

**PHARMA SCIENCE MONITOR****AN INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES**Journal home page: <http://www.pharmasm.com>**FAST DISPERSING TABLETS REVIEW**

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ABSTRACT

In this investigation fast dissolving tablets were prepared using different Superdisintegrants like crospovidone, croscarmellose sodium and sodium starch glycolate by direct compression method. FDTs were evaluated for physicochemical properties like thickness, uniformity of weight, content uniformity, hardness, friability, wetting time, dispersion time *in vitro* disintegration time and *in vitro* dissolution. Wetting time of formulations containing Croscarmellose sodium was least and tablets showed fastest disintegration. The drug release from FDTs increased with increasing concentration of superdisintegrants and was found to be highest with formulations containing Croscarmellose sodium. The tablet disintegrated within 16 to 45 seconds. Almost 96% of drug was released from the formulation within 16 min. The release of drug from FDTs was found to follow non-Fickian diffusion kinetics. Stability studies of the tablets shows non significant change.

KEYWORDS: Fast dispersing tablet, crospovidone, superdisintegrants, non-fickian diffusion.

INTRODUCTION

Fast dispersing tablets (FDT) are novel type of tablets that disintegrate/dissolve/disperse in saliva within 15 to 60 s, when placed upon the tongue without the need of water. Due to this advantage of FDTs leads to their suitability for geriatric and pediatric patients at anytime, anywhere.[1-3]. Their growing importance was underlined recently when European pharmacopoeia adopted the term "Orodispersible tablet" as a tablet that to be placed in the mouth where it disperses rapidly before swallowing. According to European pharmacopoeia, the ODT should disperse/disintegrate in less than three minutes. United States Food and Drug Administration (FDA) define orally disintegrating tablets as "A solid dosage form which contains a medicinal substance or active ingredient which disintegrates rapidly within a matter of seconds when placed upon the tongue". US Food and Drug Administration Center for Drug Evaluation and Research (CDER) defines, in the 'Orange Book', an ODT as "a solid dosage form containing medicinal substance, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue".[4] The bioavailability of some drugs may be increased due to absorption of drug in oral cavity and also due to pregastric absorption of saliva containing dispersed drugs that pass down

into the stomach. The amount of drug which is subjected to first pass metabolism is reduced as compared to conventional tablet.[5].

Drug is selective Beta-1 receptor antagonist. Activation of Beta-1 receptor by epinephrine increase the heart rate and blood pressure. Drug blocks these receptors which reverses the effect of epinephrine, lowering the heart rate and blood pressure. In addition beta blocker prevent the release of renin, which is a hormone produced by the kidneys which leads to constriction of blood vessels.[6] FdTs prepared by many techniques like freeze drying, sublimation, direct compression, spray drying, tablet molding, cotton candy and mass extrusion.[7-8] Among these the direct compression method is the better option for manufacturing of the FDTs because it has main advantage like low manufacturing cost and high mechanical integrity of the tablet. The fast dispersing tablet prepared by direct compression method. in general, are based on the action established by superdisintegrants such as croscarmellose sodium, and crospovidone. The effect of functionality differences of the superdisintegrants on tablet disintegration has been studied. The objective of the present work to develop fast dispersing tablets by croscarmellose sodium, sodium starch glycolate and crospovidone are used as superdisintegrants. Effect of method of preparation on dissolution rate, disintegration time and wetting time was studied.[9].

MATERIAL AND METHOD

Valdecoxib, Etoricoxib, Meloxicam, Olanzapine those are marketed product. croscarmellose sodium, crospovidone, sodium starch glycolate, dc mannitol, microcrystalline cellulose, talc and magnesium stearate.[10]

Preparation of tablets by direct compression method: Tablet containing 5 mg of Drug were prepared by direct compression method and the various formulae used in the study are shown in [Table 1]. The drug, diluents and superdisintegrants were pass through sieve no 44 separately and properly mixed together (in a plastic container), and In dry state, the drug with other ingredients was mixed for the period of 10min to get in uniformly mix powder. these powders were lubricated with magnesium stearate and talc and then finally raspberry was added. The tablets were prepared by direct compression method by manual feeding using 8 mm biconcave punches on a 'Rimek mini press 1' a 10 station rotary compression machine.

EVALUATION : The prepared tablets were evaluated for hardness, thickness and diameter, friability, disintegration time, wetting time, drug content, in-vitro dissolution studies, and stability studies.

Thickness [11]

Thickness of tablets was important for uniformity of tablet size. Thickness was measured using screw gauge on randomly selected samples.

Hardness [11]

The resistance of tablet for shipping or breakage, under conditions of storage, transportation and handling, before usage, depends on its hardness. The hardness of tablet of each formulation was measured by Monsanto hardness tester. Four tablets from each batch were selected and evaluated, and the average value with standard deviation was recorded.

Friability [12]

Friability is the measure of tablet strength. Roche friabilator was used for testing the friability using the following procedure. Twenty tablets were weighed accurately and placed in the tumbling apparatus that revolves at 25 rpm dropping the tablets through a distance of six inches with each revolution. After 4 min., the tablets were weighed and the percentage loss in tablet weight was determined.

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Weight variation [12]

Twenty tablets were weighed individually and the average weight was determined. The % deviation was calculated and checked for weight variation as per IP.

Estimation of drug content [12]

Estimation of drug content test as described in the IP was followed. Ten tablets were weighed and average weight was calculated. All tablets were crushed and powder equivalent to 10 mg drug was dissolved in 10 ml of 0.1N HCl and shaken for 1 h. From above solution 1 ml was withdrawn and diluted up to 10 ml and again withdraws 1 ml out of 10 ml and makes up to 10 ml with 0.1N HCl. Solution was filtered and absorbance was measured spectrophotometrically at 281 nm against reagent blank. Amount of drug present in one tablet was calculated.

Disintegration test [12]

Randomly six tablets were selected from each batch for disintegration test. Disintegration test was performed without disc in distilled water using USP disintegration apparatus.

Wetting Time [13]

Wetting time of dosage form is related with the contact angle. Wetting time of the mouth dissolving tablets is another important parameter, which needs to be assessed to give an insight

into the disintegration properties of the tablets; a lower wetting time implies a quicker disintegration of the tablet. The wetting time of the tablet can be measured using a simple procedure.

Method:

Five circular tissue papers of 10 cm diameter are placed in a petridish with a 10 cm diameter. Ten ml of water containing Eosin, a water soluble dye is added to petridish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as wetting time.

Water absorption ratio

Water absorption ratio (**R**) is calculated using the formula

$$R = 100 \times [W_a - W_b] / W_b$$

Where, W_a = weight of tablet after absorption

W_b = weight of tablet before absorption

***In vitro* Dispersion time [14]**

The disintegration time for mouth dissolving tablets needs to be modified as disintegration is required without water, thus the test should mimic disintegration in salivary content. For this purpose, a Petridish (10 cm diameter) was filled with 9 ml of phosphate buffer solution, pH 6.8 (which correlates pH of saliva). The tablet was carefully put in the center of Petridish and time for the tablet to completely disintegrate into fine particles was noted.

***In vitro* drug release [12]**

The *in vitro* release rate of Drug1 from fast dispersing tablets was determined by using USP dissolution testing apparatus II (Paddle type). The dissolution test was performed using 500 ml of 0.1 N HCl, at $37 \pm 0.5^\circ\text{C}$ and 50 rpm. 2 ml aliquots were withdrawn from the dissolution apparatus and the samples were replaced with fresh dissolution medium. Sampling interval time was 2 min and withdrawn upto 16 min. Then, aliquots were filtered. After filtration, the amount of drug released was determined from the standard calibration curve of pure drug.

STABILITY STUDY [15]

Stability testing of drug products begins as a part of drug discovery and ends with the demise of the compound or commercial product. To assess the drug and formulation stability, stability studies were done according to ICH guidelines. The stability studies were carried out on the best formulation as per ICH guidelines. The most satisfactory formulation sealed in aluminum packaging and kept in humidity chamber maintained at $30 \pm 2^\circ\text{C}/65 \pm 5\% \text{ RH}$ and $40 \pm 2^\circ\text{C}/75$

± 5 % RH for 2 months. The samples were analyzed for the drug content, *in vitro* dissolution studies, disintegration time and other physicochemical parameters after 30 days and 60 days.

Table No : 1 Formula for the preparation of FDTs

Ingredients	F1 mg	F2 mg	F3 mg	F4 mg	F5 mg	F6 mg	F7 mg	F8 mg	F9 mg	F10 mg
Drug	5	5	5	5	5	5	5	5	5	5
SSG	0	0	0	5.2	11.2	2.5	2.5	5.5	5.5	0
Crospovidone	6	7.5	0	5.25	0	11.25	2.5	5.5	0	5.5
CCS	7.5	0	7.5	5.25	0	0.75	6	0	5.5	5.5
Mannitol	100.27	100.27	105	100	102	102	103	105	105	105
MCC	27	27	27	25	25	25	25	25	25	25
Magnesium stearate	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75
Talc	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75
Raspberry	0.5	0.5	1.15	1.5	1.5	1.15	1.15	1.15	1.15	1.15
Aerosil	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75
Total wt.	150	150	150	150	150	150	150	150	150	150

CONCLUSION

In the present study, an attempt was made to prepare FDTs in order to increase its onset of action by increasing its dissolution by its faster disintegration which is requirement for severe hypertensive condition and for better patient compliance, as it can be swallowed without the use of water.

The FDTs were prepared by direct compression method using simplex lattice design. In these dosage form three superdisintegrating agent were used namely crospovidone, croscarmellose sodium and sodium starch glycolate in order to decrease the disintegration time. The process was carried out and the formula was prepared by the observed response and desirable values. The best formulation was found to be best in terms of cost effectiveness as one super disintegrant was used, disintegration time was found to be 17.16 sec with sufficient hardness, friability and release the maximum amount of the drug in 16 min. It showed no significant change in physicochemical properties, drug content, disintegrating time and *in vitro* dissolution pattern after storage at $30 \pm 2^\circ\text{C}/65 \pm 5\%$ RH and at $40 \pm 2^\circ\text{C}/75 \pm 5\%$ RH during stability studies for two months. Thus, the objective of the present investigation to design and prepared FDTs was achieved.

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