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FORMULATION AND *IN-VITRO* EVALUATION OF ACECLOFENAC ORODISPERSIBLE TABLETS

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ABSTRACT

The object of the study was to formulate and evaluate Aceclofenac orodispersible tablets (ODT) by wet granulation method using different super disintegrants in different concentrations. Orodispersible tablets produce rapid dissolution of drug and absorption thereby producing rapid onset of action. Five batches (AFD1, AFD2, AFD3, AFD4, AFD5) of Aceclofenac orodispersible tablets were prepared and characterized for hardness, friability, thickness, uniformity of weight, drug content, disintegration time, *In-vitro* dissolution studies. Formulation (AFD5) was found to be better formulation in terms of rapid disintegration and maximum percentage of drug release compared to other formulations.

INTRODUCTION: Orodispersible tablet [8, 9, 10] is a solid dosage form containing medicinal substances or active ingredients which disintegrate rapidly when placed upon a tongue. Super disintegrants [3, 11, 12] added to provide quick disintegration due to combined effect of swelling and water absorption. This promotes wettability and dispersibility which in turn enhance the rate of disintegration and dissolution.

Aceclofenac [4] is a non steroidal anti inflammatory drug (NSAID). The mechanism of action is based on the inhibition of prostaglandin synthesis. Aceclofenac is a potent inhibitor of enzyme cyclooxygenase which is involved in the production of prostaglandins. Aceclofenac inhibits the synthesis of inflammatory mediators like cytokines, interleukins (IL)-1, tumor necrosis factor (TNF) and prostaglandin E (PGE2) production.

MATERIALS AND METHOD

Materials: Aceclofenac was received from Koushik pharmaceutics (Chennai, India), croscarmellose sodium, sodium starch glycolate, microcrystalline cellulose, saccharin sodium, starch, poly vinyl pyrrolidone, talc were received from Tablets of India (Chennai, India) as gift samples. All the other ingredients used were of analytical grade. Composition of various Aceclofenac orodispersible tablets are depicted in **table 1**.

Method: Aceclofenac orodispersible tablets were formulated by wet granulation method [5]. A part of polyvinyl pyrollidone (PVP) was added slowly to 5ml of isopropyl alcohol (IPA) and dissolved by continuous stirring. Aceclofenac, polyvinyl pyrrolidone, croscarmellose sodium, sodium starch glycolate, microcrystalline cellulose, starch and saccharin sodium were passed through sieve 40# separately and mixed well. Previously prepared binding solution was added to the above ingredients and mixed well to form a coherent mass.

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TABLE 1: COMPOSITION OF VARIOUS FORMULATIONS

Ingredients (mg)	AFD-1	AFD-2	AFD-3	AFD-4	AFD-5
Aceclofenac	100	100	100	100	100
Croscarmellose sodium	4	8	-	-	4
Sodium starch glycolate	-	-	4	8	4
Micro crystalline cellulose	50	46	50	46	46
Starch	30	30	30	30	30
Poly vinyl pyrrolidone(paste)	0.4	0.4	0.4	0.4	0.4
Saccharin sodium	10	10	10	10	10
Talc	2	2	2	2	2
Iso propyl alcohol	Q.S	Q.S	Q.S	Q.S	Q.S
Flavor (vanilla)	2	2	2	2	2
Magnesium stearate	2	2	2	2	2

Total weight of tablet = 200mg AFD- Aceclofenac orodispersible tablet

The coherent mass was passed through sieve 40# and dried at 60-70°C for one hour in hot air oven. The dried granules were passed through sieve 20#. The granules were lubricated with magnesium stearate, talc. Pre compression studies such as angle of repose, bulk density, tapped density, compressibility index, Hausner's ratio were carried out for granules and compressed into tablets using tablet compression machine (Rimek).

Precompression Studies: The granules of each formulation was evaluated by various parameters [2, 6] such as bulk density, tapped density, angle of repose, compressibility index and Hausner's ratio.

1. **Angle of Repose:** Angle of repose of granules was measured by cylinder method. If the angle of repose is within 35° it indicates good flow property. The results showed that the angle of repose was found in the range of 32° to 34°

2. **Bulk Density**: Bulk density of granules of all formulations was determined by using measuring cylinder. Bulk density was found in the range of 0.18 to 0.23 g/cm^3 .

3. **Tapped Density**: Tapped density of granules of all formulations was determined by using measuring cylinder. Tapped density was found in the range of 0.21 to 0.23 g/cm^3 .

4. **Compressibility Index:** If the compressibility index of granules is 11 to 15 it shows good flow character. Compressibility of granules of all formulations was found in the range of 11.52 to 14.02

5. **Hausner's ratio:** If Hausner's ratio is 1.12 to 1.18 it shows good flow character. Hausner's ratio of granules of all formulations was found in the range of 1.12 to 1.16

Evaluation:

1. **Uniformity of Weight:** 20 tablets were selected randomly and average weight was calculated. Then tablets were weighed individually and individual weight was compared with the average weight.

2. **Hardness and Friability:** Tablets were evaluated for hardness and friability testing using Monsanto hardness tester and Roche friabilator respectively.

3. **Disintegration Time:** Tablet disintegration study was performed for each batch of formulated Aceclofenac oro dispersible tablets.

4. **Water Absorption Ratio:** A tissue paper sized at 12cm×10.75cm folded twice was kept in a small petri dish containing 6ml of phosphate buffer p^H buffer 7.4. A tablet was placed on the paper and the time for complete wetting was measured. The wetted tablet was weighed and the water absorption ratio (R) was determined using the following formula

$$Wa\text{-}Wb/wa\times100 = R$$

Wa, Wb= weight of the tablet before and after study.

Results of various evaluation parameters are depicted in **table 2**.

TABLE 2: EVALUATION OF ORODISPERSIBLE TABLETS OF ACECLOFENAC

Formulation	Weight variation(%)	Hardness (kg/cm^2)	Friability (%)	Drug content (%)	Disintegration Time (seconds)	Wetting time (seconds)	Water absorption Ratio
AFD-1	0.273	4	0.73	98.66	35	9	53.27
AFD-2	0.194	4	0.68	99.03	40	7	55.01
AFD-3	0.088	3.5	0.81	97.96	41	6	52.02
AFD-4	0.128	4	0.65	98.36	47	9	51.07
AFD-5	0.122	4	0.72	99.68	30	11	50.09

5. **Estimation of Drug Content:** The content of active ingredients was analyzed by using phosphate buffer pH 7.4.

6. **Dissolution Study:** The dissolution study[1,4] was carried out by USP type 2 (paddle) dissolution appparatus using phosphate buffer P^H 6.8 as dissolution medium with 100 rpm at 37°c for 10 minutes. Samples were filtered and absorbance was measured at 274nm using UV-VIS spectrophotometer 9UV, Shimadzu Corporation, Japan. The percentage of drug release was calculated. The results of *in vitro* dissolution study are depicted in table.3 and fig.1

TABLE 3 : *IN VITRO* DISSOLUTION PROFILE OF ACECLOFENAC ORODISPERSIBLE TABLETS

Time(minutes)	Drug release(%) AFD-1	Drug release(%) AFD-2	Drug release(%) AFD-3	Drug release(%) AFD-4	Drug release(%) AFD-5
1	70.46	71.25	71.29	72.12	75.16
2	77.52	76.22	77.23	76.98	79.98
3	81.78	80.34	79.11	78.15	85.14
4	84.92	83.09	82.67	85.23	91.25
5	86.71	85.54	85.89	90.12	100.12
6	92.24	91.78	91.81	93.56	-
7	98.22	97.73	97.67	97.89	-
8	100.02	99.81	99.75	99.78	-
9	100.45	100.36	100.23	100.12	-
10	-	-	-	100.48	-

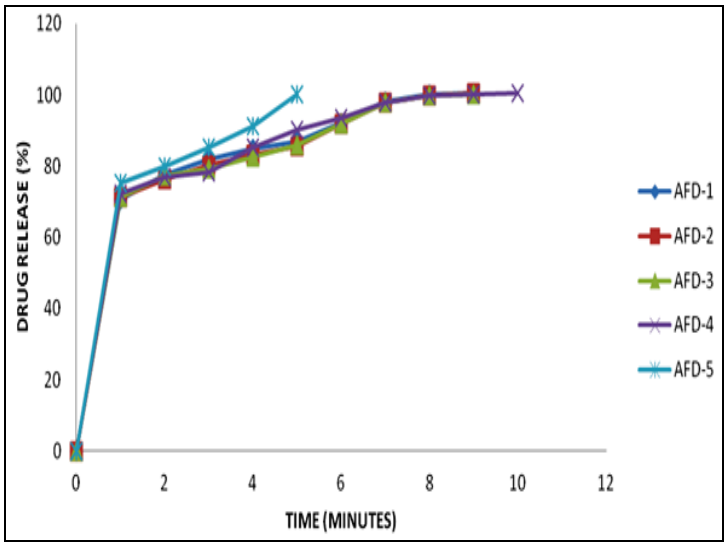

FIGURE 1: *IN VITRO* DISSOLUTION PROFILE OF ACECLOFENAC ORODISPERSIBLE TABLETS

RESULTS AND DISCUSSION: Oro Dispersible Tablets(ODT) of aceclofenac were prepared by wet granulation method with two different [7] super disintegrants. The evaluation studies were carried out for granules and compressed tablets of different batches. Evaluation studies were carried out for uniformity of weight, thickness and diameter, hardness, friability, disintegration time, wetting time and water absorption ratio.

All the parameters were found to be within the limits. Hardness of dispersible tablets are usually 2.5-5kg/cm^2. Hardness of the tablets of all formulations was within the range of 5kg/cm^2. Standard limit for uniformity of weight of tablet is ±7.5%.All the tablets were within limits. Friability test was carried out and maximum weight loss is not more than 1%.

Friability of all the formulated tablets was within the range of 0.082±0.32% to 0.097±0.38%. Disintegration study was performed and disintegration time of AFD-1, AFD-2, AFD-3, AFD-4, AFD-5 were 35, 40, 41, 47,30 seconds respectively. Disintegration time of AFD-5 was found to be 30 seconds. Disintegration time of AFD-5 was less compared to other formulations. Drug content of AFD-1, AFD-2, AFD-3, AFD-4, AFD-5 were found to be 98.66%, 99.03%, 97.96%, 98.36%, 99.68% respectively. All the five formulations showed a rapid drug release. AFD-5 showed 100.12% of drug release at the end of five minutes compared to other formulations. This is due to the presence of both the super disintegrants namely CrosCarmellose Sodium and Sodium Starch Glycolate in equal concentrations.

CONCLUSION: Formulation (AFD-5) containing both Sodium Starch Glycolate and CrosCarmellose Sodium was found to be better formulation in terms of rapid disintegration and maximum percentage of drug release compared to other formulations. There is further scope to conduct *in-vivo* studies, pharmacokinetic studies, toxicity studies.

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