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Formulation and In-Vitro Evaluation of Fast Dissolving Tablets of Anti-Ulcer Drugs

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ABSTRACT

Pantoprazole is a proton pump inhibitor that decreases the amount of acid produced in the stomach mainly used to treat erosive esophagitis and other condition involving excess stomach acid such as Zollinger-Ellison syndrome. The objective of present study was to Formulate and Evaluate fast dissolving tablets of Pantoprazole sodium. In the preformulation study, IR Spectra of pure drug and with different polymers showed no interaction (no shift in peak). To enhance faster disintegration rate, super disintigrants such as croscarmallose sodium, Crospovidone and Sodium starch glycolate were tried. To evaluate their role in fast dispersion, they were used in different concentrations hence in the present study 9 formulations were prepared. The prepared tablets were subjected to various parameters like uniformity of weight, hardness, friability, drug content, water absorption ratio, wetting time, in vitro disintegration time and in vitro dissolution studies. The effect of different super disintigrants over the Drug release profile was investigated. In the study, all powder blends showed good flow ability (angle of repose below 30º), bulk density in the range between 0.33-0.37 g/cm^3 tapped density in the range between 0.34 and 0.39 g/cm^3, and the compressibility index was found to be between 5.83 and 9.98 %, which ensures the blend that may be suitable for direct compression in to tablets. In vitro disintegration time for all formulation batches i.e. F-1 to F-9 showed wide variation in the range between 8.78.64 to 19.35 seconds and % Drug dissolved at 30 seconds. The prepared tablets exhibited satisfactory physico-chemical characteristics. The prepared formulations containing superdisintegrants, Crospovidone Along with microcrystalline cellulose showed faster dispersion and dissolution profile as compared with other two superdisintegrants containing formulations. Moreover, the study revealed Crospovidone showed satisfactory results than the superdisintegrants like croscarmilose sodium and sodium starch glycolate.

Keywords: Pantoprazole, Fast dissolving tablets, polymers, *in-vitro* drug release.

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INTRODUCTION

Fast dissolving tablet is a solid dosage form that dissolves or disintegrates within a minute in the oral cavity without the need of water and has a pleasant taste. FDT is also known as orally disintegrating tablet, fast-dissolving tablet, fast-melting tablet or mouth melting tablet. Orally disintegrating tablets are also called as Orodispersible tablet, quick disintegrating tablets Fast Disintegrating tablets. Fast disintegrating tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets and rapid melt. European pharmacopoeia has used the term orodispersible tablet for tablet that disperse readily and within 3 min in mouth before swallowing.

When water is not available, in the case of motion sickness (kinetosis) and sudden episodes of coughing during the common cold, allergic conditions and bronchitis for these reasons, tablets which can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Rapidly dissolving or disintegrating tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people.

Pantoprazole is a proton pump inhibitor that decreases the amount of acid produced in the stomach mainly used to treat erosive esophagitis and other condition involving excess stomach acid such as Zollinger-Ellison syndrome.

MATERIALS AND METHOD

Preformulations Studies

Standard calibration curve of pantoprazole sodium: Pantoprazole exhibits peak absorbance at 288 nm in Phosphate buffer having pH 6.4 represents the maximum absorbance (λmax) of the drug.

Procedure:

λmax of pantoprazole = 288nm

Beer's range of pantoprazole = 1-5 µg/m

Preparation of standard solution:

1º stock: 100 mg of pantoprazole was weighed accurately into 100 ml volumetric flask and the volume was made up with Phosphate buffer.

2º stock: Pipette 1ml of the solution into another 100ml volumetric flask and the volume was made with the water. (i.e.: 10µg/ml in water.)

Preparation of working standard solution: Aliquots of standard solution 1ml, 2ml, 3ml, 4ml, 5ml were pipette into 10ml volumetric flasks. The volume made up with water. The absorbance of each concentration was measured at 288 nm using Phosphate buffer as a blank.

Table 1: Standard calibration data of Pantoprazole in phosphate buffer (pH 6.4)

Sl. No.	Concentration (µg/ml)	Absorbance at 288 nm Trial 1	Trail 2	Trail 3	Average	S.D
1	1	0.026	0.029	0.026	0.027	0.0014
2	2	0.059	0.056	0.059	0.057	0.0014
3	3	0.082	0.089	0.084	0.085	0.0029
4	4	0.113	0.112	0.114	0.113	0.0008
5	5	0.139	0.147	0.140	0.142	0.0035

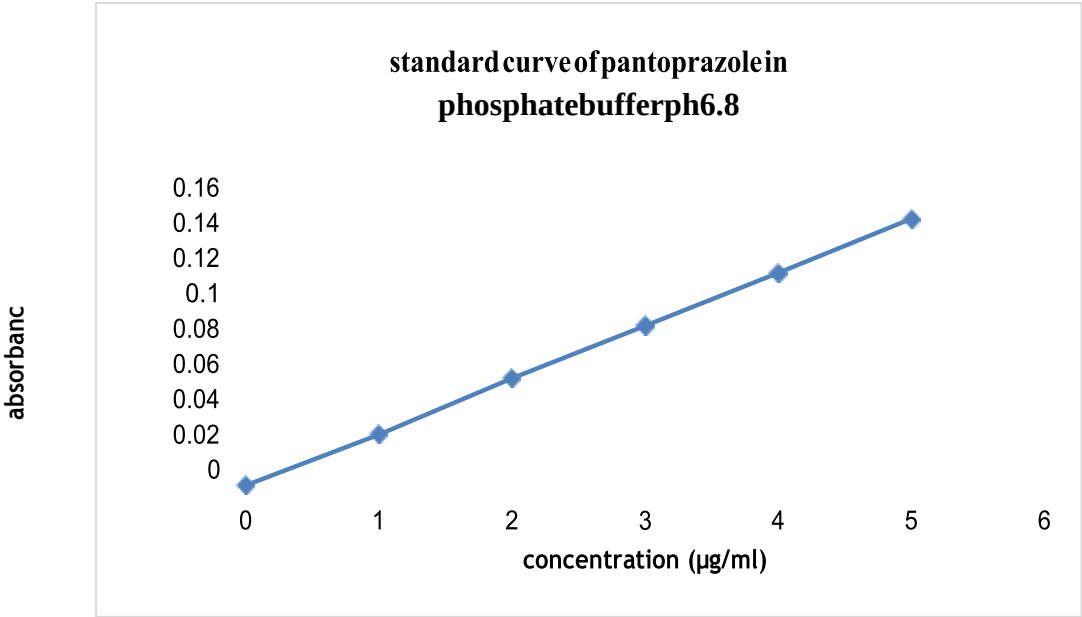

Figure:1 Standard Curve of Pantoprazole in Phosphate buffer(P^H 6.8)

Formulation

The drug was mixed with proper portion of superdisintegrants. Care was taken to confirm the proper mixing of drug and superdisintegrants. Then the mixture is passed through sieve No.44, after addition of the other excipients. The mixture was blended with lubricating agent (magnesium stearate) and glidant. Finally the blend was subjected for compression using 10mm on Rimek mini press 10 station machines**.**

Table 2 Formulations Pantoprazole Sodium

S.No	Ingredients(mg)	Formulations								
		F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
1	Pantoprazole	20	20	20	20	20	20	20	20	20
2	Sodium starch glycolate	10	15	20	.....	.....	.....	.....	.....	.....
3	Cros Carmilose sodium	.....	.....	.....	10	15	20	.....	.....	.....
4	Cros Povidone	.....	.....	.....	.....	.....	.....	10	15	20
5	Talc	3	3	3	3	3	3	3	3	3
6	Saccharin	4	4	4	4	4	4	4	4	4
7	Magnesium stearate	2	2	2	2	2	2	2	2	2
8	Micro crystalline cellulose	161	156	151	161	156	151	161	156	151
Total		200	200	200	200	200	200	200	200	200

RESULTS AND DISCUSSION

Table 3: Pre-compression parameters of pantoprazole powder mixture

Formulation code	Angle of repose(θ)	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Compressibility	Hausner's Ratio
F1	29.02±1.32	0.35±0.012	0.39±0.005	9.98±0.78	1.11±0.009
F2	28.15±1.97	0.33±0.005	0.36±0.008	7.98±0.16	1.08±0.002
F3	27.06±1.19	0.36±0.017	0.38±0.007	5.99±0.04	1.06±0.012
F4	27.6±1.80	0.35±0.003	0.37±0.003	6.06±0.07	1.06±0.007
F5	29.02±1.48	0.36±0.012	0.39±0.002	8.10±0.16	1.08±0.003
F6	25.88±1.17	0.35±0.015	0.36±0.001	14.04±0.23	1.16±0.017
F7	27.70±1.75	0.33±0.020	0.34±0.002	6.89±0.09	1.07±0.015
F8	26.36±1.48	0.37±0.007	0.39±0.003	5.83±0.03	1.06±0.005
F9	27.70±1.38	0.33±0.014	0.35±0.002	5.86±0.02	1.06±0.006

Table 4: Evaluation of post compression parameters of fast dissolving tablet containing Pantoprazole:

Formulation	Thickness(mm)	Wetting time (sec)	Water abs. ratio(%)	In vitro dispersion Time(sec)
F_1	3.02 ±0.03	32±2.13	86±3.12	26±0.8
F_2	3.05±0.02	27±3.7	84±2.98	23±0.2
F_3	3.12±0.02	28±4.1	87±3.19	21±0.8
F_4	3.17±0.12	22±3.41	91±0.02	18±1.2
F_5	3.08±0.8	21±3.1	93±1.94	17±0.8
F_6	3.1±0.17	19±1.2	95±2.12	19±0.59
F_7	3.1±1.2	29±2.87	76±2.10	28±1.2
F_8	3.05±0.8	30±3.78	74±1.20	26±0.22
F_9	3.2±0.12	28±1.28	78±2.28	25±0.58

FTIR STUDIES

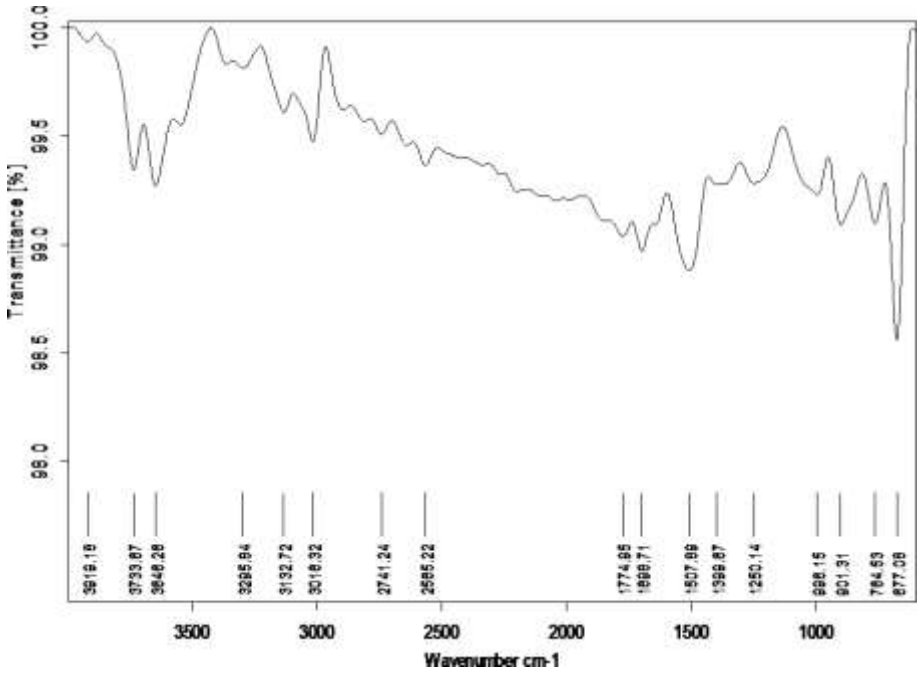

Figure 2: FTIR of Pure Pantoprazole

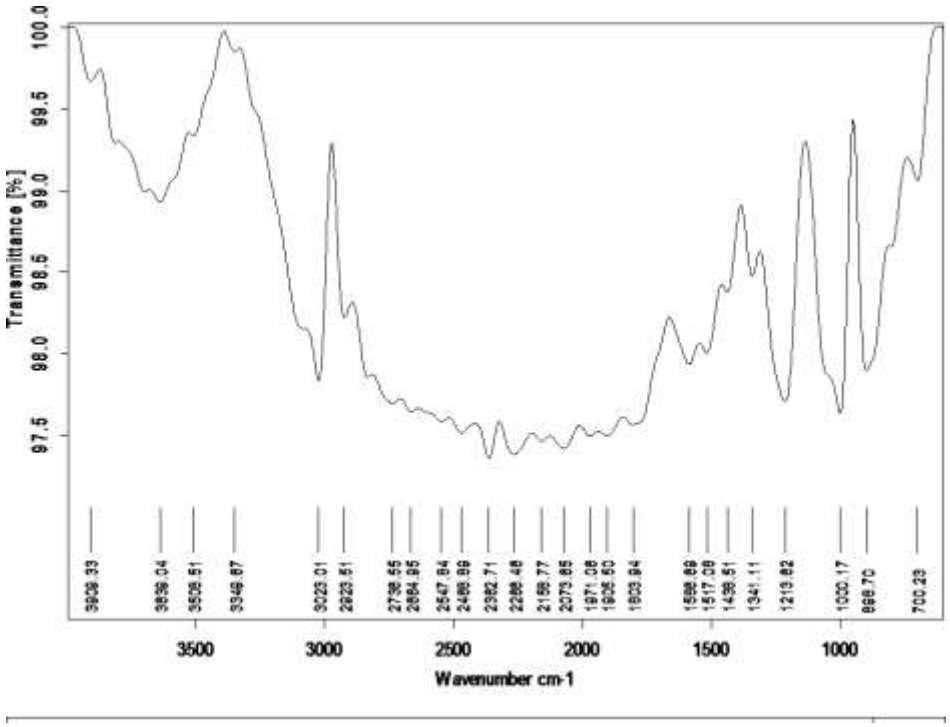

Figure 3: FTIR of Pantoprazole. + Cross Povidone.

Table 5: In vitro dissolution study of formulations (F1)

Weight of the tablet = 204 mg. Amount of drug present= 19.4mg

Time (min)	Abs	Concentration (µg/ml)	D.F.	Amount in 5ml	Amount in 900ml	CLA	CDR	%CDR
0	0	0	0	0	0	0	0	0
2	0.0269	0.9438	10	0.04719	8.494	0	8.494	43.78
4	0.0356	1.2491	10	0.06245	11.2491	0.04719	11.2890	58.14
6	0.0489	1.7157	10	0.08578	15.4413	0.10964	15.5509	80.15
8	0.0542	1.9017	10	0.09508	17.1153	0.19542	17.3107	89.23
10	0.0571	2.0035	10	0.1001	18.0315	0.2905	18.322	94.44

Table 6: In vitro dissolution study formulations F2

Weight of the tablet = 205 mg. Amount of drug present= 19.6mg

Time (min)	Abs	Concentration (µg/ml)	D.F.	Amount in 5ml	Amount in 900ml	CLA	CDR	%CDR
0	0	0	0	0	0	0	0	0
2	0.0281	0.9859	10	0.04929	8.8731	0	8.8731	45.27
4	0.0371	1.3017	10	0.06508	11.7153	0.04929	11.7645	60.02
6	0.0498	1.7473	10	0.08736	15.7257	0.1143	15.840	80.81
8	0.0531	1.8631	10	0.0931	16.7679	0.9879	17.7558	90.59
10	0.0584	2.0491	10	1.0245	18.4419	1.081	19.5229	99.60

Table 7: *In vitro* dissolution study of formulations F3

Weight of the tablet = 206 mg. Amount of drug present= 19.72 mg

Time (min)	Abs	Concentration (µg/ml)	D.F.	Amount in 5ml	Amount in 900ml	CLA	CDR	%CDR
0	0	0	0	0	0	0	0	0
2	0.0312	1.0947	10	0.0547	9.8523	0	9.8523	49.96
4	0.0361	1.2666	10	0.0633	11.3994	0.0547	11.4541	58.08
6	0.0501	1.7578	10	0.0878	15.8202	0.118	15.9382	80.82
8	0.0539	1.8912	10	0.0945	17.0208	0.2058	17.2266	87.35
10	0.0594	2.0842	10	0.1042	18.7578	O.3003	19.0581	96.64

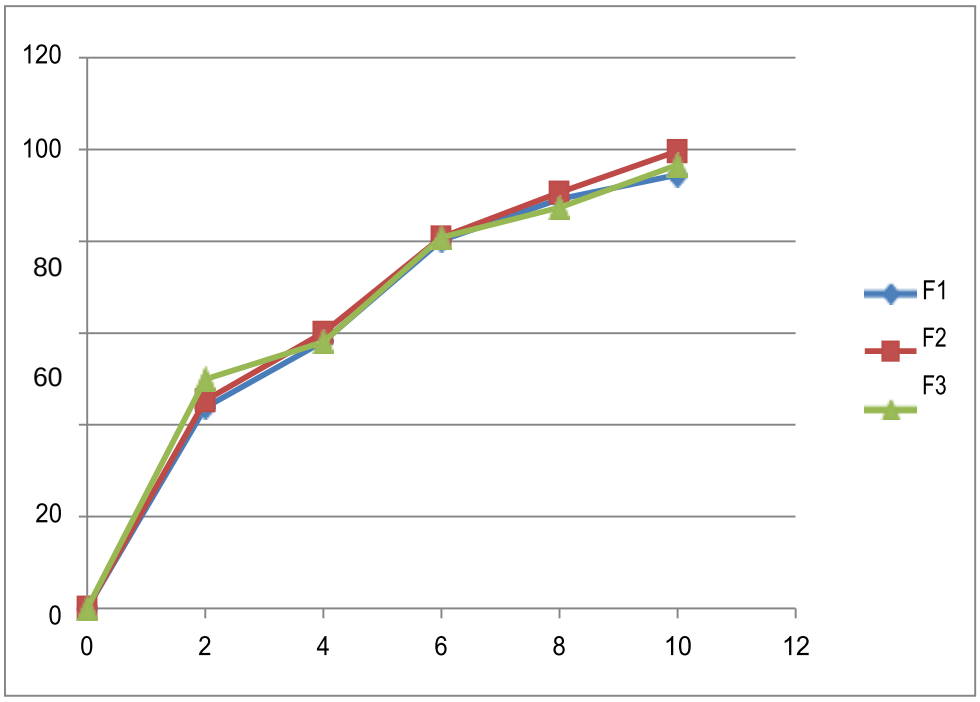

Figure 10: In vitro drug release for F1, F2 and F3

Table 8: In vitro dissolution study of formulations F4

Weight of the tablet = 202 mg. Amount of drug present= 19.56 mg

Time (min)	Abs	Concentration (µg/ml)	D.F.	Amount in 5ml	Amount in 900ml	CLA	CDR	%CDR
0	0	0	0	0	0	0	0	0
2	0.0271	0.9508	10	0.0475	8.5572	0	8.5572	43.74
4	0.0301	1.0561	10	0.0528	9.50	0.475	9.9799	51.02
6	0.0467	1.6385	10	0.0819	14.7465	0.5278	15.2743	78.08
8	0.0514	1.8035	10	0.0901	16.2315	0.6097	16.8412	86.10
10	0.0571	2.0035	10	0.1001	18.0315	1.5107	19.5422	99.9

Table 9: In vitro dissolution study of formulation F5

Weight of the tablet = 203mg. Amount of drug present = 19.8

Time (min)	Abs	Concentration (µg/ml)	D.F.	Amount in 5ml	Amount in 900ml	CLA	CDR	%CDR
0	0	0	0	0	0	0	0	0
2	0.0279	0.9789	10	0.0489	8.8101	0	8.8101	44.49
4	0.0312	1.0947	10	0.0547	9.8523	0.0489	9.9012	50
6	0.0498	1.7473	10	0.0873	15.72	0.1036	15.8236	79.91
8	0.0542	1.9017	10	0.0950	17.1153	0.1909	17.3062	87.40
10	0.0571	2.0035	10	0.1001	18.0315	0.2859	18.3174	92.51

Table 10: In vitro dissolution study of formulations F6

Weight of the tablet = 203 mg. Amount of drug present= 19.76 mg

Time (min)	Abs	Concentration (µg/ml)	D.F.	Amount in 5ml	Amount in 900ml	CLA	CDR	%CDR
0	0	0	0	0	0	0	0	0
2	0.0259	0.9087	10	0.0454	8.1783	0	8.1783	41.38
4	0.0321	1.1263	10	0.0563	10.1821	0.0454	10.1821	51.52
6	0.0498	1.7473	10	0.0873	15.7257	0.1017	15.8274	80.09
8	0.0550	1.9298	10	0.0964	17.3682	0.189	17.5572	88.85
10	0.0594	2.0842	10	0.1042	18.7578	0.2854	19.0432	96.37

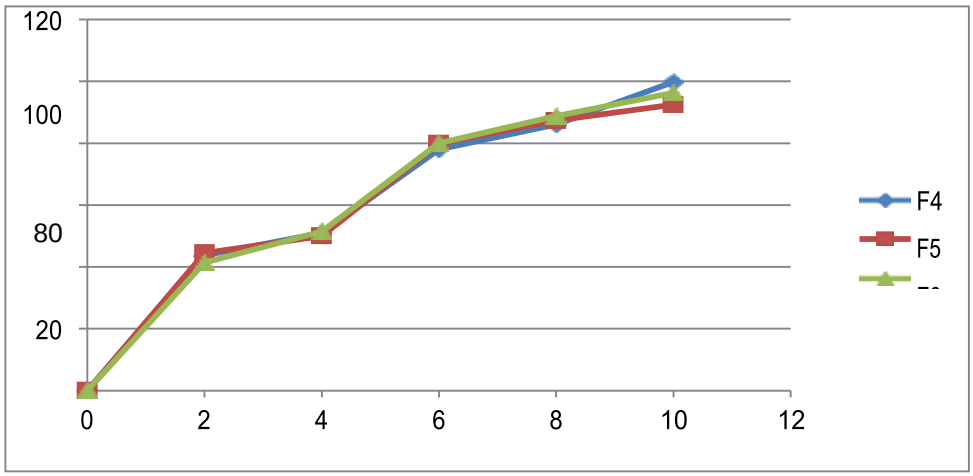

Figure 11: *In vitro* dissolution study of formulations F4, F5 and F6

Table 11: *In vitro* dissolution study of formulations F7

Weight of the tablet = 205 mg. Amount of drug present= 19.62 mg

Time min	abs	Concentration (µg/ml)	D.F	Amount in 900ml	CLA	CDR	%CDR
0	0	0	0	0	0	0	0
2	0.0281	0.9859	10	00492	8.8731	8.8731	45.22
4	0.0312	1.0947	10	0.0547	9.8523	9.9015	50.46
6	0.0514	1.8035	10	0.0901	16.2315	16.3354	83.25
8	0.0539	1.8912	10	0.0945	17.0208	17.2148	87.74
10	0.0571	2.0035	10	0.1001	18.0315	18.32	93.37

Table 12: *In vitro* dissolution study of formulations F8

Weight of the tablet = 206 mg. Amount of drug present= 19.56 mg

Time (min)	Abs	Concentration (µg/ml)	D.F.	Amount in 5ml	Amount in 900ml	CLA	CDR	%CDR
0	0	0	0	0	0	0	0	0
2	0.0301	1.0561	10	0.0528	9.5049	0	9.5049	48.59
4	0.0334	1.1719	10	0.0585	10.5471	0.0528	10.6018	54.20
6	0.0514	1.8035	10	0.0901	16.2315	0.1113	16.3428	83.55
8	0.0550	1.9298	10	0.0964	17.3682	0.2014	17.5696	89.82
10	0.0594	2.0842	10	0.1042	18.7578	0.2978	19.0556	97.42

Table 13: *In vitro* dissolution study of formulations F9

Weight of the tablet = 205 mg. Amount of drug present= 19.46 mg

Time (min)	Abs	Concentration (µg/ml)	D.F.	Amount in 5ml	Amount in 900ml	CLA	CDR	%CDR
0	0	0	0	0	0	0	0	0
2	0.0301	1.0561	10	0.0528	9.5049	0	9.5049	48.84
4	0.0371	1.3017	10	0.0650	11.7153	0.0528	11.7681	60.47
6	0.0550	1.9298	10	0.0964	17.3682	0.1178	17.48	89.85
8	0.0571	2.0035	10	0.1001	18.0315	0.2142	18.2457	93.76
10	0.0614	2.1543	10	0.1077	19.3887	0.3143	19.703	101.24

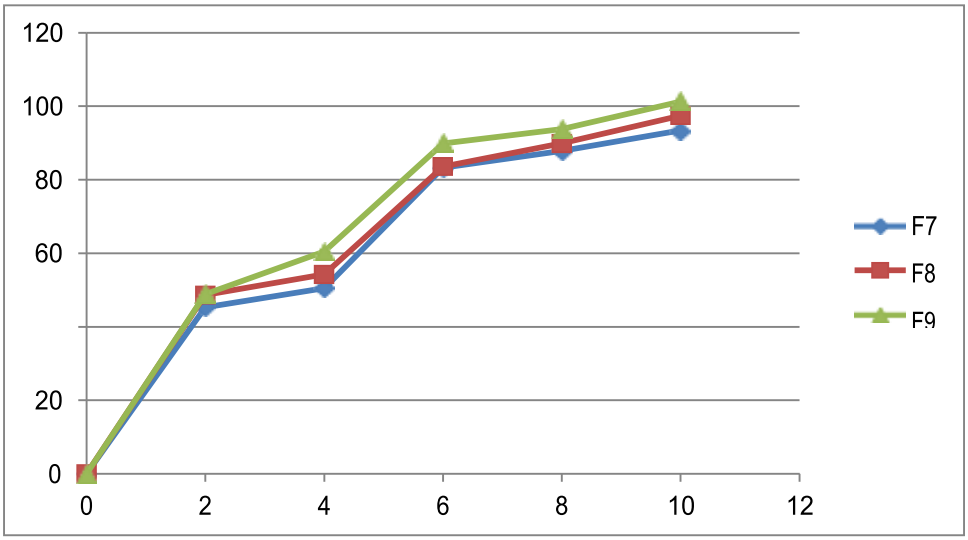

Figure 3: *In vitro* dissolution study of formulations F7, F8 and F9

CONCLUSION

Pantoprazole Sodium, the selective H2 blocker could be used to develop the FDT to release the drug in mouth and immediate absorption for the benefit of effective therapeutic action. The tablets prepared met the standard evaluation parameters with a slight deviation within the prescribed limits. The short term stability studies carried out were confirmative of the drug stability in the tablets during the present study. The disintegration studies revealed that the

tablets prepared with crospovidone shown faster disintegration as compared to tablets prepared with croscarmilose sodium and sodium starch glycolate. Even the dissolution studies confirmed that the tablets prepared with crospovidone, shown faster drug release as compared to tablets prepared with croscarmilose sodium and sodium starch glycolate. From the above said it could safely concluded that the fast dissolving tablets of Pantoprazole Sodium prepared with crospovidone showed better disintegration time and the dissolution profile. Further it is advised that the same work should be confirmed for its therapeutic efficacy with the experimental and clinical trials.

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