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FORMULATION AND EVALUATION OF ORAL DISINTEGRATION TABLETS OF OMEPRAZOLE

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Abstract:

Omeprazole fast disintegrating tablets were prepared by using different superdisintegrants like crospovidone, croscarmellose sodium and Sodium starch glycolate by direct compression. Precompression parameters were conducted for all formulations blend and were found to be satisfactory. The prepared tablets were evaluated for various parameters like content uniformity, hardness, friability, wetting time, water absorption ratio, disintegration time and In-vitro dissolution. The results indicated that the tablets complied with the official specifications. The disintegration studies shown that the all formulations disintegrated in less than 1 minute. The formulation F3 shown less disintegration time of 15 seconds. The croscarmellose sodium and sodium starch glycolate shown more disintegration time than crospovidone. In the present study, three Superdisintegrants representing each of the three main classes of superdisintegrants differed in their ability to disintegrate model tablet into their primary particles when used at the same w/w percentage concentration.

Key words: *Omeprazole, crospovidone, croscarmellose sodium and Sodium starch glycolate*

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INTRODUCTION:

The Center for Drug Evaluation and Research (CDER), US FDA defined Oral Disintegrating Tablets (ODT) as "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue."

A fast disintegrating or dissolving system or tablet can be defined as a solid dosage form that can disintegrate or dissolve within 30 seconds, in the oral cavity resulting in a solution or suspension without administration of water. The fast disintegrating tablets are synonymous with fast dissolving tablets; melt in mouth tablets, rapimelts, Porous tablets, Orodispersible, quick dissolving or rapidly disintegrating tablets.

EXPERIMENTAL METHOD:

Materials

Omeprazole, Mannitol, Micro crystalline cellulose, Crospovidone, croscarmellose sodium, Sodium starch glycolate, Aspartame, Flavors, Magnesium stearate, Talc all the chemicals used were lab grade

The basic approach used to study and evaluation of Fast disintegration tablet. For this study different superdisintegrants like crospovidone, croscarmellose and sodium starch glycolate were selected to formulate the Fast disintegrating tablets of Omeprazole by direct compression technique.

Table 1: Formulations of Omeprazole containing different superdisintegrants.

Ingredients (mg)	Formulations								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Omeprazole	20	20	20	20	20	20	20	20	20
MCC	201	197	193	201	197	193	201	197	193
Crospovidone	4	8	12	-	-	-	-	-	-
Croscarmellose sodium	-	-	-	4	8	12	-	-	-
Sodium starch glycolate	-	-	-	-	-	-	4	8	12
Mannitol	10	10	10	10	10	10	10	10	10
Aspartame	5	5	5	5	5	5	5	5	5
Magnesium stearate	5	5	5	5	5	5	5	5	5
Talc	5	5	5	5	5	5	5	5	5
Flavour	qs	qs	qs	qs	qs	qs	qs	qs	qs
Total	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**

Weight variation, Thickness, Hardness, Friability, Wetting time, Water absorption ratio, Content uniformity, In-vitro disintegration time,In-vitro release studies are the evaluation tests performed for the prepared tablets.

RESULTS AND DISCUSSION:

Table 2: Standard graph for Omeprazole

S. No	Concentration (µ/ml)	Absorbance (302 nm)
1	0	0
2	2	0.113
3	4	0.253
4	6	0.338
5	8	0.469
6	10	0.578

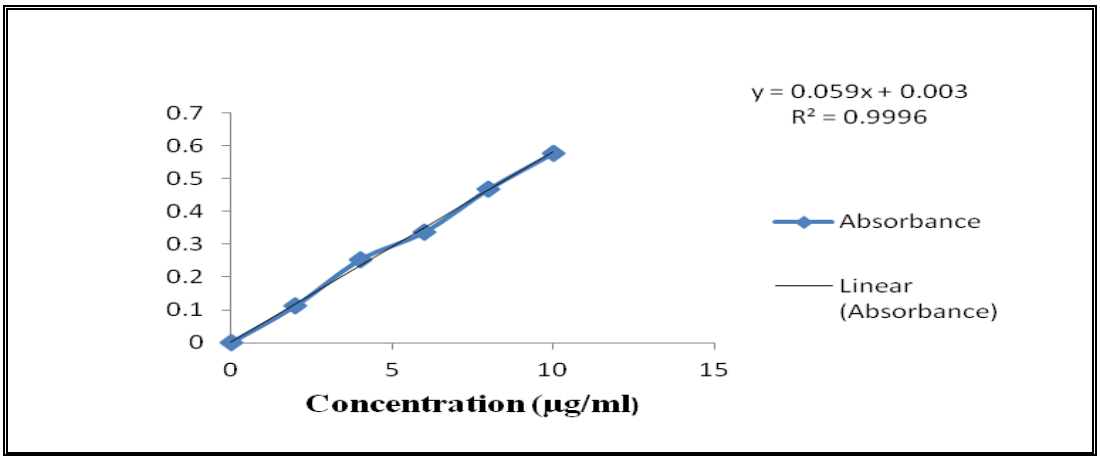

Fig 1: Standard graph Omeprazole

Preformulation studies

Table 3: Preformulation studies of API

no	Preformulation studies	Omeprazole
1	Bulk density (gm/ml)	0.47
2	Tapped density (gm/ml)	0.54
3	Angle of repose	21.2
4	Carrs index	14.9
5	Hausner ratio	1.14

Table 4: Preformulation studies of blend of all formulation

Formulation	Bulk density (gm/cm^3)	Tapped density(gm/cm^3)	Angle of repose(θ)	Carr's Index(%)	*Hausner's* ratio
F1	0.40	0.47	21.5	14.8	1.17
F2	0.41	0.46	20.1	10.86	1.12
F3	0.41	0.47	19.6	12.7	1.14
F4	0.43	0.48	17.8	10.4	1.11
F5	0.41	0.45	19.2	8.88	1.09
F6	0.40	0.44	18.4	9.09	1.10
F7	0.44	0.50	18.5	12.0	1.13
F8	0.41	0.46	17.4	10.86	1.12
F9	0.42	0.48	17.8	12.5	1.14

Table 5: Evaluation of tablets

Formulations	F1	F2	F3	F4	F5	F6	F7	F8	F9
Content uniformity (%)	98.02±0.615	98.47±0.452	99.89±0.085	98.64±0.145	99.1±0.2	98.73±0.218	97.51±0.438	98.37±0.132	98.56±0.065
Disintegration time (Sec)	25±0.0707	20±0.577	15±0.577	46±1.00	41±1.527	37±1.137	56±1.527	46±1.63	39±1.41
Water absorption ratio	51±0.707	42±1.527	34±1.00	61±0.802	56±1.159	47±1.418	64±0.702	62±1.193	52±1.310
Wetting time (sec)	34±1.414	26±1.069	21±1.527	54±0.793	48±1.101	44±1.014	61±1.258	53±0.721	44±1.527
Friability (%)	0.65±0.035	0.66±0.058	0.63±0.040	0.66±0.026	0.69±0.067	0.65±0.020	0.65±0.026	0.64±0.035	0.66±0.015
Thickness (mm)	1.2±0.063	1.1±0.109	1.2±0.05	1.2±0.135	1.1±0.057	1.2±0.1	1.1±0.045	1.1±0.115	1.10.0577
Hardness (kg/cm^2)	2.5±0.028	2.4±0.152	2.6±0.057	2.4±0.10	2.4±0.152	2.4±0.656	2.4±0.200	2.5±02.30	2.5±0.1
Weight variation (mg)	250±0.707	248±0.989	249±0.848	248±0.282	248±0.424	251±0.777	250±0848	249±0.777	252±0.707

Drug release study by *in-vitro* drug dissolution

Table 6: Cumulative percentage drug release of CP & CCS and formulations.

Sno	Time	Cumulative percentage of drug release of formulation					
		F1	F2	F3	F4	F5	F6
1	0	0	0	0	0	0	0
2	1	22.38±0.730	25.85±1.000	28.09±0.844	17.54±0.965	18.13±1.395	21.64±0.837
3	2	28.67±0.605	38.30±0.861	46.23±0.984	20.23± 0.962	25.34±0.968	29.83± 0.949
4	3	34.39±0.628	43.73±0.888	57.85±0.717	25.88±0.895	31.85±0.835	36.79± 1.25
5	4	42.82±0.850	51.51±0.846	68.53±0.977	31.45± 0.879	39.04±1.368	43.30± 1.67
6	5	48.86±0.554	61.24±0.865	77.89±1.059	42.50± 1.248	45.95±1.354	51.83± 1.68
7	6	56.21±0.743	66.87±0.725	87.24±1.064	48.65± 1.365	52.34±0.865	60.38± 1.396
8	7	58.56±0.820	75.50±1.672	91.41±0.767	53.81± 1.845	60.41±0.849	69.69± 1.311
9	8	67.80±0.921	78.07±0.791	96.36±0.750	60.79± 1.568	66.25±0.759	73.47± 1.386
0	9	73.59±0.811	84.03±0.853	97.42±1.021	69.87± 1.648	74.81±0.839	85.13± 1.568
11	10	86.42±0.637	93.25±0.782	99.29±0.410	76.16± 1.349	81.71±1.125	92.36± 1.649

Table 7: Cumulative percentage drug release of SSG formulations.

Sno	Time	Cumulative percentage of drug release of formulation		
		F7	F8	F9
1	**0**	**0**	**0**	**0**
2	1	14.32±0.917	16.94±1.023	18.46± 1.026
3	2	18.54± 0.934	20.03± 1.325	23.23± 1.132
4	3	22.98± 0.934	26.53± 1.068	27.50± 1.165
5	4	29.53± 0.987	32.80± 1.235	32.01± 1.421
6	5	33.91± 0.865	39.62± 1.481	46.92± 1.134
7	6	41.77± 0.935	46.15± 1.368	53.08± 1.128
8	7	50.16± 0.948	53.79± 1.248	59.24± 1.169
9	8	54.51± 0.978	61.72± 1.168	66.27± 1.187
10	9	61.48± 0.967	69.79± 1.125	79.50± 1.194
11	10	71.55± 0.932	73.64± 1.091	86.35± 1.178

Table 8: Comparison F3, F6, F9 formulations.

S.No	Time	Cumulative percentage of drug release of formulation		
		F3	F6	F9
1	**0**	**0**	**0**	**0**
2	1	28.09±0.844	21.64±0.837	18.46± 1.026
3	2	46.23±0.984	29.83± 0.949	23.23± 1.132
4	3	57.85±0.717	36.79± 1.25	27.50± 1.165
5	4	68.53±0.977	43.30± 1.67	32.01± 1.421
6	5	77.89±1.059	51.83± 1.68	46.92± 1.134
7	6	87.24±1.064	60.38± 1.396	53.08± 1.128
8	7	91.41±0.767	69.69± 1.311	59.24± 1.169
9	8	96.36±0.750	73.47± 1.386	66.27± 1.187
10	9	97.42±1.021	85.13± 1.568	79.50± 1.194
11	10	99.29±0.410	92.36± 1.649	86.35± 1.178

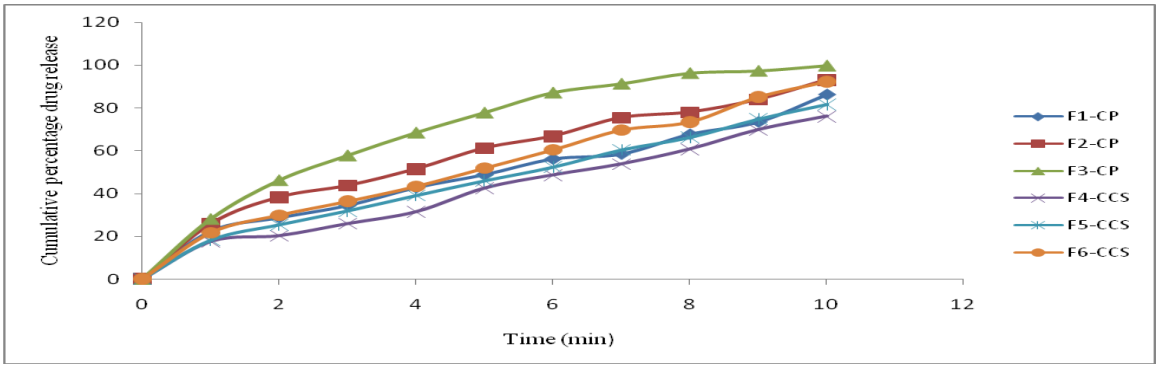

Fig 2: Cumulative percentage drug release of CP & CCS formulations

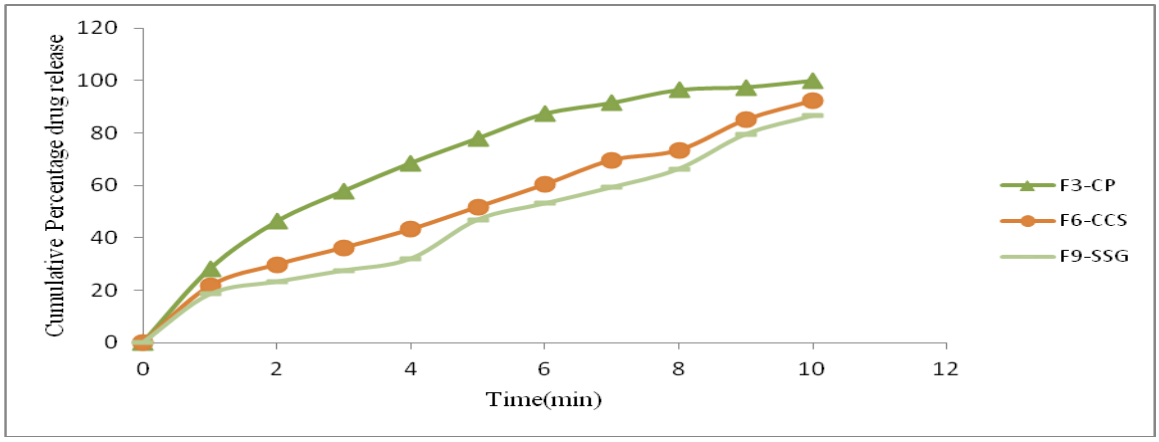

Fig 3: Cumulative percentage drug release of SSG formulations.

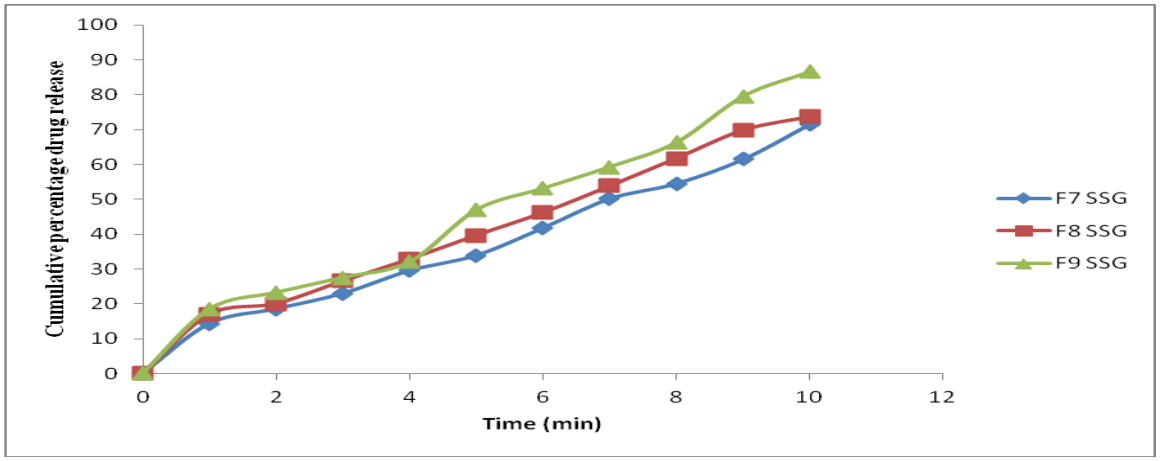

Fig 4: Comparison F3, F6, F9 formulations

SUMMARY AND CONCLUSION:

Fast disintegrating tablets of Omeprazole were prepared by using different superdisintegrants like crospovidone, croscarmellose sodium and Sodium starch glycolate by direct compression. Precompression parameters were conducted for all formulations blend and were found to be satisfactory.

The prepared tablets were evaluated for various parameters like content uniformity, hardness, friability, wetting time, water absorption ratio, disintegration time and *In-vitro* dissolution. The results indicated that the tablets complied with the official specifications. The disintegration studies shown that the all formulations disintegrated in less than 1 minute. The formulation F3 shown less disintegration time of 15 seconds. The croscarmellose sodium and sodium starch glycolate shown more disintegration time than crospovidone. In the present study, three Superdisintegrants representing each of the three main classes of superdisintegrants differed in their ability to disintegrate model tablet into their primary particles when used at the same w/w percentage concentration. In conclusion, it can be stated that the objective of the study has been achieved. From the above study the formula used for F3 formulation was concluded as an optimized formulation due to its less disintegration time and good % drug release when compared with other formulations.

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