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FORMULATION AND EVALUATION OF ORAL DISINTEGRATING TABLET OMEPRAZOLE

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Abstract:

Omeprazole is a proton pump inhibitor, which is clinically used in the treatment of several conditions which includes peptic ulcer disease, Gastrointestinal reflux disease zolliger - ellision syndrome, erosive adenomas, and helicobacter pylori diseases etc. In this present study shows that formulation of oral disintegrating tablet of omeprazole is formulated by using excipients like crosscarmellose sodium, hydroxy propyl beta cyclodextrin Talc, lactose, Mannitol, Magnesium stearate by wet granulation method. preformation studies were conducted for all formulations mixture and were found to be acceptable. the formulated tablet is evaluated for weight variation, Hardness, Friability, disintegration, and in-vitro dissolution. The result shows that the tablets obey with the official standards. The disintegration studies indicates that the formulated tablets disintegrated in less than 60 second the F1 formulation shows less disintegrating time all that is 15 sec. The cross povidone and crosscarmellose sodium acts as super disintegrats for rapid disintegration of tablets, Mannitol and lactose acts as diluent in the tablet formulation they improve bulk and volume of tablet, Hydroxy propyl beta cyclodextrin used as complexing agents which improve the aqueous solubility of omeprazole which results in improve stability and bioavailability, Magnesium stearate acts as lubricant used for easily ejection of tablet from die cavity

Key words: Antiulcer medication, fast disintegrating tablet, omeprazole, crosscarmellose sodium, cross povidone, hydroxy propyl beta cyclodextrin, hydroxy propyl methyl cellulose, mannitol, talc, Magnesium stearate,

INTRODCTION:

Currently oral disintegrating tablet (ODTs) demand and development has vastly increased, ODTs completely differ from conventional tablets in that they are designed to be disintegrated and dissolved on the tongue within a few seconds.

The centre for Drug evaluation and Research (CDER), US FDA defined as oral disintegrating tablet (ODT) As a solid dosage form containing Active pharmaceutical ingredient which disintegrate within 30 seconds in absence of additional water in the buccal cavity before swallowing.

When the oral disintegrating tablet kept on the oral cavity resulting in a solution or suspension form. Orally disintegrating tablets offer many advantages for the people who have difficulty in swallowing, this ODTs shows greater patient compliance in mainly peoples

includes paediatric and geriatric population. omeprazole is a class of proton pump inhibitor which inhibit H+ K+ ATPase pump. which totally abolish HCL secretion on both resting as well as by food, omeprazole does not show its action at neutral PH but at PH <5 shows its action

IDEAL PROPERTIES OF OMEPRAZOLE:

1) No water required for the administration

2) ODTs disintegrate in the mouth within 30min

3) Taste masking property and added additives available for this ODTs

3) Having greater mouth feel

4) ODTs shows less friable

5) Formulation of tablet by using conventional processing and packaging equipment

6) ODTs shows rapid onset of action

Advantages :

1) ODTs provides high rate of patient compliance to the pepe who have difficulty in swallowing such as paediatric, geriatrics, psychiatric patients, kidney failure and bed ridden patients

2) No need to take additional water for administration of tablet

3) ODTs avoid the risk of chocking or suffocation during oral administration

4) Fast disintegration and dissolution hence show rapid onset of action

Disadvantages :

1) ODTs gave lack of tensile strength so care must take during handling required

2) Incase of ODTs not formulated properly they shows unpleasant taste and grittiness in the mouth

3) cost effectiveness

4) Difficult to formulate as MDT

5) people with decreased saliva production face difficult problems during administration

Experimentalmethod:

Materials :

Omeprazole, crosscarmellose sodium, crosspovidone, hydroxy propyl beta cyclodexrin,hydroxy propyl methyl cellulose, lactose, talc, mannitol, magnesium streate all of these pharmaceutical chemicals used for the formulation.

The basic need is used to study and evaluate the rapid disintegrating tablet, different superdisintegrants like crosscarmellose sodium, cross povidone were selected for the formulation of oral disintegrating tablet of omeprazole by wet granulation method

TABLE 1: Formulation of omeprazole

TABLET INGREDIENTS (mg)	**FA1**	**FA2**	**FA3**	**FA4**	**FA5**	**FA6**	**FA7**	**FA8**	**FA9**
Omeprazole	10	10	10	10	10	10	10	10	10
Mannitol	30	30	30	30	30	30	30	30	30
Lactose	33	33	33	33	33	33	23	13	3
Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Mg.stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Hydroxy propyl beta cyclodextrin	50	50	50	50	50	50	60	70	80
Crosscarmellose sodium	21	20	18	14	12	9	18	18	18
Hydroxy propyl methyl cellulose	3	4	6	10	12	15	6	6	6
total	150	150	150	150	150	150	150	150	150

METHOD OF PREPARATION:

1. Accurately weighed the quantity of omeprazole, super disintegrants like crosscarmellose sodium, crosspovidone and additives like mannitol, lactose, Hpmc, Hydroxy propyl beta cyclodextrin, were taken into a motar and mix well then sifted through mesh screen no 60

2. All the powder materials were granulated with liquid binder

3. Wet mass was sieved through mesh screen no 10mm, granules obtained were air-dried in the oven for 2h at 50°c

4. set the moisture contents of granules maintained between 1-2%

5. Above blend compressed with 100mg was compressed by using 6mm by using normal concave punches, Magnesium stearate and tacl 15% is used as a lubricant, tablets were formulated by using rotary tablet machine and set the compression force for the tablets

Weight variation, Hardness, Friability, Invitro-disintegration, Invitro-dissolution, content uniformity, are the evaluation tests performed for the formulated tablets.

RESULTS AND DISCUSSION:

TABLE 2: Evaluation of tablets

TABLET INGRIENTS(mg)	FA1	FA2	FA3	FA4	FA5	FA6	FA7	FA8	FA8
Omeprazol	10	10	10	10	10	10	10	10	10
Mannitol	30	30	30	30	30	30	30	30	30
Lactose	33	33	33	33	33	33	23	13	3
Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Mg. stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Hydroxy propyl beta cyclodextrin	50	50	50	50	50	50	60	70	80
Crosscarmellose sodium	21	20	18	14	12	9	18	18	18
Hydroxy propyl methyl cellulose	4	6	10	12	15	6	6	6	6
Total	150	150	150	150	150	150	150	150	150

Drug release study by in-vitro drug dissolution

Table 3: cumulative percentage drug release of formulation

Time (H)	% Of Drug release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	27.54	22.43	19.36	18.95	15.81	19.59	26.91	19.12	18.28
2	28.71	29.86	26.15	19.76	29.99	20.12	33.75	22.87	19.17
3	32.82	33.91	28.82	20.31	36.76	23.71	35.38	26.40	20.83
4	35.90	47.85	34.67	25.50	44.52	36.68	41.59	36.56	25.50
5	43.73	48.21	41.24	36.93	58.19	39.15	47.16	39.11	33.19
6	46.24	52.53	48.17	45.15	69.74	40.99	55.72	41.08	34.77
7	59.19	63.99	56.78	48.89	70.60	41.17	60.80	46.41	48.99
8	65.98	68.20	59.99	51.73	71.25	55.25	69.98	52.32	49.02
9	76.21	74.85	65.52	55.81	75.15	69.79	74.64	58.49	55.14
10	83.75	79.17	69.63	69.13	88.70	74.38	78.48	60.70	66.30
11	84.63	81.90	78.38	78.96	89.31	89.42	83.15	75.16	78.11
12	98.55	88.13	89.11	89.73	96.68	93.05	95.34	89.21	86.23

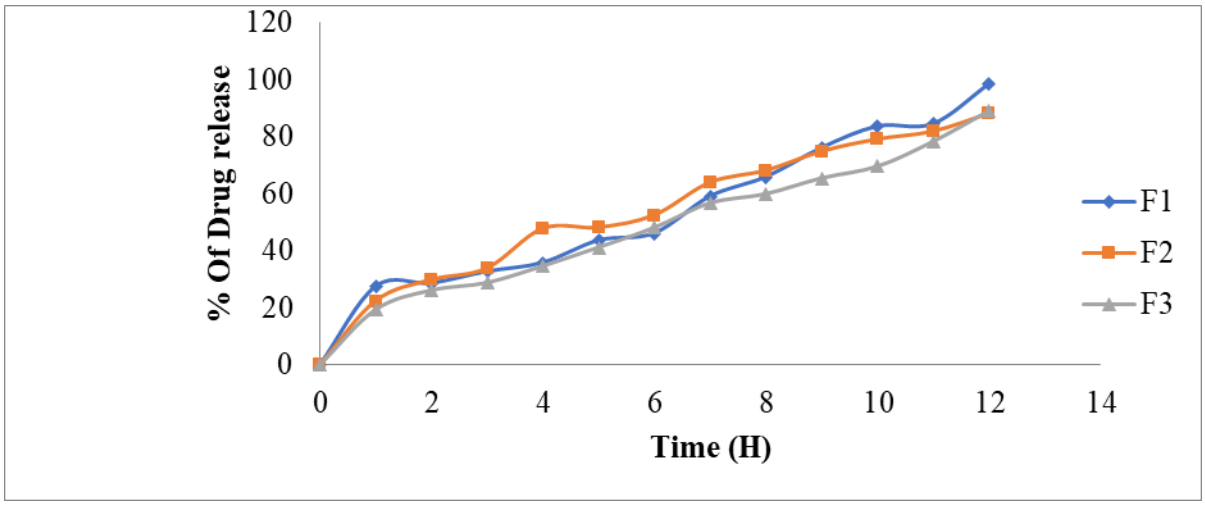


Fig 1: Cumulative percentage of drug release in F1, F2, F3 formulation

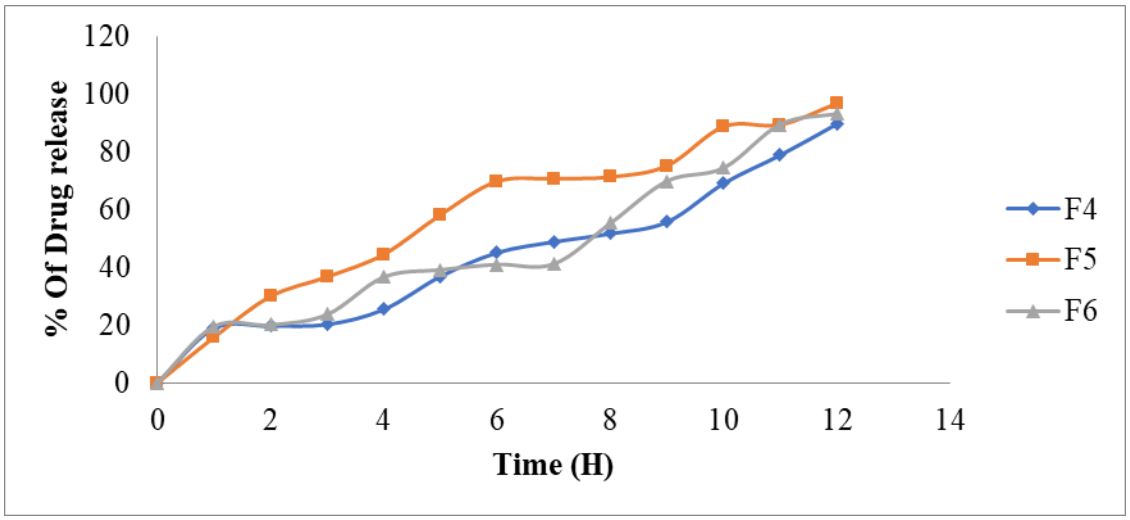


Fig 2: Cumulative percentage of drug release in F4, F5, F6 formulations

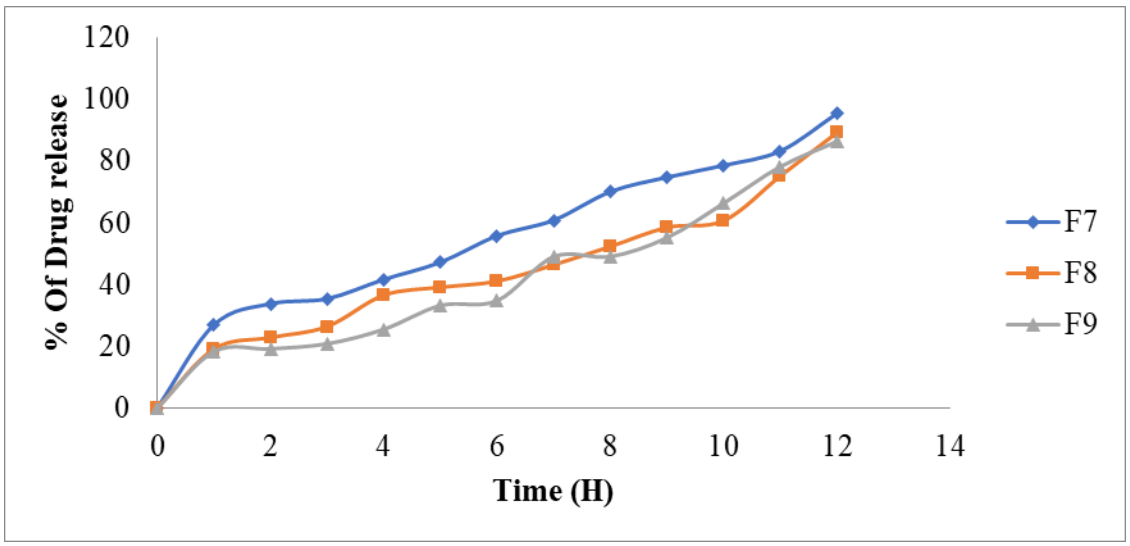
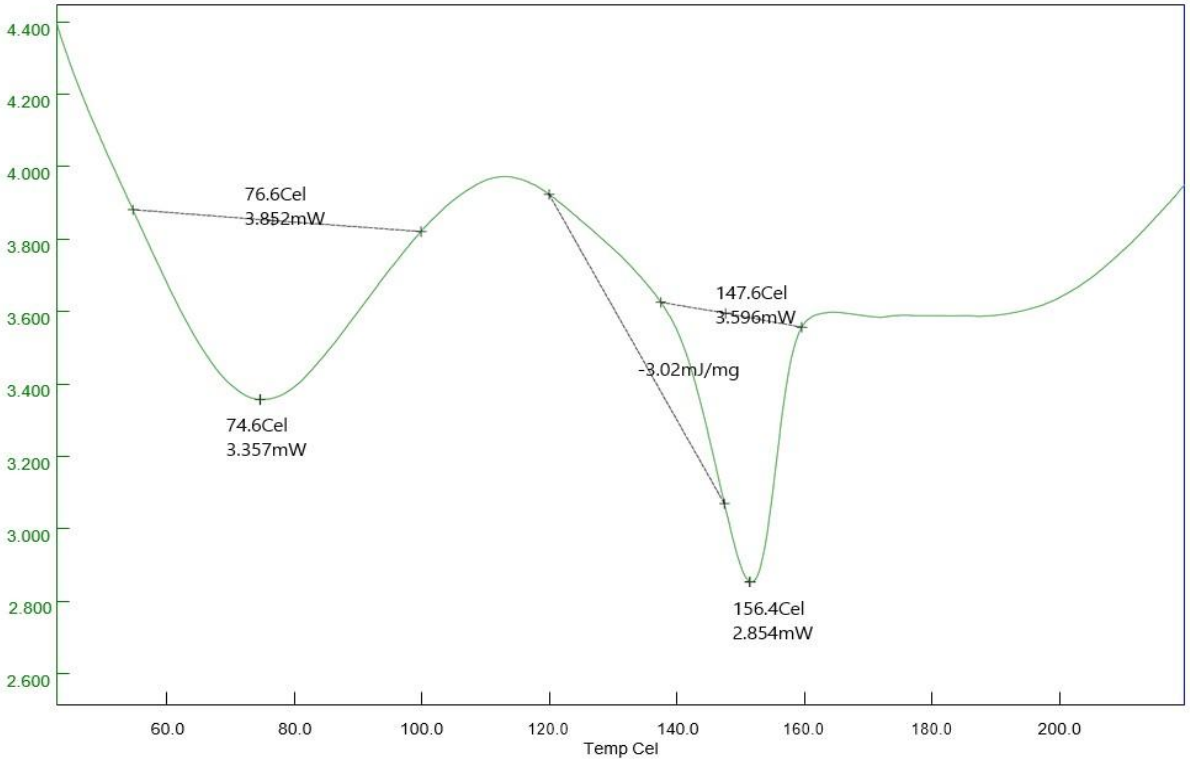


Fig 4: Cumulative percentage of drug release in F7 ,F8, F9 formulations

DSC CURVE OF OMEPRAZOLE

Fig: 5 omeprazole DSC



KINETICS:

Table 4: Kinetics Parameters of Omeprazole

CUMULATIVE (%) RELEASE Q	TIME (T)	ROOT (T)	LOG(%) RELEASE	LOG (T)	LOG (%) REMAIN	RELEASE RATE (CUMULATIVE % RELEASE / t)	1/CUM% RELEASE	PEPPAS log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
27.54	1	1.000	1.440	0.000	1.860	27.540	0.0363	-0.560	72.46	4.642	4.169	0.473
28.71	2	1.414	1.458	0.301	1.853	14.355	0.0348	-0.542	71.29	4.642	4.146	0.495
32.82	3	1.732	1.516	0.477	1.827	10.940	0.0305	-0.484	67.18	4.642	4.065	0.576
35.9	4	2.000	1.555	0.602	1.807	8.975	0.0279	-0.445	64.1	4.642	4.002	0.640
43.73	5	2.236	1.641	0.699	1.750	8.746	0.0229	-0.359	56.27	4.642	3.832	0.810
46.24	6	2.449	1.665	0.778	1.730	7.707	0.0216	-0.335	53.76	4.642	3.774	0.867
59.19	7	2.646	1.772	0.845	1.611	8.456	0.0169	-0.228	40.81	4.642	3.443	1.199
65.98	8	2.828	1.819	0.903	1.532	8.248	0.0152	-0.181	34.02	4.642	3.240	1.401
76.21	9	3.000	1.882	0.954	1.376	8.468	0.0131	-0.118	23.79	4.642	2.876	1.766
83.75	10	3.162	1.923	1.000	1.211	8.375	0.0119	-0.077	16.25	4.642	2.533	2.109
84.63	11	3.317	1.928	1.041	1.187	7.694	0.0118	-0.072	15.37	4.642	2.486	2.155
98.55	12	3.464	1.994	1.079	0.161	8.213	0.0101	-0.006	1.45	4.642	1.132	3.510

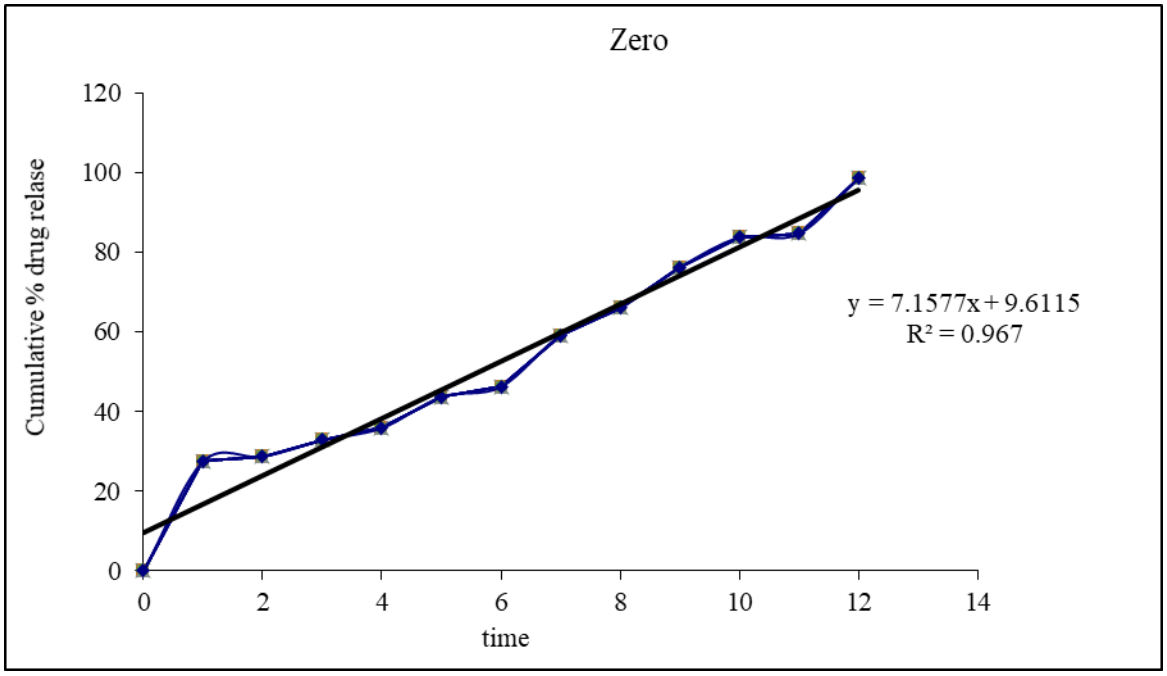


Fig 6 : Zero order release kinetics graph

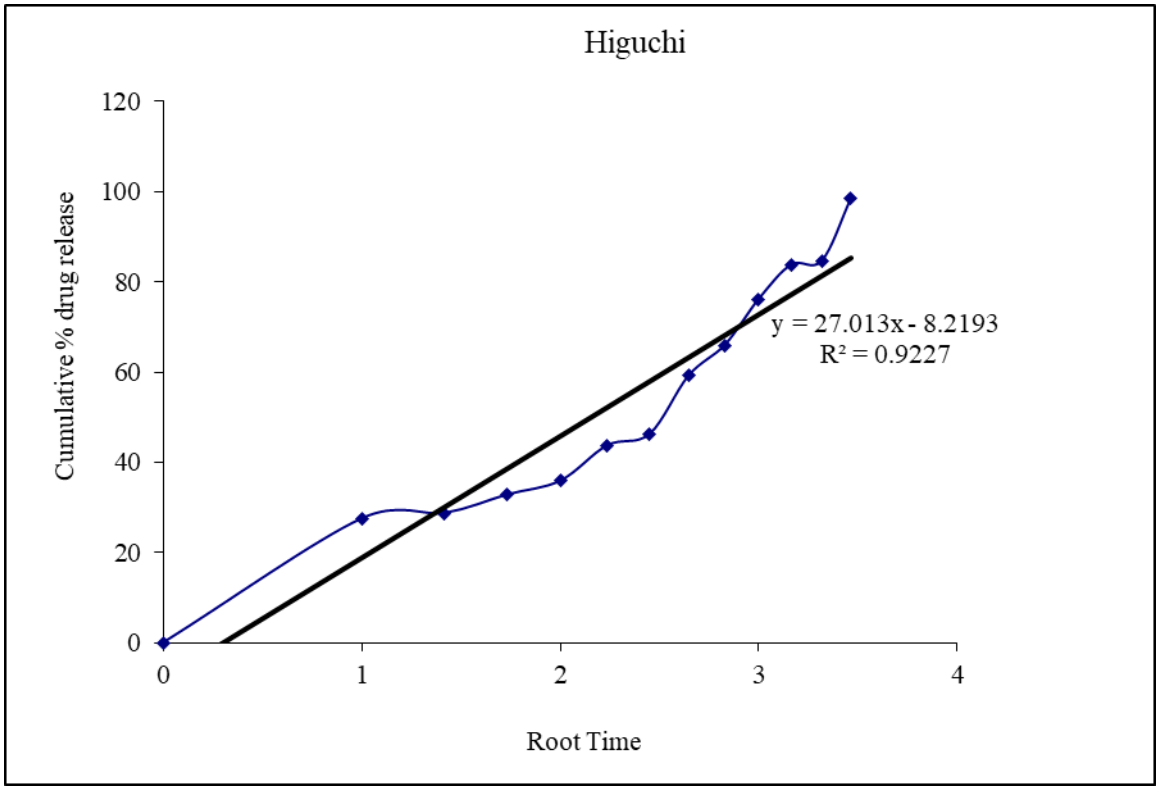


Fig 7 : Higuchi release kinetics graph

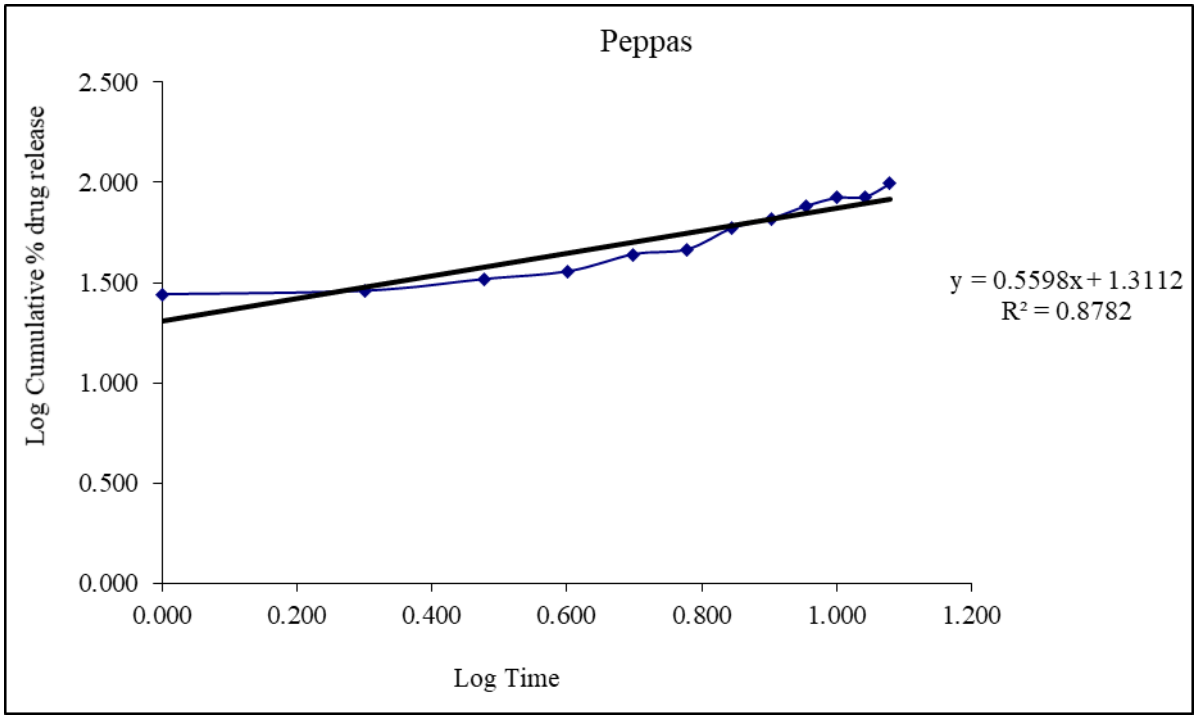


Fig 8: Kars mayerpeppas graph

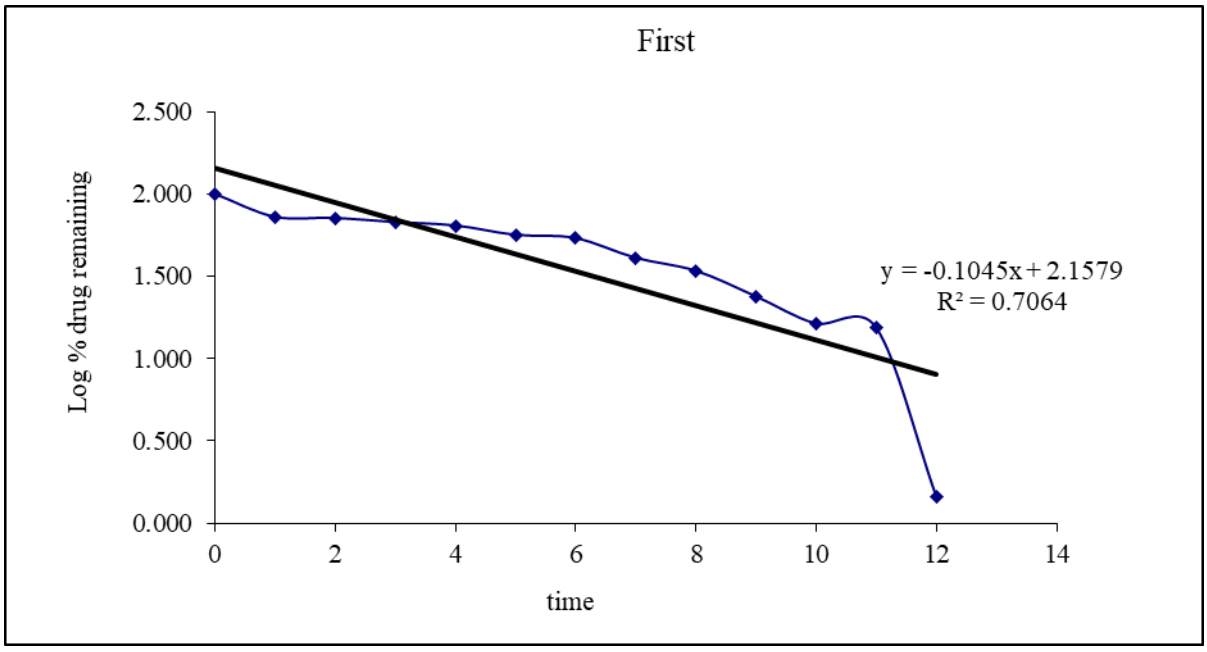


Fig 9: First order release kinetics graph

FTIR

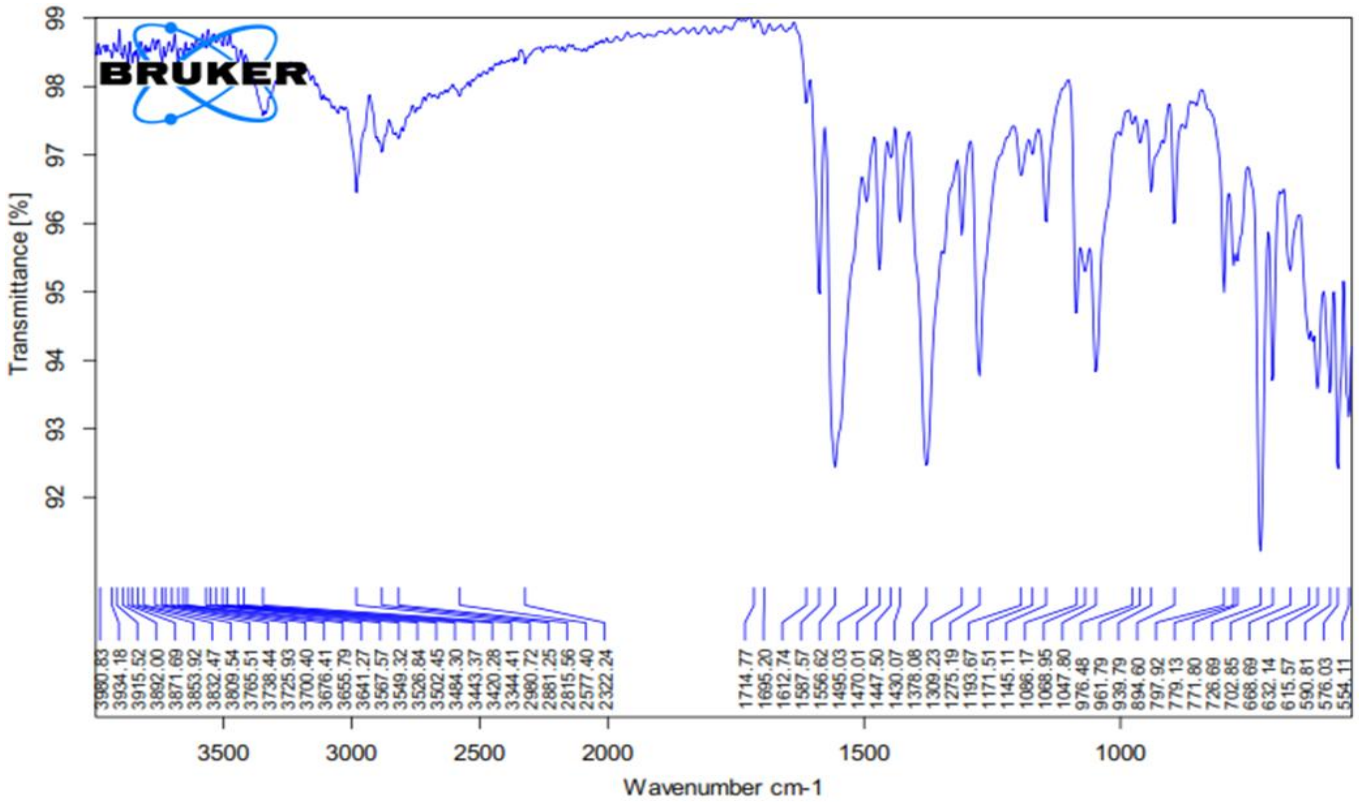


Fig 10:Pure drug FTIR

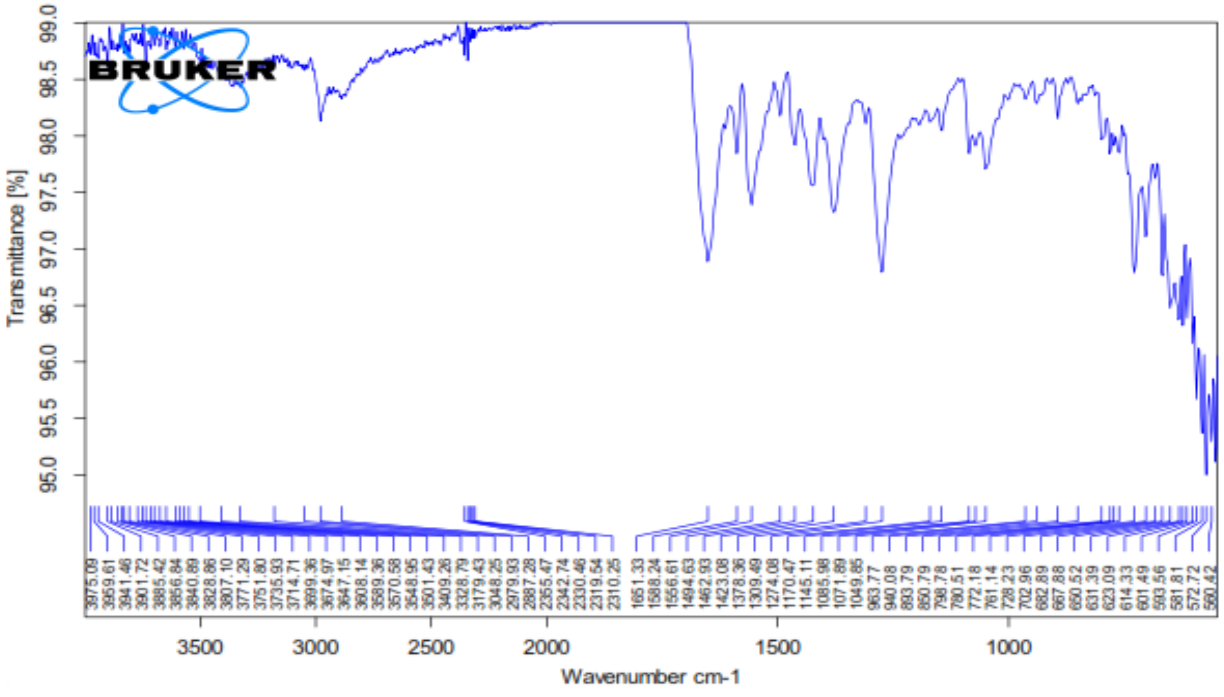


Fig 11: OPTIMISED

Summaryandconclusion:

Oral disintegrating tablets of omeprazole were prepared by using different super disintegrants like cross carmellose sodium, cross povidone, by wet granulation method, Compression pre-formulation studies were conducted for all formation mixture and were found to be acceptable. The formulated tablets were evaluated for various evaluation tests like weight variation, hardness, friability, disintegration and invitro vitro dissolution studies are conducted. The results shows that the tablets obey with the official standards, the disintegration studies indicate all the formulated tablets disintegrated less than 1 minute and F1 formulation shows less disintegrating time of lessthan15sec. In conclusion it can be stated that the purpose of the study has been attain from the above study the formula used for the F1 formulation was concluded as a perfect formula due to its less disintegration time and maximum drug release when compared with the other formulation

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