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RESEARCH ARTICLE

Comparative Success of Natural Superdisintegrant over Synthetic Superdisintegrants in Fast Disintegrating Tablets

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ABSTRACT

In the present study, fast disintegrating tablets of Amlodipine Besylate were prepared by direct compression methods for better patient compliance and immediate action in angina. The tablets were prepared by using synthetic superdisintegrants (Crospovidone and Croscarmellose sodium) and natural superdisintegrant (*Plantago ovata*) at different concentrations. The prepared tablets were evaluated for weight variation, hardness, Friability, disintegration time, wetting time, dispersion test, drug content and in vitro dissolution tests. The tablets were subjected for stability study at 25°C /60% RH and 40°C/ 75% RH. The results clearly shows Natural superdisintegrant (husk of *Plantago ovata*) requires less disintegration time as compared to synthetic superdisintegrants. Hence present study reveals that the fast disintegrating tablets prepared by using husk of *Plantago ovata* as superdisintegrants having better appearance and it having rapid disintegration time.

Keywords: fast disintegrating tablets, Superdisintegrants, *Plantago ovata*.

1. INTRODUCTION

Over a decade, the demand for development of patient's friendly dosage form. The elder peoples constitute a major portion of population because of their increasing expectancy about life. [1] Hence, there has been an enhanced demand for more patients friendly and compliant dosage forms. Which results in increasing demand for developing new technology has been increase annually. [2] Several fast dissolving drug delivery systems have been investigated in an attempt to overcome the above limitations of conventional solid dosage forms. Scientist at Wyeth Laboratories in UK pioneered fast dissolving drug delivery during the late 1970s[3] fast dissolving tablets commonly known as Orally Disintegrating tablets, mouth dissolving tablets, fast dissolving tablets.

Fast disintegrating tablets mainly prepared by direct compression using superdisintegrants additions method. Disintegrants are substances or mixture of substances added to the drug formulation that facilitates breakup or disintegration of tablet content into smaller particles that dissolve more rapidly than in the absence of disintegrants. Examples of superdisintegrants are crosscarmelose, crosspovidone, sodium starch glycolate which represent example of crosslinked cellulose, crosslinked polymer and a crosslinked starch respectively. [4, 5]These are the commonly used synthetic origin superdisintegrants, similarly various natural origin substances like karaya, modified starch and agar have been used in the formulations of ODTs. The uses of natural origin substances are comparatively cheaper with desired properties like abundantly available, non-irritating and non-toxic in nature. Mucilage of *Plantago ovata* has various characteristics like binding, disintegrating and sustaining properties. [6] Hence, in present study the husk of *Plantago ovata* is used in orally disintegrating tablets. These tablets were compared with the tablets prepared by using synthetic superdisintegrants crosscarmelose sodium and crosspovidone for disintegration time and wetting time. The model drug used for study is Amlodipine Besylate, which is an ahtihypertensive drug used in angina pectoris.

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2. MATERIALS AND METHODS:

Amlodipine Besylate was obtained as gift samples from Aurobindo Pharmaceuticals Ltd. Hyderabad. The Husk of *Plantago ovata* was purchased from local market of Shirpur. All materials used in formulation study were of Pharmaceutical grade.

2.1 Assignment of formulation code:

Various formulations of Amlodipine Besylate(API) fast disintegrating tablets(FDTs) were designed utilizing natural superdisintegrant husk of *Plantago ovata* (PO) and synthetic superdisintegrants as Crosscarmelose sodium(CCS), Crospovidone (CP) each varied at three different concentrations(2.5, 3.0 and 3.75). All of the other ingredients were kept constant. A total of such nine formulations prepared were designated with their codes and will be referred with the same in further sections. The assigned formulation codes were as follows: PO1, PO2, and PO3 for formulations containing *Plantago ovata* as a superdisintegrants with concentrations 2.5, 3.0, 3.75 % respectively. Similarly, CCS1, 2, 3 and CP1, 2, 3 were the assigned code for the formulations prepared with these respective superdisintegrants at the percentage levels provided for PO above.

2.2 Tablets formulation:

Direct compression method is used for the formulation of Amlodipine Besylate orally disintegrating tablets. The husk of *Plantago ovata* was crushed using mortar and pestle until gets fine powder, that can passed through # 60 sieve. This crushing and sifting step left the chances of coloring spots due to husk of *Plantago ovata*

Weigh the materials in different proportions (Table No.1) and Shift the API (Amlodipine Besylate), Crosscarmelose sodium, Crospovidone, MCC, Mannitol, and Lactose through 30# sieve separately and geometrically mix them together for 10 min. into mortar. Simultaneously sift talc, Magnesium stearate and *Plantago ovata* husk powder through 60 # sieve and it added to above 30 # sieve passed material, then lubricate it for 5 min. After lubrication the blend was compressed using twelve station single rotary compression machine with single (8 mm) punch. The weight was first adjusted for 160 mg tablets then simultaneously hardness and thickness was adjusted in such a way, which gives better friability results. The tablets were tested for in process as well as finished product testing.

2.3 Tablets Evaluation Test:

In process parameters evaluation

Weight variation test*:* [7]

Weight variation test was done by weighing 20 tablets individually on electronic balance, calculating the average weight and comparing the individual tablets weight to the average. The tablet then complies or not with pharmacopoeia limit is tested. The following percentage deviation in weight variation is allowed.

Ingredients	Quantity (% w/w)		
	1	2	3
Amlodipine Besylate	6.25	6.25	6.25
Superdisintegrants	2.50	3.00	3.75
MCC 102	25.31	25.18	25.00
Lactose Monohydrate	31.64	31.48	31.25
Mannitol	30.37	30.18	30.00
Magnesum Stearate	1.26	1.25	1.25
Talc	2.53	2.52	2.50

Table 1: Composition of Amlodipine Besylate Fast Disintegrating Tablets in Percentage.

Average weight	% difference
130 – 324 mg	7.5

Table 2: Percentage deviations

Hardness test*:* [8]

Tablet hardness is measured with hardness tester like Monsanto for six tablets from each formulation. A tablet is placed in hardness tester and load required to crush the tablet is measured. The hardness of ODTs is generally kept lower than conventional tablets as increased hardness delays the disintegration of the tablets.

Thickness*:*

The thickness of three tablets from each batch was determined using a Vernier caliper.

Friability test*:* [8]

Friability is a crucial parameter for evaluation of ODT which can be measured by using Roche Friabilator. Attempts for decreasing the disintegration time increasing the friability of ODTs than conventional tablets. Ten tablets weighed initially after 25 RPM for min tablets dedusted and reweighed. Friability is expressed in % and calculated by formula

$$F = \frac{(\text{Wt. initial} - \text{Wt. final}) \times 100}{\text{Wt. initial}}$$

Disintegration time*:* [9]

To test the disintegration time, one tablet is placed in each tube of USP apparatus. The 900ml distilled water at

37°C ±2°C is used as media. To complies EP limits all tablets should pass through 10# sieve within 3 Min.

2.4 Finished product parameter

Drug content: [10]

Ten tablets were powdered and the blend equivalent to 5 mg of Amlodipine Besylate was weight and dissolved in suitable quantity of pH 1.2 solutions. Solutions was filtered and diluted drug contents analyzed spectrophotometrically at 239 nm using Perkin Elmer.

Wetting time and water absorption ratio: [11]

A piece of tissue paper folded twice was kept in a culture dish containing 6 ml of purified water. A tablet having a small amount of amaranth powder on the upper surface was placed on the tissue paper. The time required to develop a red colour on the upper surface was placed on the tissue paper. The time required to develop a red colour on the surface of the tablets was recorded as wetting time. The same procedure without amaranth was followed for determining the water absorption ratio. The wetted tablets was weighed and the water absorption ratio

R, was determined according to the following equation

R= 100(Wa-Wb)/Wb

Where, Wb and Wa were the weights of the tablets before and after study.

Dispersion Test: [11]

Uniformity of dispersion was checked as per Indian Pharmacopoeia. Two tablets were placed in 100 ml water (25°C in beaker). The tablets were allowed to disintegrate and dispersion was stirred with a glass rod until a smooth dispersion was obtained. The dispersion was passed through a 20# sieve and the sieve screen was checked for any material retained.

3. RESULTS

All nine batches were prepared under same conditions and on same instruments to minimize variations. Superdisintegrants are generally used by formulation scientist for developing FDTs or for improvement of solubility of drugs. The primary requirements of all nine formulations are quicker disintegration time.

The results of Amlodipine Besylate FDTs evaluation of different batches are shown in Table No. 3. The weight variation of 160 mg tablets was found maximum up to ± 1.2 % RSD. Hardness was found to be within 4.5 to 5.0 kg/cm2 which limit friability within 0.4 % only. The drug Contents was found to be within limits and all tablets were passing the dispersion test.

Batches	Weight Variation (mg ± S.D.)	Hardness (kg/cm^2±S.D.)	Friability (%)	Disintegration Time (Sec)	Drug Content (%)	Wetting Time (Sec)
PO 1	160±0.7	4.5±0.24	0.29	25	97.2	56
PO 2	160±0.8	5.0±0.25	0.28	23	96.9	55
PO 3	160±0.7	5.0±0.24	0.35	22	98.6	54
CCS 1	161±1.8	5.0± 0.21	0.24	36	99.2	54
CCS 2	160±0.6	4.5±0.24	0.31	35	95.9	56
CCS 3	160±0.62	4.0±0.22	0.41	32	97.5	57
CP 1	159±1.2	4.5±0.24	0.38	38	96.9	54
CP 2	160±0.9	5.0±0.23	0.34	38	97.4	57
CP 3	161±1.2	4.5±0.23	0.31	37	98.8	54

Table 3: Evaluation of formulated tablets

4. DISCUSSION

The evaluation results of all nine batches were found to be satisfactory within limit and the disintegration time of *Plantago ovata* was quite good than synthetic superdisintegrants viz CCS and crospovidone. This clearly indicates that Husk of *Plantago ovata* has good disintegrating property (Table No.04 & Graph No.01). The Husk of *Plantago ovata* creates hydrodynamic pressure when comes in contacts with saliva and disintegrates the tablets within few seconds by swelling. The all above tests clearly indicates that the Husk of *Plantago ovata* was found to be much effective at only 3.75% in optimized batch (PO3).

In present study natural superdisintegrant like Husk of *Plantago ovata* shows very less disintegration time and comparable dissolution profile over the other synthetic superdisintegrants Like CCS and crospovidone. Hence it proofs success of natural superdisintegrant in orally disintegrating tablets formulation at very low concentration and cost.

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Conflict of Interest: None Declared

