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FORMULATION, CHARACTERIZATION AND EVALUATION OF ORAL DISINTEGRATING TABLETS OF ACELOFENAC

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ABSTRACT

Aims: The objective of the present research study was development of fast disintegrating tablets that dissolve or disintegrate rapidly in the saliva, within a few seconds, without the need for water. They have proved to be ideal for geriatric and paediatric population, people suffering from dysphagia, bedridden, mentally ill, nauseated and uncooperative patients, clinical conditions where water is not available and for drugs undergoing high first pass metabolism. Fast disintegrating tablets are also ideal for active people due to its advantages like faster onset of action, avoidance of first pass metabolism, taste masking of bitter drugs, improvement in solubility of poorly soluble drugs by inclusion complex formation and ultimately bioavailability enhancement of low bio available drugs. **Study Design:** Design and development of formulation includes short listing of ingredients for the formulation, effect of various process as well as formulation parameters of by direct compression method. Characterization of fast disintegrating tablet is done by weight variation, Thickness, Hardness, Friability, Disintegration time, wetting time, Drug content, Water absorption ratio, *In-vitro* dissolution studies and drug release kinetic.

KEYWORDS

Orally disintegrating tablets (ODTs), Acelofenac and Disintegration.

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INTRODUCTION

Orally disintegrating tablets (ODTs)[1]

ODTs can be described as a solid dosage form containing medicament which disintegrates rapidly when placed upon the tongue[2]. ODT release drugs absorb in oral cavity. ODT also knows fast dissolving, mouth dissolving, orodispersible, rapid disintegrating, and quick melt[2].

ODTs are preferred over conventional drug delivery system as they are easily administered by patients who have difficulty in swallowing the tablets, provide the accurate dosing due to unit solid dosage forms provide rapid onset of therapeutic action due to rapid disintegrating, by pass the hepatic first pass effect and enhanced bioavailability due to absorption from oral mucosa.

ODTs are sensitive to moisture to such an extent that, even during processing or formulation development stages, temperature and humidity have to be controlled to avoid long term stability issues and may require special packaging. Many ODTs, in an effort to decrease disintegration time, are highly porous soft-molded tablets compressed at low compression force. Sometimes if the formulation and processing parameters are not optimized, the tablets can exhibit higher friability irrespective of any hardness changes. Also, problems like capping, picking, and chipping are observed during formulation development if the formulation and processing parameters are not optimized. Several of the compressed ODTs are more robust and can withstand the rigors of bottling[3].

MATERIAL AND METHOD

Materials

Aceclofenac (Active Drug) was obtained from Comex Pharma, Karnal, CSS, Crospovidone (Synthetic super disintegrant), Avicel PH102 (Directly compressible excipient), Mannitol (Diluent), Saccharin Sodium (Sweetening agent), Talc (Glidant), Menthol (Flavouring agent), Sodium Hydroxide, Potassium Dihydrogen Phosphote (Buffering agent) were obtained from Loba Chemie Pvt. Ltd, Mumbai.

Method

Preparation of Fast Disintegrating Tablets

Aceclofenac fast disintegrating tablets were prepared by direct compression method. A total number of nine formulations were prepared. All ingredients were weighed accurately and passed through 60-mesh sieve separately and collected. They were mixed together with magnesium stearate and talc and finally compressed into tablets by using 5 mm punch using double punch hand operating tablet punching machine[4].

RESULTS AND DISCUSSION

Preparation and Evaluation of Orally Disintegrating Tablets of Aceclofenac

Orally disintegrating tablets were successfully prepared by technique direct compression. Prepared tablets were subjected to various evaluation parameters for their evaluation. All the formulated (F1-F9) tablets were passed weight variation test as the % weight variation was within the IP limits of ±7.5% of the weight. The weights of all the tablets were found to be uniform with low standard deviation values. The prepared formulation complies with the weight variation test.

The maximum thickness of the formulation was found to be 6 mm. The minimum thickness of the formulation was found to be 5.3 mm. The average thickness of the all formulation was found to be 5.7 mm. The hardness of the tablet was found to be <3.7 Kg/cm^2.

The maximum friability of the formulation was found to be 0.87%. The minimum friability of the formulation was found to be 0.6%. The % friability was less than 1% in all the formulations ensuring that the tablets were mechanically stable.

Tablets were prepared using direct compression technique. Since the material was free flowing, tablets were obtained of uniform weight due to uniform die fill. The thickness of the tablets was found in the range 5.3 mm - 6.0 mm. Uniform thickness was obtained due to uniform die fill. Hardness of the tablets was found in the range 3.4-3.7 kg/cm^2. Friability of tablets was observed in acceptable range 0.61-0.87 (Less than 1%).

Disintegration Time (DT), Wetting Time (WT), Water Absorption Ratio (WAR) and Drug Content

Disintegration time of the tablets was carried out on 6 tablets using the disintegration apparatus. According to I.P., dispersible tablets should disintegrate within 3 min. The test was carried out in triplicate. Drug content of the tablets was analyzed at 273 nm using UV spectrophotometer. The maximum drug content for the all formulation

was found to be 102.2% and minimum % drug content from the all formulation was found to be 96%. The results were within the limit specified by the IP. Disintegrating time, wetting time, water absorption ratio and drug content for the different batches containing super disintegrant shown below:

The disintegration time was found in the range 35-62 seconds for all the batches. Water absorption ratio which is important criteria for understanding the capacity of disintegrants to swell in presence of little amount of water was calculated. It was found in the range of 66-81% (Table No.5). The wetting time was found in the range 50-69 sec.

In the present study, it is observed that the disintegration time of the tablets had no effect with increasing level of crospovidone. However, disintegration time decreased with increase in the level of microcrystalline cellulose in the tablets. It indicates that increase in the level of microcrystalline cellulose had a positive effect on the disintegration of the tablets. The faster disintegration of crospovidone tablets may be attributed to its rapid capillary activity and pronounced hydration with little tendency to gel formation. Thus, these results suggest that the disintegration times can be decreased by using wicking type of disintegrants (crospovidone). Wetting times of the tablets significant decrease with increase in the level of crospovidone (2 % to 6 %). Thus; wetting times of tablets with crospovidone was found less than croscarmel lose and microcrystalline cellulose.

The disintegration time F2, F5 and F8 was found 43, 35 and 52 sec. respectively and water up take ratio was 72, 69 and 81% in batch F2, F5 and F8 respectively. The disintegration time is low in the batch F5 is due to it containing high content of crospovidone. Batch F8 shows high water uptake because crosscarmel lose have high hydration capacity to absorb water which is shown in the hydration study so for this reason it has high water absorption capacity.

***In-Vitro* Drug Release Studies**

Standard USP or IP dissolution apparatus have been used to study *in vitro* release profile using rotating paddle. *In vitro* release rate study of fast disintegrating tablet of Aceclofenac was carried out using the apparatus 2 (Paddle apparatus) method. The dissolution test was carried out using 900 ml of phosphate buffer solution, at 37 ± 0.5^0 C and 50 rpm. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus at 0, 5, 10, 15, 20, 25 and 30 min and withdrawn volume was replaced with fresh dissolution media. The withdrawn samples diluted with dissolution medium and then filter it with whattman filter paper and assayed at 273 nm. The dissolution characteristics of aceclofenac fast disintegrating tablets are given in Table No.6, 7 and 8. Figure No.2, 3 and 4 shows the dissolution rate profile of different formulation batches prepared by direct compression method.

In vitro release of all the batches was done which is shown in Table No.8, 9 and 10. In this batches F2, F5 and F8 shows the 62%, 63% and 57% drug release (30 min) respectively in phosphate buffer (pH 7.4) which contains super disintegrants concentration (4%) and mannitol.

Drug Release Kinetics

There are number of kinetic models, which describe the overall release of drug from the dosage forms the qualitative and quantitative changes in a formulation may alter drug release profile and *in vivo* performance. Correlation coefficient (R^2) was determined for kinetic models (Zero order, First order, Higuchi, Hixson Crowel and Peppas model) and compared with each other, the model showing the greatest Correlation coefficient (≈1) was taken as best fit model.

Kinetic model study, was found that batch F2 (MCC 4%) fitted to first order kinetics. Formulation batches F3, F4, F5, F6, F7, F8, and F9 fitted to both zero order kinetics and Hixson crowel kinetics. F1 (n=0.884 i.e. non fickian diffusion) batch formulation show that korsmeyer peppas model.

Drug Kinetics[6]

Table No.1: Formula Used in the Preparation of Fast Disintegrating Tablets of Aceclofenac Containing MCC, CP and CCS as Superdisintegrant for Direct Compression Method

S.No	Excipients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Aceclofenac	100	100	100	100	100	100	100	100	100
2	MCC	3	6	9	-	-	-	-	-	-
3	CP	-	-	-	3	6	9	-	-	-
4	CCS	-	-	-	-	-	-	3	6	9
5	Mannitol	44.8	41.8	38.8	44.8	41.8	38.8	44.8	41.8	38.8
6	Sod. Saccharin	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
7	Mg Stearate	1	1	1	1	1	1	1	1	1
8	Talc	1	1	1	1	1	1	1	1	1
9	Manthol	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
10	Total	150	150	150	150	150	150	150	150	150

Table No.2: Various Kinetic Models and Their Applications[7-10]

S.No	Kinetics Models	Equation	Applications
1	Zero Order Kinetics	$Q_t = Q_0 + K_0t$ Q_t = Amount of drug dissolved in time t; Q_0 = Initial amount of drug in solution, which is zero; K_0 = Zero order rate constant.	Described the drug dissolution of several types of modified release pharmaceutical dosage forms, such as in the case of some transdermal systems, as well as matrix tablets with low soluble drugs in coated forms, osmotic systems, etc.
2	First Order Kinetics	$\text{Log } Q_t = \text{Log } Q_0 + K_t/2.303$ Q_t = Amount of drug dissolved in time t; Q_0 = Initial amount of drug in solution, which is zero; K_t = First order rate constant.	Describes the drug dissolution in pharmaceutical dosage forms such as those containing water-soluble drugs in porous matrices
3	Higuchi Kinetics	$M_t / M_\infty = k_H t^{1/2}$ M_t = Amount of drug released at time t; M_∞ = Amount of drug released at infinite time; K_H = Higuchi release rate constant expressing design variable of system	Describes the drug dissolution from several types of modified release pharmaceutical dosage forms such as transdermal systems and matrix tablets with water soluble drugs
4	Korsmeyer Peppas Model	$M_t/M_\infty = K t^n$ M_t = Amount of drug released at time t; M_∞ = Amount of drug released at infinite time; K = Peppas release rate constant; n = Slope of the line called as release exponent.	Describes the drug dissolution pharmaceutical polymeric dosage form, when more than one type of release phenomena could be involved
5	Hixson-Crowel Model	$W_0^{1/3} - Wt^{1/3} = \kappa t$ W_0 is initial amount of drug in the pharmaceutical dosage form; Wt is the remaining amount of drug in the pharmaceutical dosage form at time t; κ (kappa) is a constant incorporating the surface-volume relation.	Applies to pharmaceutical dosage form such as tablets, where the dissolution occurs in planes that are parallel to the drug surface if the tablet dimensions diminish proportionally, in such a manner that the initial geometrical form keeps constant all the time.

Table No.3: Physical Parameters of Formulations

S.No	Formulation code	Weight variation (%)	Thickness (mm) ±SD	Hardness (kg/cm^2) ±SD	Friability (%)
1	F1	4.2	5.6±0.5	3.5±0.3	0.61
2	F2	5.2	5.3±0.5	3.4±0.1	0.78
3	F3	5.6	6.0±0.0	3.4±0.3	0.62
4	F4	4.5	5.6±0.5	3.6±0.1	0.61
5	F5	6.6	5.6±0.5	3.4±0.2	0.70
6	F6	5.6	5.6±0.5	3.7±0.1	0.74
7	F7	6.6	5.6±0.5	3.4±0.2	0.80
8	F8	6.9	6.0±0.0	3.7±0.2	0.69
9	F9	6.5	5.3±0.5	3.5±0.3	0.87

Table No.4: DT, WT, WAR and Drug content of the Different Formulation Batches

S.No	Formulation code	DT (sec) ± SD	WT (sec) ± SD	WAR (%) ± SD	Drug content (%) ± SD
1	F1	54±3.0	68±2.1	66.7±0.1	98.3±0.3
2	F2	43±3.0	69±0.6	72.6±0.5	101.2±0.7
3	F3	41±1.5	64±1.5	78.0±0.6	98.6±0.5
4	F4	36±2.5	58±2.0	70.0±0.9	100±0.5
5	F5	35±1.5	55±1.5	69.7±2.3	97.5±0.3
6	F6	37±1.5	50±1.5	74.5±3.4	100±0.5
7	F7	62±1.5	56±1.5	71.5±0.8	96.2±0.7
8	F8	52±1.5	60±1.0	81.1±3.4	102.2±0.5
9	F9	51±1.5	64±1.2	75.6±2.4	101.8±0.5

Table No.5: Dissolution Profile of Tablets having MCC as a super disintegrant from Formulation Batches F1 to F3

S.No	Time (min.)	% Cumulative drug release (% CDR) ± SD		
		F1	F2	F3
1	0	0	0	0
2	5	10.5 ±0.2	12.9 ±0.3	13.0±0.1
3	10	20.5 ±0.4	26.6 ±0.0	26.6±0.1
4	15	28.6 ±0.6	32.8 ±0.2	30.8±0.1
5	20	37.1 ±0.4	41.0 ±0.5	40.8±0.1
6	25	45.9 ±0.4	57.7 ±0.2	49.4±0.9
7	30	50.1 ±0.2	62.1 ±0.2	56.4±0.1

Table No.6: Dissolution Profile of Tablets having CP as a super disintegrant from Formulation batches F4 to F6

S.No	Time (min.)	% Cumulative drug release (% CDR) ± SD		
		F4	F5	F6
1	0	0	0	0
2	5	16.3±0.4	17.1±0.1	18.3±0.1
3	10	19.7±0.0	25.0±0.1	22.5±0.1
4	15	27.5±0.1	32.5±0.1	29.6±0.1
5	20	36.7±0.1	45.4±0.4	36.7±0.1
6	25	41.3±0.6	58.7±0.1	53.6±0.6
7	30	53.8±0.6	63.5±0.1	58.9±0.1

Table No.7: Dissolution Profile of Tablets having CCS as a super disintegrant from Formulation Batches F7 to F9

S.No	Time (min.)	% Cumulative drug release (% CDR) ± SD		
		F7	F8	F9
1	0	0	0	0
2	5	15.8±0.2	15.5±0.9	12.6±0.0
3	10	18.4±0.1	22.5±0.4	20.3±0.6
4	15	25.9±0.0	28.4±0.0	24.5±0.6
5	20	32.2±0.1	36.3±0.1	37.0±0.6
6	25	45.1±0.0	49.6±0.1	45.3±0.6
7	30	54.7±0.1	57.8±0.0	57.2±0.1

Table No.8: Drug Release Kinetics Models (in phosphate buffer, pH 7.4)

Batch	Correlation Coefficient (R^2)					
	Zero order	First order	Higuchi	Hixson Crowell	Korsmeyerp eppas	Best fit model
F1	0.990	0.996	0.994	0.990	0.997	Korosmeyer peppas (Non Fickian diffusion, n= 0.884)
F2	0.979	0.989	0.968	0.987	0.986	First order
F3	0.976	0.949	0.934	0.976	0.941	Zero order, Hixson crowel
F4	0.976	0.949	0.934	0.976	0.941	Zero order, Hixson crowel
F5	0.985	0.970	0.960	0.985	0.974	Zero order, Hixson crowel
F6	0.960	0.933	0.911	0.960	0.921	Zero order, Hixson crowel
F7	0.962	0.931	0.903	0.962	0.911	Zero order, Hixson crowel
F8	0.982	0.955	0.941	0.982	0.965	Zero order, Hixson crowel
F9	0.982	0.953	0.941	0.982	0.970	Zero order, Hixson crowel

Table No.9: *In-vitro* Release data of Formulations F2, F5 and F8: Zero Order Kinetics Model

S.No	Time (min)	% Cumulative drug released		
		F2	F5	F8
1	0	0	0	0
2	5	12.94	17.16	15.56
3	10	26.65	25.03	22.57
4	15	32.81	32.53	28.43
5	20	41.04	45.41	36.37
6	25	57.76	58.74	49.66
7	30	62.17	63.56	57.84

Table No.10: *In-vitro* Release data of Formulations F2, F5 and F8, First Order Kinetics Model

S.No	Time (min)	% Cumulative drug retained			Log % Cumulative drug retained		
		F2	F5	F8	F2	F5	F8
1	0	100	100	100	2	2	2
2	5	86.92	82.83	84.44	1.94	1.92	1.93
3	10	73.35	74.96	77.43	1.87	1.87	1.89
4	15	69.11	67.46	71.57	1.84	1.83	1.85
5	20	59.12	54.59	63.63	1.77	1.74	1.8
6	25	50.57	41.26	50.34	1.7	1.62	1.7
7	30	43.5	36.44	42.16	1.64	1.56	1.62

Table No.11: *In-vitro* Release data of Formulations F2, F5 and F8, Higuchi Model

S.No	Time (min)	Square root of Time (min)	% Cumulative drug released		
			F2	F5	F8
1	0	0	0	0	0
2	5	2.24	12.94	17.17	15.56
3	10	3.16	26.65	25.04	22.57
4	15	3.87	32.81	32.54	28.43
5	20	4.47	41.04	45.41	36.37
6	25	5	57.76	58.74	49.66
7	30	5.48	62.17	63.56	57.84

Table No.12: *In-vitro* Release data of Formulations F2, F5 and F8: Hixson Crowel Model

S.No	Time (min)	Cube root of % Cumulative drug retained		
		F2	F5	F8
1	5	28.97	27.61	28.15
2	10	24.45	24.99	25.81
3	15	23.04	22.49	23.86
4	20	19.71	18.2	21.21
5	25	16.86	13.75	16.78
6	30	14.5	12.15	14.05

Table No.13: *In-vitro* Release data of Formulations F2, F5 and F8: Koresmeyer Peppas Model

S.No	Time (min)	log of Time (min)	% Cumulative drug released			log % Cumulative drug released		
			F2	F5	F8	F2	F5	F8
1	5	0.7	12.94	17.17	15.56	1.11	1.23	1.19
2	10	1	26.65	25.04	22.57	1.43	1.4	1.35
3	15	1.18	32.81	32.54	28.43	1.52	1.51	1.45
4	20	1.3	41.04	45.41	36.37	1.61	1.66	1.56
5	25	1.4	57.76	58.74	49.66	1.76	1.77	1.7
6	30	1.48	62.17	63.56	57.84	1.79	1.8	1.76

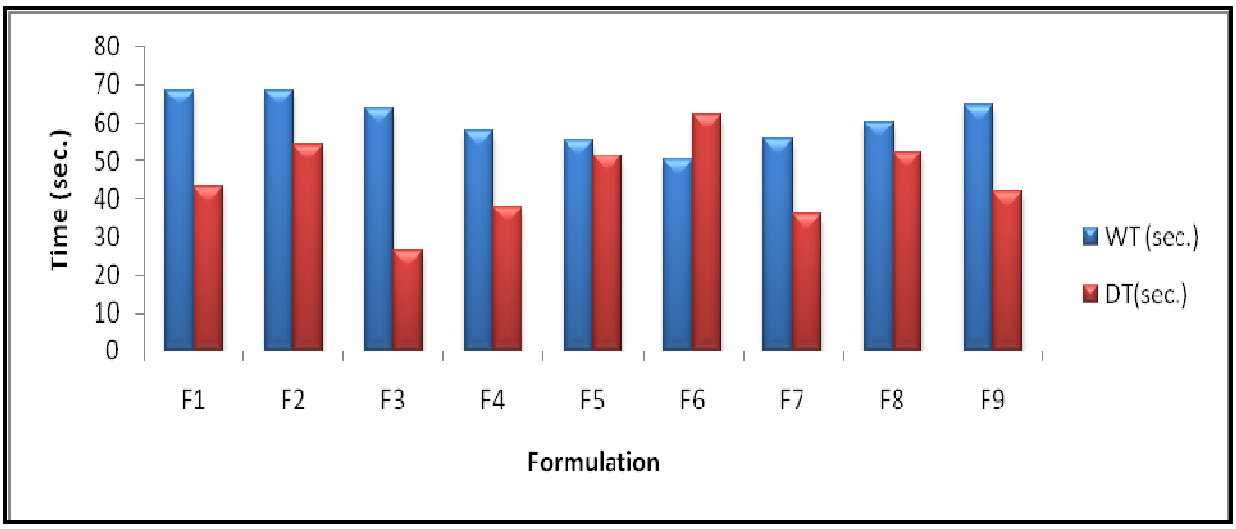

Figure No.1: DT and WT of Different Batches

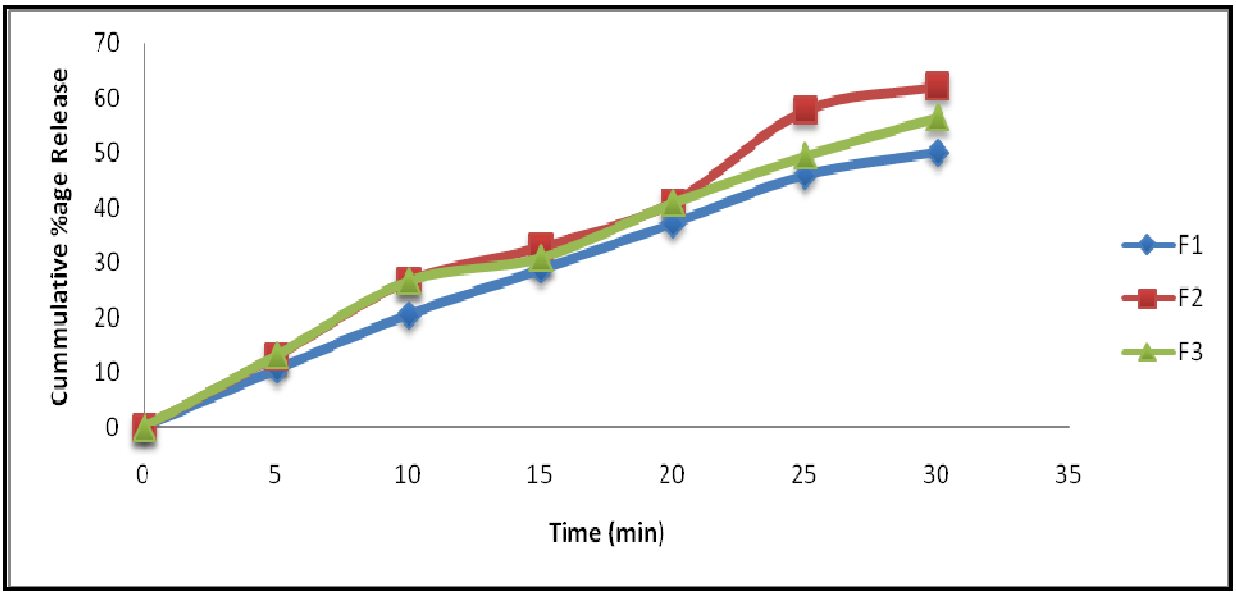

Figure No.2: Comparative Drug Release Profiles of Fast Disintegrating Tablets in Phosphate Buffer (pH 7.4) (Batch F1 to F3)

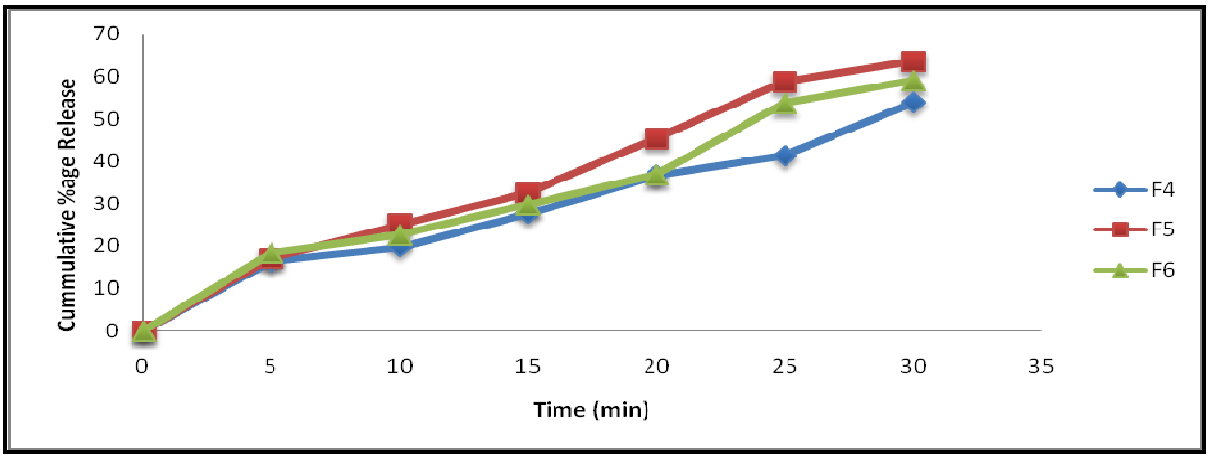

Figure No.3: Comparative Drug Release Profiles of Fast Disintegrating Tablets in Phosphate Buffer (pH 7.4) (Batch F4 to F6)

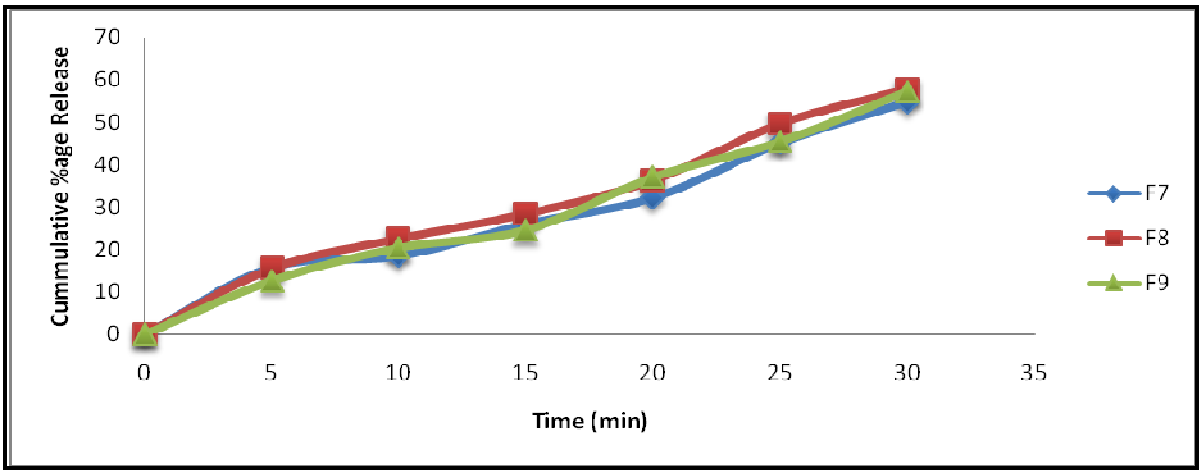

Figure No.4: Comparative Drug Release Profiles of Fast Disintegrating Tablets in Phosphate Buffer (pH 7.4) (Batch F7 to F9)

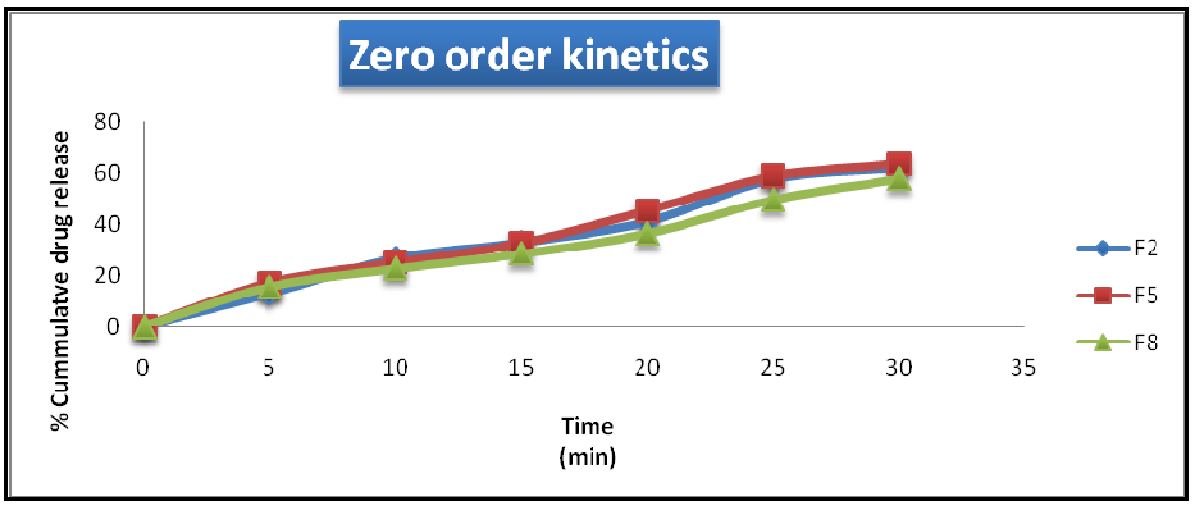

Figure No.5: Zero Order Kinetics Models of Different Batches (F2, F5 and F8)

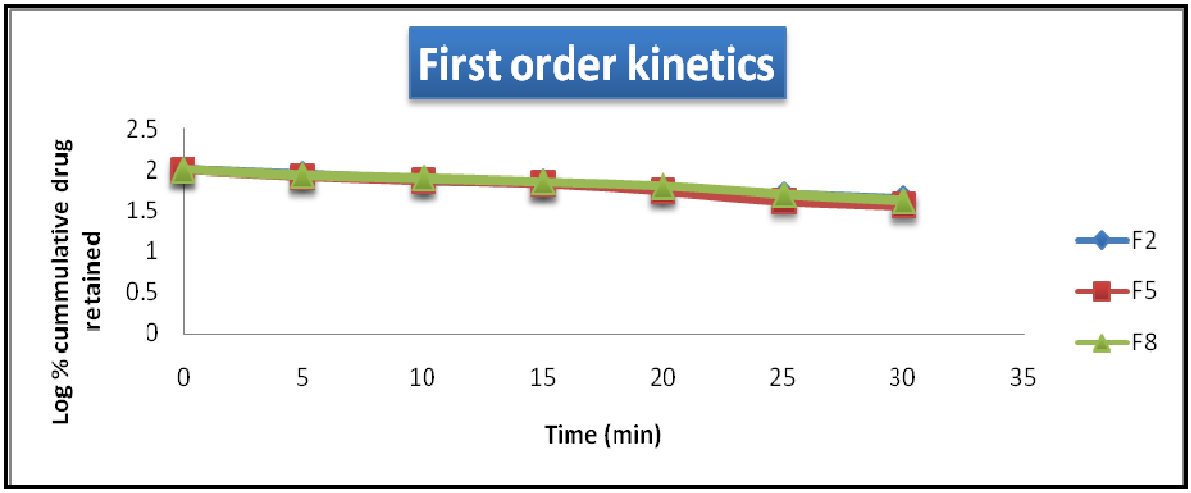

Figure No.6: First Order Kinetics Models of Different Batches (F2, F5 and F8)

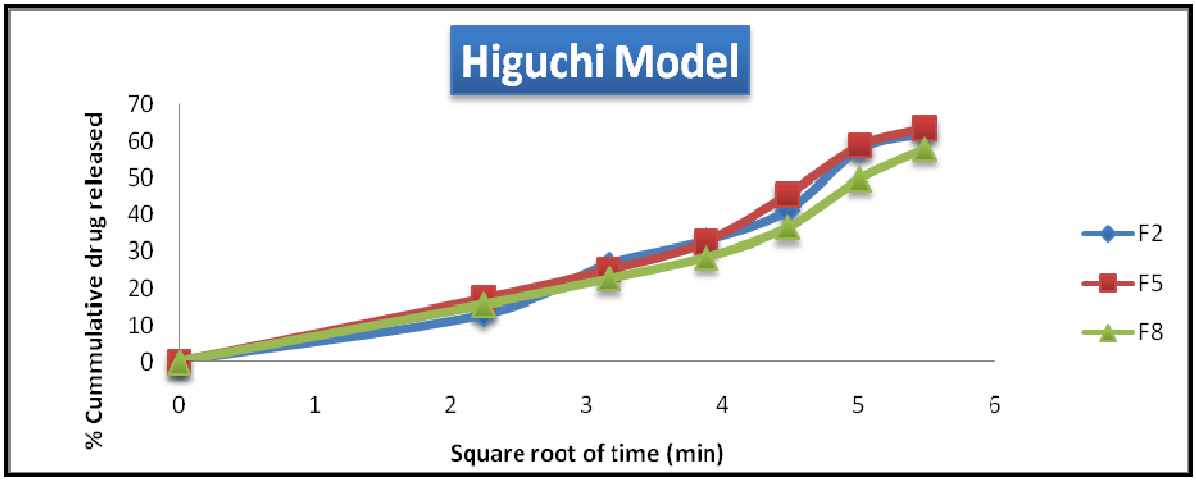

Figure No.7: Higuchi Kinetics Models of Different Batches (F2, F5 and F8)

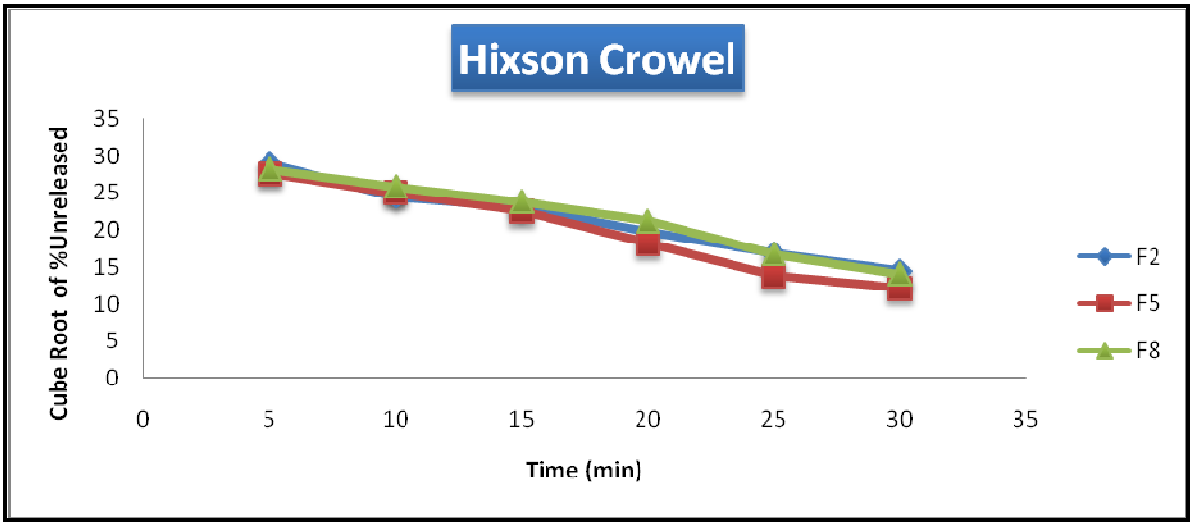

Figure No.8: Hixson Crowel Kinetics Models of Different Batches (F2, F5 and F8)

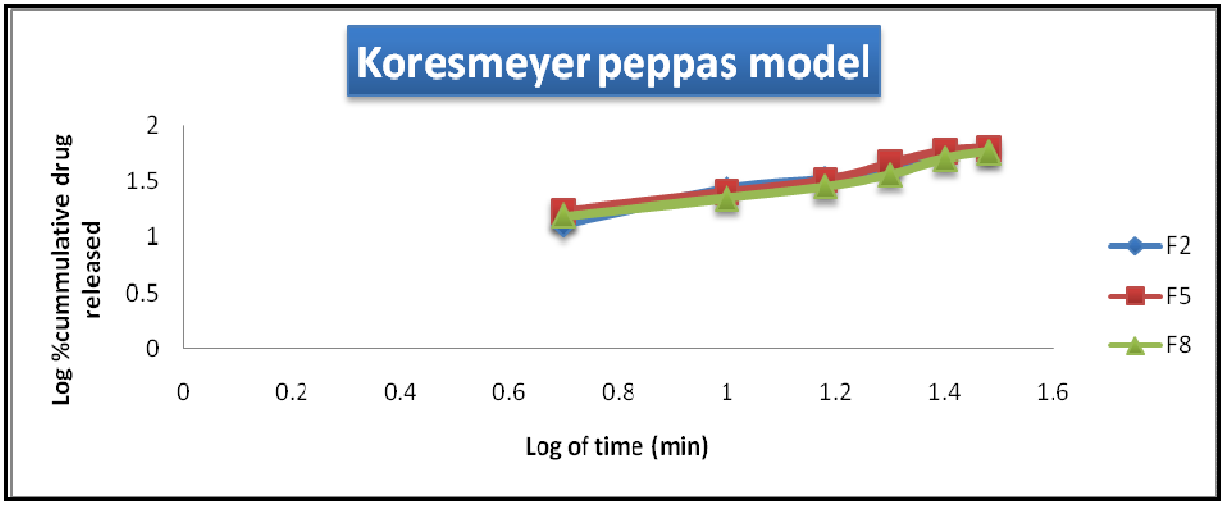

Figure No.9: Koresmeyer Peppas Kinetics Models of Different Batches (F2, F5 and F8

CONCLUSION

It was observed that when crospovidone sodium used at 4% concentration (formulation F5) with solubilising agent mannitol, drug release (63.5%) was maximum in 30 min, disintegration time was least (35 sec.), wetting time of 55 sec. and water absorption ratio of 69%. It is concluded that crospovidone can be effectively used as super disintegrant in aceclofenac fast disintegrating tablets. Wetting time of tablets was found to be crospovidone < croscarmel lose sodium < microcrystalline sodium. The drug release in 5 min and 30 min increased crospovidone > microcrystalline cellulose > croscarmel lose sodium.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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