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In Vitro Determination of Aceclofenac Mouth Dissolving Tablets

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of article

Abstract

In the present study, Mouth Dissolving Tablets (MDTs) of aceclofenac were formulated by direct compression technique. Sodium starch glycolate and crospovidone were employed as superdisintegrants in various concentrations like 2%, 3% and 4% w/w. All prepared tablets were evaluated for weight variation, hardness, drug content, friability, disintegration time, *in vitro* wetting time and percent drug release. MDTs containing 4% w/w concentration of crospovidone give best results and is therefore considered as the best formula. It has shown 30 s disintegration time, 25 s wetting time and 79.34% *in vitro* release of drug in 25 min (Polim. Med. 2013, 43, 4, 227–229).

Key words: aceclofenac, mouth dissolving tablets, crospovidone, sodium starch glycolate.

Dysphagia is a common problem found among all age groups that result in patient non-compliance [1–3]. Various advancements have taken place in drug delivery systems. Mouth Dissolving Tablets (MDTs) is one of them. It makes administering the drug to dysphagia patients easy and convenient. Advantages of MDTs include the possibility to administer it without water; it acts as liquid dosage form and shows higher oral bioavailability [4–6]. Superdisintegrants are the main ingredients used in MDTs. Various superdisintegrants reported in literature include sodium starch glycolate, hydroxyl ethyl cellulose, croscarmellose sodium, crospovidone, etc [7–11]. Aceclofenac is a widely used anti-inflammatory drug which inhibits the cyclooxygenase enzyme and reduces pain [12]. In the present study crospovidone and sodium starch glycolate were evaluated at different concentrations to fabricate MDTs of aceclofenac.

Materials and Methods

Materials

Aceclofenac was obtained from Lark Laboratories Ltd., Bhiwadi (Rajasthan), India. Crospovidone, sodium starch glycolate, sodium saccharin, mannitol, mi-

crocrystalline cellulose and magnesium stearate were purchased from CDH Laboratories, New Delhi. Analytical grade solvents and chemicals were used.

Preparation of MDTs

MDTs of aceclofenac were fabricated by using a direct compression method. Drug, sodium saccharin and superdisintegrants were passed through a number 40

Table 1. Composition of MDTs

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Aceclofenac	100	100	100	100	100	100
Sodium saccharin	2	2	2	2	2	2
Crospovidone	4	6	8	–	–	–
Sodium starch glycolate	–	–	–	4	6	8
Mannitol	30	30	30	30	30	30
Microcrystalline cellulose	62	60	58	62	60	58
Magnesium stearate	2	2	2	2	2	2
Total weight	200	200	200	200	200	200

sieve and mixed with mannitol. Microcrystalline cellulose was mixed in a blend and then the blend was lubricated with magnesium stearate. Tablets were prepared using 2%, 3% and 4% w/w concentration of superdisintegrants. The blends were compressed to form MDTs using flat round punches of Cadmach Punching machine. The compositions of formulations are represented in Table 1.

Evaluation of Prepared MDTs

Weight Variation or Uniformity of Weight

Twenty tablets were selected at random and weighed individually using an electronic balance. The weight variation was calculated by comparing the weight of individual tablet with the average weight of 20 tablets.

Hardness

To evaluate tablet hardness, hardness testers such as Monsanto type or Pfizer type are currently in use. Hardness was determined in 5 tablets using Monsanto Type Digital Hardness Tester (EH-01P, USP 1217).

Friability

Friability percentage of compressed tablets was intended to determine the physical strength of tablets. Friability was measured using a Roche Friabilator (Electrolab, Mumbai). Ten pre-weighed tablets were rotated at 25 rpm for 4 min. The tablets were then reweighed and the percentage of loss in weight was calculated.

Content Uniformity

Twenty tablets were powdered. The percentage of drug content was determined using tablet powder equivalent to 100 mg aceclofenac and was dissolved in 100 ml methanol. The required dilutions (1 µg/ml) were analyzed spectrophotometrically at 275 nm.

Disintegration Time

In vitro disintegration time of tablets was determined by using disintegration apparatus (ELECTROLAB DISINTEGRATION TESTER (USP)-ED2L) carried out at $37^{\circ} \pm 2^{\circ}\text{C}$ in water.

Wetting Time

Wetting time was evaluated by placing a tissue paper in a petridish containing 10 ml water. MDT was placed on tissue paper and the wetting was recorded.

In-Vitro Dissolution Studies

In-vitro dissolution of aceclofenac tablets were studied using USP dissolution test apparatus Type II (ELECTROLAB TDT-8L, Mumbai, India) paddle type at 50 rpm and with the use of 900 ml of phosphate buffer (pH 7.5). The dissolution medium temperature was maintained at $37 \pm 0.5^{\circ}\text{C}$. Five ml of aliquots were withdrawn at specific intervals of 0, 5, 10, 15, 20, and 25 min and analyzed for drug content by measuring the absorbance at 275 nm. The volume withdrawn at each time interval was replaced by the same amount of fresh dissolution medium to maintain sink conditions. The percent drug released was calculated and plotted against time [13].

Results and Discussion

Weight variation was found within the limits as specified by Indian Pharmacopoeia (2007). The determined test parameters for tablets are depicted in Table 2. Mean weight of all fabricated MDTs was found in range of 197 to 204 mg. Hardness of tablets was in range 3.45 to 5.07 Kg/cm². Hardness and friability loss (0.64–0.74%) conclude that prepared tablets had a good mechanical strength. Percent drug content in all MDTs was found to be high (equal or more than 99.00%). Wetting time was found between the ranges 25 to 45 seconds. In the study it was found that as the level of crospovidone increases, the wetting time of

Table 2. Evaluation parameters of tablets

Parameter	F1	F2	F3	F4	F5	F6
Weight variation (mg)	200.01 \pm 1.41	201.00 \pm 1.02	200.03 \pm 1.43	200.03 \pm 1.71	200.00 \pm 2.11	200.03 \pm 1.09
Hardness (kg/cm ²)	3.46 \pm 0.06	4.00 \pm 0.90	4.26 \pm 0.81	3.92 \pm 0.51	3.51 \pm 0.01	3.78 \pm 0.68
Drug content	99.01 \pm 0.11	98.23 \pm 0.78	99.00 \pm 0.21	99.04 \pm 0.06	99.16 \pm 0.03	99.15 \pm 0.09
Friability	0.70 \pm 0.01	0.68 \pm 0.04	0.40 \pm 0.01	0.72 \pm 0.02	0.71 \pm 0.01	0.69 \pm 0.02
Disintegration time (s)	46.00 \pm 0.26	41.00 \pm 0.70	30.00 \pm 0.11	54.00 \pm 0.21	48.00 \pm 0.10	42.00 \pm 0.12
Wetting time (s)	37.00 \pm 0.02	32.00 \pm 0.11	25.00 \pm 0.19	45.00 \pm 0.14	41.00 \pm 0.12	38.00 \pm 0.10
% Drug release at 25 minutes	75.31	77.33	79.34	66.82	68.85	76.78

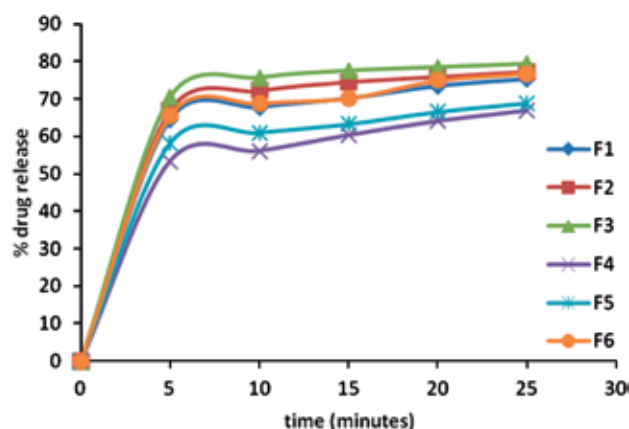


Fig. 1. *In vitro* drug release profile of different formulations of aceclofenac MDTs

tablet decreases; the case with sodium starch glycolate was the same. F3 formulation containing crospovidone (4% w/w) as superdisintegrants has shown disintegration time of 30 second. F3 batch also has shown best *in vitro* drug release as compared to all other formulations. The *in vitro* dissolution profile of drug from tablet is depicted in Figure 1.

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