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FORMULATION AND EVALUATION OF ENTERIC COATED TABLETS PANTOPRAZOLE SODIUM BY DIRECT COMPRESSION METHOD

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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.

Key words: *Pantoprazole, Direct compression, Proton pump inhibitor, Cellulose acetate phthalate, Eudragit L100*

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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 most important reasons for enteric coating can be summarized as follows: - to protect acid-labile drugs from gastric fluid (e.g. enzymes and certain antibiotics), - to prevent gastric distress or nausea due to irritation from a drug (e.g. sodium salicylate), - to deliver drugs intended for local action in the intestines (e.g. intestinal antiseptics could be delivered to their site of action in a concentrated form and bypass systemic absorption in the stomach), - to deliver drugs that are optimally absorbed in the small intestine to their primary absorption site in their most concentrated form, - to provide a delayed-release component for repeat action .

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). 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 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

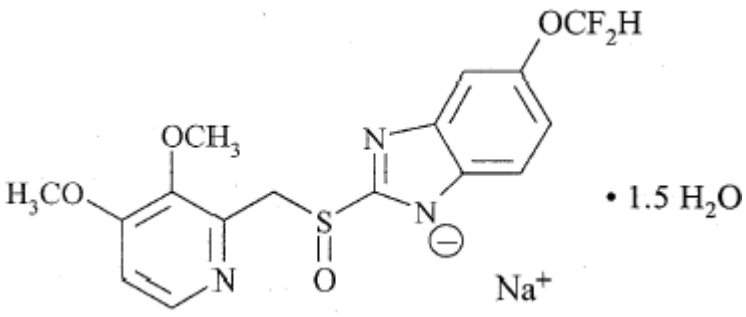
DRUG AND EXCIPIENTS PROFILE:

1.1 PANTOPRAZOLE

Chemistry: Chemically, pantoprazole sodium sesquihydrate, is a sodium 5- (difluoromethoxy)-2[[(3,4,dimethoxy-2pyridinyl)methyl] sulfinyl] -1H benzimidazole sesquihydrate.

Molecular formula: $C_{16}H_{15}F_2N_3O_4S.\ 1.5\ H_2O$

Molecular weight: 432.4 gm/mol.



. 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

Calibration data of pantoprazole sodium in phosphate buffer (pH 6.8)

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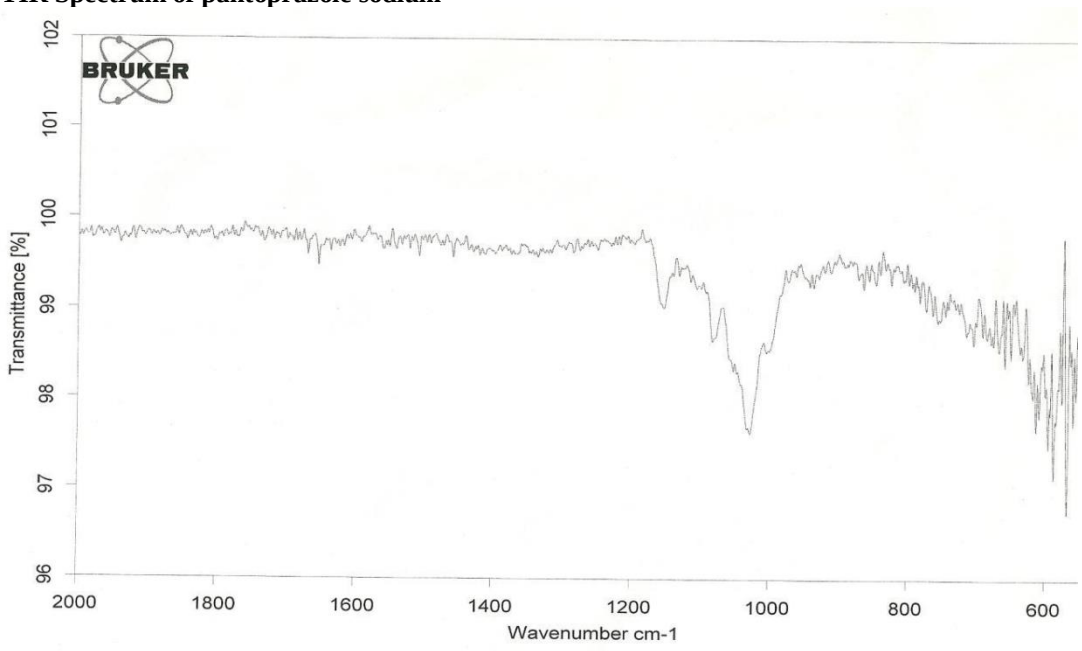
5	8	0.305±0.0075
6	10	0.373±0.0051
7	12	0.468±0.0020

*Mean±SD, *n* = 3

FTIR Spectrum of pantoprazole sodium



Standard band frequency of Pantoprazole Sodium

Wave number in cm^{-1}	Characteristic
1900	C=H
1650 - 1580	N-H bending
1600 - 1400	Aromatic C=C stretching
1400 - 1000	C-N bending
1373	C-F
1049	S=O

The spectra obtained from the physical mixture show that all the principle peaks are at or around the requisite wave number of pure drug. Thus it may be inferred that there was no chemical interaction between drug and polymer and the purity and integrity of drug was maintained in the physical mixtures.

Evaluations:

Precompression parameters

The prepared pantoprazole powder blend for tabletting was prepared by direct compression method. 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 30 º (25.79 ± 0.24 to 29.52 ± 0.14) also indicate the good flowability of the prepared granules.

Formulation studies:

Preparation of of pantoprazole sodium tablets:

The pantoprazole sodium sesquihydrate tablets were prepared by direct compression method A total of nine formulations (F1-F9) by using a rotary tablet compression machine (8 mm diameter, Riddhi 10 stn mini tablet press RDB4-10, Rimek, Ahmedabad, India). Compositions of the pantoprazole sodium sesquihydrate tablets are shown in **Table 1**

Table 1 :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

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 2).**

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 favorable result.

Table 2 . 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

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 3).**

Physicochemical evaluation of pantoprazole sodium enteric coated tablets:
The tablets which shows 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 4**. 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.

Table 4 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 5. Physicochemical evaluation parameters of enteric coated tablets

Polymer	Batch Code	Parameter		
		Weight Variation (mg) *	Hardness Kg/cm^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
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

***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 1.2 N 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 3 hrs. 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.

Table 6. *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 7. *In vitro* drug release of pantoprazole sodium (C2F3)

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	0.019	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

***** Mean±SD, $n = 3$

Table 8. *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

* Mean±SD, $n = 3$

Table 9. *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 10. *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 11. *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

* Mean±SD, *n* = 3

Table 12. *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 13. *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

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

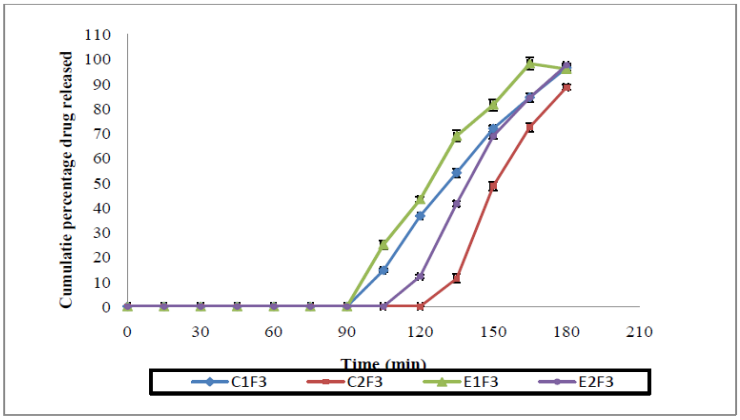
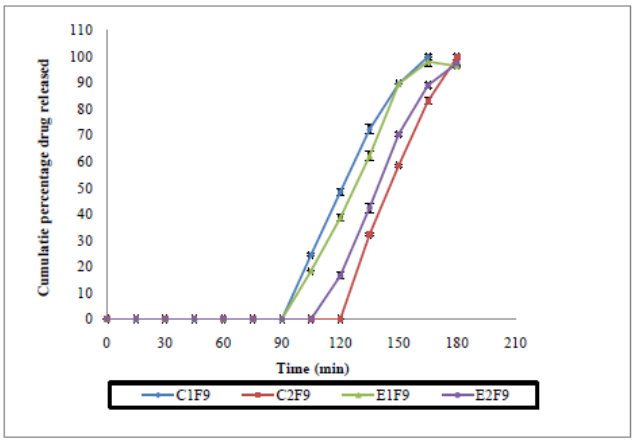


Figure 2. *In vitro* drug release of pantoprazole sodium (C1F9 to E2F9)



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 14**. 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.

Physicochemical evaluation of pantoprazole sodium enteric coated tablets

The tablets which shows 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 . 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.

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

SUMMARY:

The aim of the present study was to formulate and evaluate of enteric coated pantoprazole sodium sesquihydrate tablets by using manotol, dicalcium phosphate, microcrystalline cellulose, crossrmelose sodium, magnesium starate and talc.

FT-IR study was carried out to check any possible interactions between the drug and the excipients manotol, dicalcium phosphate, microcrystalline cellulose, crosscarmelose sodium, Pantoprazole sodium sesquihydrate were prepared by direct compression method using different concentration of, Avicel PH (MCC) as filler, mannitol and dicalcium phosphate as diluents, croscarmellose sodium as disintegrating agents, magnesium stearate and talc was used as a glidant and lubricant respectively. The granules were evaluated for the precompression parameters like angle of repose, bulk density, tapped density and compressibility index. The flow characteristics of the granules were assessed by determining their angle of repose and Carr's Index. The values of compressibility index and angle of repose signify good flowability of the granules for all the batches. This shows that the granules had smooth flow properties ensuring homogenous filling of the die cavity during the compression (punching) of tablets.

Coating has been done for the selected formulation from the proposed formulation 1-9. Coating materials like CAP and Eudragit L100 with the difference concentration.

The *in vitro* dissolution studies were carried out for compressed and coated tablets using USP dissolution apparatus type II. The cumulative percentage of drug release from the tablets varied and depends on the type of polymer used and its concentration.

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.

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