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FORMULATION AND EVALUATION OF MELT IN MOUTH TABLETS OF ACECLOFENAC

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ABSTRACT

Aceclofenac is an NSAID (Non Steroidal Anti Inflammatory Drug) have been indicated for various painful inflammations, including post traumatic pain and proved as effective as other Non Steroidal Anti Inflammatory Drugs with lower indications of GI adverse effects and thus resulted in greater compliance with treatment. Aceclofenac fast dispersible (melt in mouth) tablets have been prepared by direct compression method. Fast disintegrating drug delivery system offers a solution for those patients having difficulty in swallowing tablets/ capsules etc. Effect of superdisintegrants such as crosscarmellose sodium and sodium starch glycolate on wetting time, disintegration time, drug content, dissolution time has been studied. Disintegration time and dissolution parameters were less in the tablets containing crosscarmellose sodium than sodium starch glycolate. All the formulation showed disintegration time in range of 85 to 130 seconds along with rapid in vitro dissolution. It was concluded that the fast dissolving tablets of the poor soluble drug can be made by direct compression technique using selective super disintegrants showing enhanced dissolution, taste masking and hence better patient compliance and effective therapy.

KEYWORDS

Aceclofenac, Fast disintegrating, Crosscarmellose sodium and Sodium starch glycolate.

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INTRODUCTION[1]

Aceclofenac is a non-steroidal agent with marked anti-inflammatory and analgesic properties. The mode of action of Aceclofenac is largely based on the inhibition of prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclo-oxygenase, which is involved in the production of prostaglandins. Aceclofenac can be administered twice daily as 100mg orally in the treatment of rheumatoid arthritis. Geriatric patient

may have difficulty in swallowing and chewing the tablets resulting in patient non compliance and ineffective therapy.

To overcome these problems mouth dissolving tablet is a good alternative, since they disintegrate and dissolve rapidly in saliva without the need for drinking water. The development of a fast dissolving tablet also provides an opportunity for a line extension in the market place.

Thus the present drug is chosen as a suitable candidate for the formulation of fast disintegrating tablet using two super disintegrants- crosscarmellose sodium and sodium starch glycolate.

MATERIAL AND METHODS

MATERIALS

Aceclofenac, flavour and mannitol were received as gift samples from Sangrose laboratories, Mavelikkara, Kerala. Sodium starch glycolate and microcrystalline cellulose were obtained from commercial sources. All other reagents were of analytical grade.

METHOD

Direct compression method

Accurate amount of all the ingredients and drug were separately weighed and mixed by geometric dilution method. Then they were passed through sieves. The prepared aceclofenac- excipient complex was sifted in a dry clean mortar for 15 minutes and then weighed individually and directly compressed in a single punch tabletting machine using 9mm round, concave punch, keeping the average weight of tablet as 205mg. The different formulations selected are shown in Table No.1.

Evaluation of melt in mouth tablets

The prepared fast melting tablets were evaluated for their thickness, hardness, friability, weight variation, drug content, wetting time, disintegration time and dissolution profile. A weight equivalent to 10mg of aceclofenac was accurately weighed and transferred into 100ml volumetric flask. The volume was made up with phosphate buffer pH 7.4 and analyzed at 275 nm using UV visible spectrophotometer. The drug content of sample was estimated from standard graph. Disintegration test was conducted using Tablet disintegration apparatus. One tablet was placed in each of the six tubes of the basket and the apparatus was operated with disc, using water as the disintegration fluid. Six tablets from each batch were selected and evaluated, and the average disintegration time was recorded with standard deviation. The dissolution profile was assessed using phosphate buffer of pH 7.4 as dissolution medium[2]. Temperature of dissolution medium was maintained at 37 ± 0.5^0C. Aliquot of dissolution medium was withdrawn at a specific time interval and filtered. The filtered solutions were analysed spectro photometrically at 275nm and drug content was determined from standard calibration curve. Dissolution rate was studied for all designed formulations[3-7].

RESULT AND DISCUSSION

The most important parameter that needs to be developed for the fast dispersible or melt in mouth tablet is the disintegration time. In present study all the formulations disintegrated within 140 sec, which fulfills the official requirement 3 min. It is observed that disintegration time of formulations containing crosscarmellose sodium decreased from 110 to 85 sec and that of sodium starch glycolate decreased from 130 to 104 sec on increasing the concentration of the respective superdisintegrants. 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 to be in the range of 0.32 cm - 0.36 cm. Hardness of the tablets was found to be in the range 3.2-3.6 kg/cm^2. Friability of tablets was observed in the acceptable range 0.56-0.87% (less than1%). *In vitro* dissolution studies of various formulations at different time intervals are reported in Table No.3. Formulation with crosscarmellose sodium showed a good dissolution rate 97.75% in 2 minutes. The dissolution parameters were consistent with disintegration times of crosscarmellose sodium and sodium starch glycolate containing tablets. Dispersible tablets prepared with superdisintegrants must be protected from atmospheric moisture.

Table No.1: Formulation of melt in mouth tablets of Aceclofenac

S.No	Ingredients	F1(mg)	F2(mg)	F3(mg)	F4(mg)	F5(mg)	F6(mg)
1	Aceclofenac	100	100	100	100	100	100
2	Micro crystalline cellulose	50	50	50	50	50	50
3	Cross carmellose sodium	-	25	-	30	40	-
4	Sodium starch glycolate	25	-	30	-	-	40
5	Magnesium stearate	2	2	2	2	2	2
6	Orange flavour	3	3	3	3	3	3
7	Mannitol	25	25	20	20	10	10
8	Total weight (mg)	205	205	205	205	205	205

Table No.2: Evaluation of melt in mouth tablets of Aceclofenac

S.No	Parameters	F1	F2	F3	F4	F5	F6
1	Weight variation	Pass	Pass	Pass	Pass	Pass	Pass
2	Hardness(kg/cm^2)	2.4	2.6	2.6	2.6	2.4	2.6
3	Thickness (cm)	0.36	0.32	0.32	0.35	0.34	0.35
4	Friability (%)	0.875%	0.768%	0.568%	0.563%	0.667%	0.775%
5	Wetting time(sec)	190	170	180	155	173	160
6	Disintegration time(sec)	130	110	124	95	85	104

Table No.3: *In vitro* dissolution profile of formulations F1-F6

S.No	Time in mints	Cumulative percentage of drug release					
		F1	F2	F3	F4	F5	F6
1	0	0	0	0	0	0	0
2	2	18.78	53.48	48.37	90.81	93.28	50.92
3	4	27.99	67.81	60.91	91.82	97.75	67.04
4	6	38.27	75.24	62.95	92.29	97.89	76.97
5	8	49.61	81.26	65.26	94.74	98.12	82.14
6	10	51.78	88.72	68.54	96.12	98.86	90.59

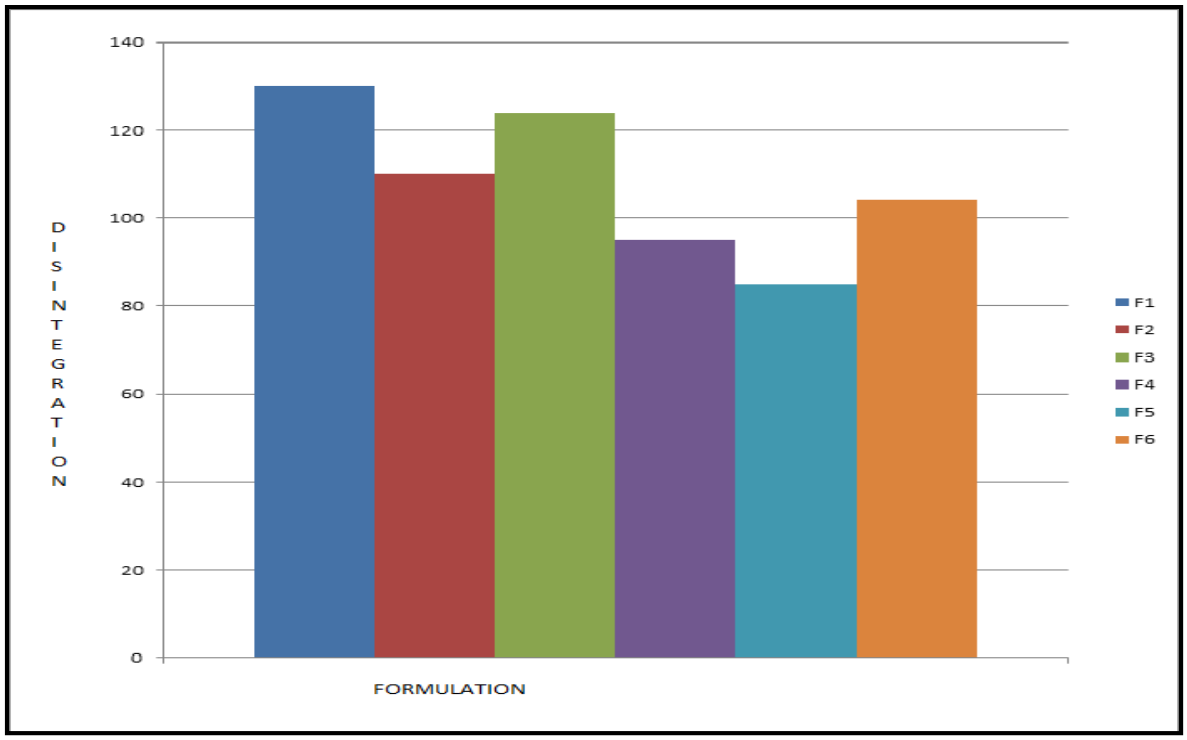

Figure No.1: Disintegration profile of various formulations vs time

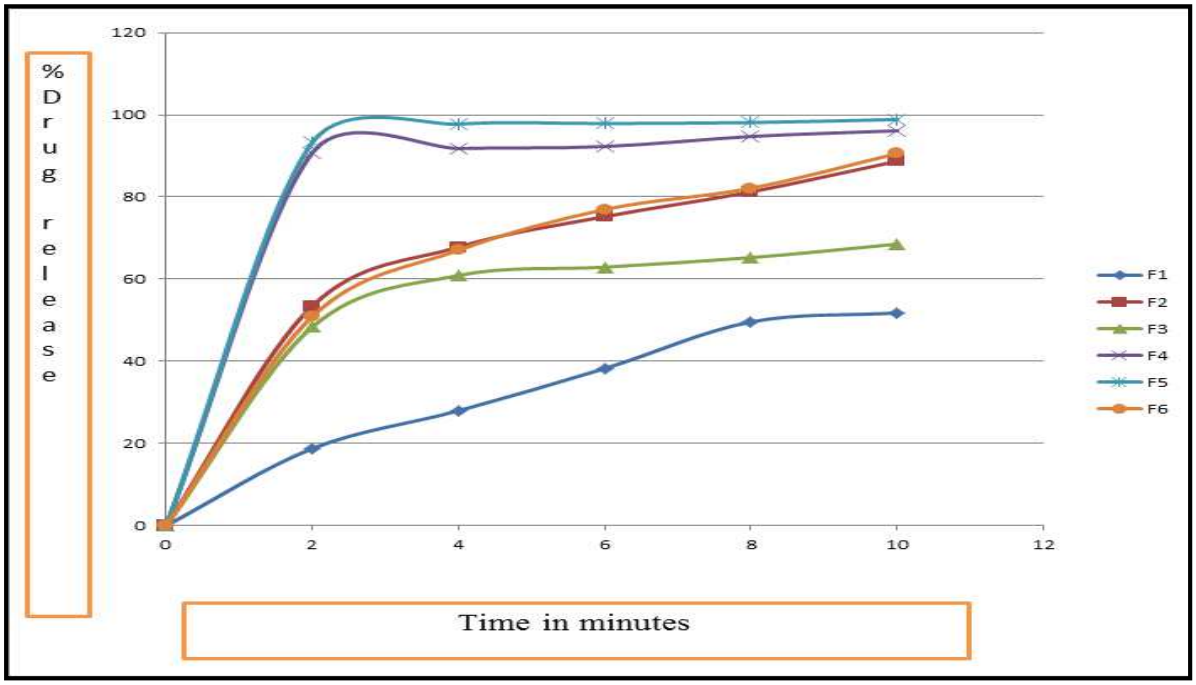

Figure No.2: Dissolution profile of tablet formulation

CONCLUSION

From the present study, it can be concluded that melt in mouth Aceclofenac tablets can be prepared by direct compression with superdisintegrants. Evaluation parameters like hardness and friability indicated that the tablets in all formulations were

mechanically stable. All the prepared formulations passed weight variation test and the percentage drug content of all tablets were found to be within the acceptable limits. *In vitro* dispersion time, wetting time, *in vitro* disintegration time parameters signified that superdisintegrant cross carmellose sodium act as good disintegrant. (i.e. F5 formulation). *In vitro* dissolution studies showed maximum drug release from F5 tablets. Thus, formulation F5 was selected as the optimized batch. Formulation F5 was found to be excellent melt in mouth tablets with good taste. The simplicity and cost-effectiveness of direct compression technique was the reason for choosing the method of formulation. In direct compression, savings can occur in a number of areas, including reduced Processing time and thus reduced labour costs, fewer manufacturing steps and pieces of equipment, less space and lower consumption of power. The future potential for orodispersible tablets is promising because of the availability of new technologies combined with strong market acceptance and patient demand. Melt in mouth tablets may be developed for most of the available drugs in near future.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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