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Formulation and evaluation of enteric coated tablets of Pantoprazole

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ABSTRACT
Pantoprazole is a proton pump inhibitor, belongs to group of benzimidazole, Pantoprazole sodium were prepared by direct compression method using different concentration of, microcrystalline cellulose as filler, mannitol and dicalcium phosphate as diluents, crosscarmellose 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. 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

A R T I C L E I N F O

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C O N T E N T S

1. Introduction

The tablet enteric coating is perhaps one of the oldest pharmaceutical processes still in existence. Enteric refers to the small intestine; therefore enteric coatings prevent release of medication before it reaches the small intestine. Enteric-coated dosage forms do not release the active ingredient until they have been transported down to the neutral reacting part of the small intestine; hence they offer the best possibilities for the protection of unstable drugs at low pH values. The modified enteric-coated Pantoprazole sodium formulation that provide immediate release in the small intestine and simultaneously provide sustained input of drugs that have an absorption window and at the same time may improve or maintain bioavailability of the formulation. The most potent suppressors of gastric acid secretion are inhibitors of the gastric H+, K+-ATPase (proton pump) (Nicole, 2010). In typical doses, these drugs diminish the daily production of acid (basal and stimulated) by 80% to 95%. Available PPI's for clinical use: Omeprazole, esomeprazole, lansoprazole, pantoprazole, rabeprazole. The primary treatment goal patients with peptic ulcer and GERD are relief of symptoms, prevention of complications related to the disease and healing of ulceration. Pantoprazole is a substituted benzimidazole

derivative that targets gastric acid proton pumps, the final common pathway for gastric acid secretion. The drug covalently binding to the proton pumps, causing prolonged inhibition of gastric acidsecretion (Richard, 2009). But the drug causes irritation to gastric mucosa which may lead to nausea and vomiting. The stability of pantoprazole is rapidly degrades in acid medium of the stomach, but has acceptable stability in alkaline conditions. Therefore, pantoprazole should be delivered into the intestine. Hence, formulation of pantoprazole as an enteric coated tablet may solve the stability problem of drug in the stomach and release the drug in the intestine. The main objectives of the present study was To formulate and evaluate enteric coated tablets Pantoprazole sodium by direct compression method, Selection of suitable coating material to develop the dosage form, To overcome the drug degradation by the gastric enzymes as well as the acidic environment of the stomach.

2. Materials and Methods

Pantoprazole sodium (Signet Chemical Corporation), Mannitol (Signet Chemical Corporation) Croscarmellose sodium (SD Chemical Corporation), Micro crystalline cellulose (Cipla Pharma, Mumbai, India), Dicalcium phosphate (Fine Chem Industries, India), Magnesium stearate (Spectrochem Pvt Ltd. Mumbai), Talc (Spectrochem Pvt. Ltd. Mumbai) Eudragit L-100 (Sd fine Chem. Ltd., Mumbai, India), Cellulose acetate phthalate (SD Pharma, Mumbai, India). Preparation of pantoprazole sodium tablets: An ideal mixture of granules were directly punched into tablets weighing about 200 mg containing 40 mg of pantoprazole sodium sesquihydrate, using rotary tablet compression machine (Riddhi 10 stn mini tablet press RDB4-10, Rimek, Ahmedabad, India), using 8 mm diameter concave punches. The different batches of pantoprazole tablets were collected and stored in air tight containers (Sumit, 2009; Anroop, 2010).

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). 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 (Electrolab TDT-08L, Mumbai, I ndia) 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℃ 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).

3. Results and Discussion

The prepared pantoprazole powder blend for tabletting was prepared by direct compression method. The prepared pantoprazole powder blend were evaluated angle of repose, bulk density, tapped density, Hausner's ratio and compressibility index as given on Table 3. The bulk densities of the granules were found to be in the range of 0.306±0.03 to 0.384±0.04 gm/mL, while the tapped densities were ranged between 0.313±0.04 to 0.429±0.05 gm/ml. The flow characteristics of the granules were assessed by determining their angle of repose and Carr's Index. The values of compressibility (5.74 ± 0.13 to 10.48 ± 0.20%) signify good flowability. The angle of repose of all formulation was less than 30º (25.79 ± 0.24 to 29.52 ± 0.14) also indicate the good flowability of the prepared granules.

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 4). Hardness has to be controlled to ensure that the product is firm enough to with and 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 favorable result.

Physicochemical evaluation of coating films:

Physicochemical evaluation of cellulose acetate phthalate, Eudragit L100 and were studied for different parameters such as film thickness, film weight and film solubility. The enteric polymer cellulose acetate phthalate, Eudragit L100 were found to be completely soluble in pH6.8 and insoluble in pH1.2 (Table.5). Physicochemical evaluation of pantoprazole sodium enteric coated tablets: The tablets which show most satisfactory result in disintegration, and drug content parameters (F3 and F9) coated by dip coating method. The results of physicochemical evaluation of prepared coated tablets are shown in Table 6. The weight variation was found to be between 0.211 ± 0.024 % to 214 ± 0.021 mg. The drug content was found to be between 93.47 ± 0.23% to 98.45 ± 0.12%. The hardness was found to be from 5.2 ± 0.11 to 6.5 ± 0.15 Kg / cm2.

In-vitro drug release studies of enteric coated tablets:

The in vitro release of pantoprazole sodium from the prepared tablets was studied in ph 1.2 for 2 h and in phosphate buffer pH 6.8 for 1 h. In vitro dissolution studies were performed using USP Type II rotating paddle dissolution apparatus (Electrolab TDT-08L, India) by using 1.2N HCl and phosphate buffer (pH 6.8) as a dissolution medium. Formulation which shows most satisfactory result is C2F9, where drug release started after 2 hrs, and released maximum 99.72 by 3hrs. Remaining were respectively, released started and reached maximum, CIF3-90 min and 96.42 in 3 hrs, C2F3-2 hrs and 94.59 in 195 min, E1F3- 90 min and 98.15 in 165 min, E2F3-105 min and 97.54 in 3 hrs, C1F9-90 min and 99.79 in 165 min, EIF9-90 min and 97.97 in 165 min, E2F9-2 hrs and 97.39 in 3 hrs. The cumulative percentage releases of pantoprazole sodium from the tablets were shown in Table 7-14 and Figure 1-2.

Stability studies:

Stability of a drug in a dosage form at different environmental conditions is important as it determines the expiry date of that particular formulation. Changes in the physical appearance, color, odor, taste or texture of the formulation indicate the drug instability. Among the three enteric coated Formulation, Formulation C2F9 was selected for stability studies based on the physicochemical characterization of coating films and release characteristics.

The stability studies were carried out at 40 ± 2 °C with 75 ± 5%% RH which shown in Table 20. There were no significant changes in their physical appearance, average weight of tablets and hardness. It was observed that the initial drug content and the drug contents of the samples analyzed after 1,2,3 month of storage were similar. The release profile also not showed any significant changes indicating that there were no significant changes in the physical as well as chemical characteristics of the formulation. Hence, it can be concluded from the results that the developed tablets were stable and retain their pharmaceutical properties over a period of 3 month.

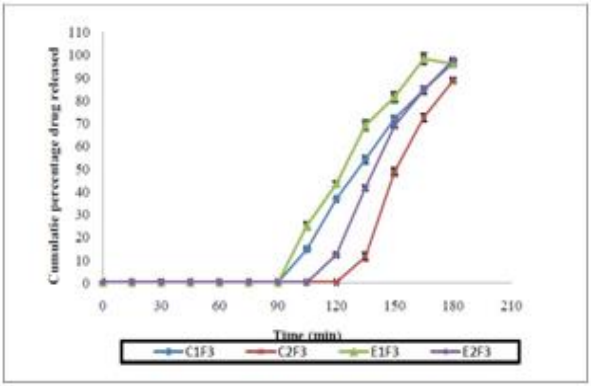

Figure.1.In-vitro drug release of pantoprazole sodium (C1F3 to E2F3)

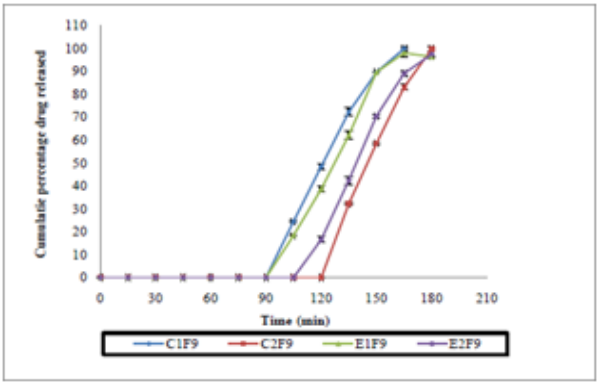

Figure.2. *In-vitro* drug release of pantoprazole sodium (C1F9 to E2F9)

Table.1. Composition of pantoprazole sodium enteric coated sodium tablets

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

Table.2. Composition of coating solution

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

Table.3.Pre compression parameters of pantoprazole sodium

Formulation Code	**Parameter**				
	Bulk density (gm/mL) *	**Tapped Density (gm/mL) ***	**Carr's Index (%)***	**Hausner's ratio***	**Angle of repose (Θ)***
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

***Mean ± SD; n=3**

Table.4.Post compression parameters of pantoprazole sodium core tablets

Formulation Code	**Parameter**				
	Hardness (Kg/cm^2)*	**Friability (%)***	**Weight Variation (mg) ***	**Drug content (%)***	**Disintegration Time (min) ***
F1	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.5.Physicochemical evaluation of different polymer coating films

Polymer	**Parameter**		
	Film solubility		**Film thickness (mm) ***
	pH 1.2	**pH 6.8**	
CAP	Insoluble	Soluble	0.21 ± 0.07
Eudragit L 100	Insoluble	Soluble	0.24 ± 0.08

***Mean±SD, *n* = 3**

Table.6.Physicochemical evaluation parameters of enteric coated tablets

Polymer	**Batch Code**	**Parameter**		
		Weight Variation (mg) *	**Hardness ($Kg/c\ m^2$*)**	**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
EudragitL 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.7. *In vitro* drug release of pantoprazole sodium (C1F3)

Time (min)	Absorbance	Conc. (µg/mL)	Conc. in 900 mL (mg /mL)	Loss	Cumulative loss	Cumulative drugreleased	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.8. *In-vitro* drug release of pantoprazole sodium (C2F3)

Time	Absorbance	Conc. (µg/mL)	Conc in 900	Loss	Cumulative loss	Cumulative	Cumulative
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	0	0	0	0	0	0
120	0	0	0	0	0	0	0
135	0.019	0.4986	4.488	0	0	4.488	11.27 ±0.90
150	0.082	2.1522	19.370	0.0049	0.0049	19.375	48.67±0.27
165	0.122	3.2021	28.818	0.0215	0.0265	28.845	72.46±0.18
180	0.149	3.9107	35.196	0.0320	0.0585	35.255	88.56±0.42
195	0.159	4.1732	37.559	0.0391	0.0976	37.656	94.59±0.70

Table.9. *In vitro* drug release of pantoprazole sodium (E1F3)

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	0.041	1.1051	9.946	0	0	9.946	24.98+0.34
120	0.071	1.9137	17.223	0.0110	0.0110	17.234	43.29+0.62
135	0.116	3.0446	27.401	0.0191	0.0301	27.431	68.91+0.72
150	0.137	3.5958	32.362	0.0304	0.0606	32.422	81.44+0.58
165	0.165	4.3307	38.976	0.0359	0.0965	39.072	98.15+0.40

Table.10. *In vitro* drug release of pantoprazole sodium (E2F3)

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	0	0	0	0	0	0
120	0.02	0.5390	4.851	0	0	4.851	12.18±0.82
135	0.07	1.8372	16.535	0.0053	0.0053	16.540	41.55±0.66
150	0.116	3.0446	27.401	0.0183	0.0237	27.425	68.89±0.72
165	0.142	3.7270	33.543	0.0304	0.0542	33.597	84.39±0.48
180	0.164	4.3044	38.740	0.0372	0.0914	38.831	97.54±0.70

Mean±SD, *n* = 3

Table.11. *In vitro* drug release of pantoprazole sodium (C1F9)

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	0.04	1.0781	9.703	0	0	9.703	24.48+0.18
120	0.079	2.1293	19.164	0.0107	0.0107	19.175	48.38±0.67
135	0.121	3.1758	28.582	0.0212	0.0320	28.614	72.20±0.58
150	0.15	3.9370	35.433	0.0317	0.0638	35.496	89.56±0.42
165	0.167	4.3832	39.448	0.0393	0.1032	39.552	99.79±0.70

Mean±SD, *n* = 3

Table.12. *In vitro* drug release of pantoprazole sodium (C2F9)

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	0	0	0	0	0	0
120	0	0	0	0	0	0	0
135	0.054	1.417	12.755	0	0	12.755	32.18+0.34
150	0.098	2.572	23.149	0.0141	0.0141	23.163	58.44+0.58
165	0.139	3.648	32.834	0.0257	0.0398	32.874	82.94+0.18
180	0.167	0.038	0.043	39.448	0.0364	0.076	99.72+0.46

Table.13. *In vitro* drug release of pantoprazole sodium (E1F9)

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	0.03	0.8086	7.277	0	0	7.277	18.36±0.42
120	0.063	1.6981	15.283	0.0080	0.0080	15.291	38.58±0.22
135	0.104	2.7296	24.566	0.0169	0.0250	24.592	62.05±0.58
150	0.15	3.9370	35.433	0.0272	0.0523	35.485	89.53±0.39
165	0.164	4.3044	38.740	0.0393	0.0917	38.831	97.97±0.48

Mean±SD, *n* = 3

Table.14. *In vitro* drug release of pantoprazole sodium (E2F9)

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	0	0	0	0	0	0
120	0.027	0.7277	6.549	0	0	6.549	16.52±0.16
135	0.071	1.8635	16.771	0.0072	0.0072	16.778	42.33±0.35
150	0.118	3.0971	27.874	0.0186	0.0259	27.899	70.39±0.63
165	0.149	3.9107	35.196	0.0309	0.0568	35.253	88.95±0.44
180	0.163	0.0381	0.042	38.503	0.0391	0.095	97.39±0.61

Mean±SD, *n* = 3

Table.15.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 color tablets	No change	No change	No change
Hardness (Kg / cm^2)*	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

4. Conclusion

An attempt was made in this research work to formulate an oral enteric coating pantoprazole sodium tablet and evaluate it. An ulcer is the disease caused by an imbalance between aggressive and defensive factors. Ulcer sarecrater-like sores which form in the lining of the stomach, just below the stomach at the beginning of the small intestine in the duodenum. Pantoprazole is a substituted benzimidazole derivative that targets gastric acid proton pumps, the final common pathway for gastric acid secretion. The drug covalently binding to the proton pumps, causing prolonged inhibition of gastric acid secretion. The stability of pantoprazole is depending on pH and it rapidly degrades in acid medium of the stomach, but stable in alkaline conditions. Therefore, pantoprazole should be delivered into the intestine. Hence, an attempt was made to formulate an enteric coated drug delivery system for pantoprazole by using various enteric coating polymers. From the reproducible results obtained from the executed experiments it can be concluded that CAP and Eudragit L 100 can be used as enteric coated polymer. Both the polymer can protect the drug from the acid environment that is in gastric pH and release the drug when it's reached in intestinal pH. In this present research work, both the polymer has been used as an enteric coating polymer, with

the best formulation. CAP and EudragitL100 have been used 6% and 8% with the best formulation. From the dissolution studies it was observed that, the enteric coated both polymer was intact for 2 hours in pH 1.2 buffer. The formulation which is said to the best formulation is C2F9, which is formulation no. 9 and coated with 8% CAP. Therefore the study proved that the pantoprazole enteric coated tablets can be used for ulcer and GERD disease. Hence, formulation of pantoprazole as an enteric coated tablet may solve the stability problem of drug in the stomach and release the drug in the intestine. After satisfied pre-compression and post compression result the of core tablets, tablets were coated with suitable coating material to develop the dosage form which is to overcome the drug degradation by the gastric enzymes as well as the acidic environment of the stomach.

5. References

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