactured by using Cellulose Acetate Phthalate (CAP) and Eudragit L100 as coating polymers. Drug stability in gastric pH and release in intestinal pH was both accomplished by the use of these polymers, which successfully shielded the medications from the acidic

environment of the stomach. Among all of the batches that were produced, the formulation C2F9, which was coated with 8% CAP, had the most favourable outcomes. It had the required dissolving profile, the suitable pre- and post-compression properties, and an excellent drug content within its composition. Pantoprazole's acid-lability may be reduced by enteric coating, according to the findings, which would make the medication more stable and effective in the treatment of stomach ulcers and Gastroesophageal Reflux Disease (GERD).

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