

Preparation and characterization of *Beta vulgaris* pulp powder as a pharmaceutical excipient

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ABSTRACT

Mouth dissolving tablet is the highly growing and highly accepted drug delivery system. In the present study, an attempt had been made to prepare fast dispersible tablets of diclofenac sodium using *Beta vulgaris* pulp powder as a pharmaceutical disintegrant. In the present investigation, wet granulation technique was used to prepare tablets, using microcrystalline cellulose as filler. Wet granulation technique is one of the most convenient and acceptable technology for preparation of fast dispersible tablets. Dispersible tablets of Diclofenac sodium were prepared with different concentrations viz; 2.5, 5, 7.5 and 10 % (w/w) of *Beta vulgaris* pulp powder and corn starch, and evaluated for physical parameters such as thickness, hardness, friability, weight variation, drug content, disintegration time and drug dissolution behavior. The formulated tablets had good appearance and better drug release properties. Studies indicated that the *Beta vulgaris* pulp powder is a good pharmaceutical adjuvant, specifically a disintegrating agent.

Keywords: *Beta vulgaris*, disintegrant, pharmaceutical excipients, diclofenac sodium

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INTRODUCTION

The tablet is the widely used dosage form because of its convenience in terms of self-administration, low cost and ease in formulation. However, geriatric and pediatric patients experience difficulty in swallowing conventional tablets, which leads to poor patient compliance. "Mouth dissolve (MD)" tablets are novel types of tablets that disintegrate/ dissolve/disperse in saliva within 15 to 60 s, without the need of water.^[1,2] This characteristic advantage leads to their suitability for geriatric and pediatric patients at anytime, anywhere. The benefits, in terms of patient compliance, rapid onset of action, increased bioavailability, and good stability make these tablets popular as a dosage form of choice in the current market. Different technological techniques, such as freeze drying, moulding, direct compression, are currently employed to prepare the formulations of this type present in the pharmaceutical market.^[3,4,5] *Beta vulgaris* (Chenopodiaceae) is an important plant found

in India. Pulp powder of this plant was used to prepare fast dispersible tablet. This type of natural plants plays an important role as pharmaceutical excipient. These are easily available, biodegradable and having low cost. Bio compatibility of these natural polymers promotes their use as in pharmaceutical formulations.

Present work used direct compression technique to prepare tablets. In present study Diclofenac sodium, a non-steroidal anti-inflammatory drug was selected as model drug. It is an acetic acid nonsteroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic properties. Diclofenac sodium is used to treat pain, dysmenorrhea, ocular inflammation, osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and actinic keratosis.^[5,6]

MATERIAL AND METHODS

Preparation of Beta vulgaris pulp powder

Beta vulgaris was purchased from local market of Meerut (Uttar Pradesh) India. The fruit was clean with water to

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remove dust from surface and further peel was removed. Pulp was cut into small pieces and put into grinder to form paste. This was further lyophilized to get solid porous mass. Size reduction was done and powder was collected. The collected powder was passed through 80 # sieve and stored in the air tight container for further study.^[1]

Characterization of *Beta vulgaris* pulp powder

Bulk density

Apparent bulk density (g/ml) was determined by placing pre-sieved bulk powder blend into a graduated cylinder via a large cylinder and measuring the volume and weight of powder blend.^[1,7,8]

$$\text{Bulk density} = \frac{\text{weight of powder blend}}{\text{volume of powder blend}}$$

Tapped density

It was determined by placing a graduated cylinder, containing a known mass of powder on mechanical tapping apparatus, which was operated for fixed number of taps (around 50). Using the weight of powder in a cylinder and its tapped volume, the tapped density was computed.^[1,7,8]

$$\text{Tapped density} = \frac{\text{weight of powder blend}}{\text{tapped volume of powder blend}}$$

Carr's index

It is an important parameter to study compressibility behavior of powder blend. Carr's index was calculated, from the results of bulk density and tapped density.^[1,7,8]

$$\text{Carr's index} = \frac{\text{bulk density} - \text{tapped density}}{\text{tapped density}}$$

Bulkiness

It is reciprocal of bulk density, and calculated as^[1,7,8]

$$\text{Bulkiness} = 1 / \text{bulk density}$$

Angle of repose

For the measurement of angle of repose, a glass funnel was taken with its tip at a given height (H), above a piece of graph paper placed on a horizontal surface. Powder was poured through the funnel until the apex of the conical pile touched the tip of the funnel. The angle of repose was calculated with the formula; $\tan \theta = H/R$, where θ is the angle of repose and R is the radius of the conical pile.^[1,7,8]

Swelling index

The swelling index is defined as the volume (in milliliters) taken up by the swelling of 1 g of powder material under specified conditions. 1 gm of the pulp powder was introduced into a 25 ml glass-stoppered measuring cylinder. Twenty five milliliters of water was added and mixture was shaken thoroughly for 10 min. It was then allowed to stand for 24 h at room temperature. Then the volume occupied by the pulp powder was noted.

Drug and other excipients procurement

Diclofenac sodium was obtained as gift sample from Cadila Pharma, Gujarat. Other materials used include cellulose microcrystalline (fine powder), talc and magnesium stearate of analytical grade were purchased from RANKEM limited, New Delhi India.

Methods

Preparation of tablets

The formula for the work was designed as per the table 1

Table 1: Formula to prepare tablets containing Diclofenac sodium as model drug.

Ingredients	Formulations							
	F1	F2	F3	F4	F5	F6	F7	F8
Diclofenac sodium	50	50	50	50	50	50	50	50
<i>Beta vulgaris</i> pulp powder	-	-	-	-	10	20	30	40
Corn starch	10	20	30	40	-	-	-	-
Magnesium stearate	9	9	9	9	9	9	9	9
Sodium saccharine	12	12	12	12	12	12	12	12
Talc	9	9	9	9	9	9	9	9
Menthol	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
Micro crystalline cellulose	113.6	109.6	105.6	101.6	113.6	109.6	105.6	101.6
Total weight of tablet	200	200	200	200	200	200	200	200

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The preparation of tablets were carried out in two different steps-

Granulation

Weighted quantity of diclofenac sodium, *Beta vulgaris* pulp powder and microcrystalline cellulose was added according to formula as per table 1. All the ingredients are mixed properly with the help of mortar and pestle and water was used as granulating agent. The wet mass was passed through sieve No 20 to prepare granules. Granules were dried at 45° C for 5 hours. Talc and magnesium stearate was added accordingly in granules of all batches and stored in air tight packets for further study.^[1,9,10]

Compression

Defined amount of granules was used to prepare tablets of all batches. Powder was compressed using a single punch tableting machine (Cadmach Machinery Co. Pvt. Ltd., India) equipped with 8 mm punch at 0.5 ton pressure.^[1,10]

Technological parameters

Weight variation

All prepared matrix tablets were evaluated for weight variation as per USP XXIV monograph. Twenty tablets of each batch were used to evaluate weight variation among tablets and standard deviation was calculated.^[1,10,11]

Friability

Tablets of all batches were used to evaluate friability as per USP XXIV monograph. Friability testing was done by Roche friabilator with triplicate readings.^[1,10,11]

Hardness

Hardness of all batches was determined using Digital Force Gauge (Model:EL=500, Electrolab). The test was carried out in triplicate for all batches as per USP XXIV monograph for uncoated tablets.^[1,10,11]

Thickness

Thickness was measured by vernier caliper as per USP XXIV monograph. The readings were carried out in triplicate and average value was noted.^[1,10,11]

Drug content

The tablets were powdered, and 50 mg equivalent weight of Diclofenac Sodium in tablet powder was accurately weighted and transferred into a 100 ml volumetric flask. Initially, 10 ml of phosphate buffer (pH6.6) was added and shaken for 10 min. then, the volume was made up to 100 ml with buffer. Subsequently, the solution in volumetric flask was filtered, and 1 ml of the filtrate was diluted and analyzed at 276 nm using ultraviolet/visible variable wavelength spectrophotometer at 276 nm (Shimadzu UV-2450, Japan). The drug content of the each sample was estimated from their standard curve.^[1,10, 12]

In vitro dissolution study

Dissolution test was performed at 37°c using the paddle method at 100 rpm with 900 ml phosphate buffer (pH6.6) as dissolution medium. For this digital tablet dissolution test apparatus (Lab India Disso 2000, India) was used. At predetermined intervals, 5 ml of the medium was sampled and filtered. The filtrate was analyzed by ultraviolet/visible variable wavelength spectrophotometer at 276 nm.^[1,10,12]

RESULTS AND DISCUSSION

Beta vulgaris pulp powder was characterized as a pharmaceutical excipient in terms of micromeritic properties and flow behavior. Bulk density, tapped density, bulkiness and angle of repose all are found to be good to use this plant based material as a pharmaceutical excipient. Swelling index was also studied with an aim to evaluate swelling behavior of polymer that also effect drug release from matrix tablets.

Bulk density, tapped density, compressibility index and flow behavior (angle of repose) were found to be good so this pulp powder can be act as a good candidate for pharmaceutical preparations (table 2). Relative study of physical parameters of tablets of each batch of *Beta vulgaris* pulp powder reveals that the tablets compressed using pulp powder as disintegrant are quite harder, so can be easily handled. The variation in the hardness, weight variation, friability and thickness values of all the fabricated tablets, in reference to average values for each parameter, were found within the official limits. Friability of tablets ranged from 0.62 to 0.82%, easily predict the fact that tablets were less friable and so provide ease of

Table 2: Characterization parameters of *Beta vulgaris* pulp powder.

Bulk density (gm/cm3)	Tapped density (gm/cm3)	Bulkiness	Angle of repose (°)	Compressibility index (%)	Swelling Index (%)
0.82 (0.21)	0.98 (0.19)	1.21 (0.17)	24.82 (0.11)	21.6 (0.30)	22 (0.18)

Table 3: Evaluation parameters of tablets containing Diclofenac sodium as model drug

Parameters	Formulations							
	F1	F2	F3	F4	F5	F6	F7	F8
Diameter (mm)	9.48	9.78	9.67	9.81	9.78	9.70	9.72	9.72
Thickness (mm)	2.54	2.55	2.45	2.41	2.43	2.44	2.40	2.41
Wetting time (sec)	20	22	25	30	28	25	18	15
Wt. variation (mg)	195	194	195	196	194	197	195	196
Hardness (kg/cm ²)	6.1	4.3	8.3	8.3	6.4	11.5	10.7	11.5
Friability (%)	0.67	0.72	0.68	0.75	0.68	0.62	0.76	0.82
Disintegration time (sec)	27	40	45	60	28	26	25	20
Drug content (mg/tablet)	49.2	49.4	49.3	49.5	49.7	49.6	49.7	49.9

handling. The comparative data of different studies of all batches has been tabulated in table 3.

Less weight variation and uniform drug content easily elicit the fact that this process of tablet formulation is reproducible and so easily adopted at industrial level. Findings of the results showed that as the concentration of pulp powder increases wetting time of tablets decreases in same proportion and so disintegrating time also go down in same manner.

In vitro dissolution study of formulations at phosphate buffer pH 6.8 reveals that Batch F8 gave better release than other batches and it was upto 98.99% in 60 minutes study. The comparative drug release from different formulations was shown in figure1.

Results easily predict the fact that formulations containing (F5, F6, F7, F8) *Beta vulgaris* pulp powder showed

better release profile than the formulations containing (F1, F2, F3, F4) corn starch. As the concentration of pulp powder increases disintegrating time of formulations decreases in same proportion. Results also showed that tablets prepared using pulp powder have relatively more hardness and less friability in comparison of tablets of corn starch. So it is easy to handle formulations prepared using *Beta vulgaris* pulp powder.

CONCLUSIONS

The comparative study of various parameters clearly states the fact that the naturally obtained *Beta vulgaris* pulp powder stands as a good candidate to act as disintegrant and it is possible to design promising Fast disintegrating tablet using this polymer. On the basis of

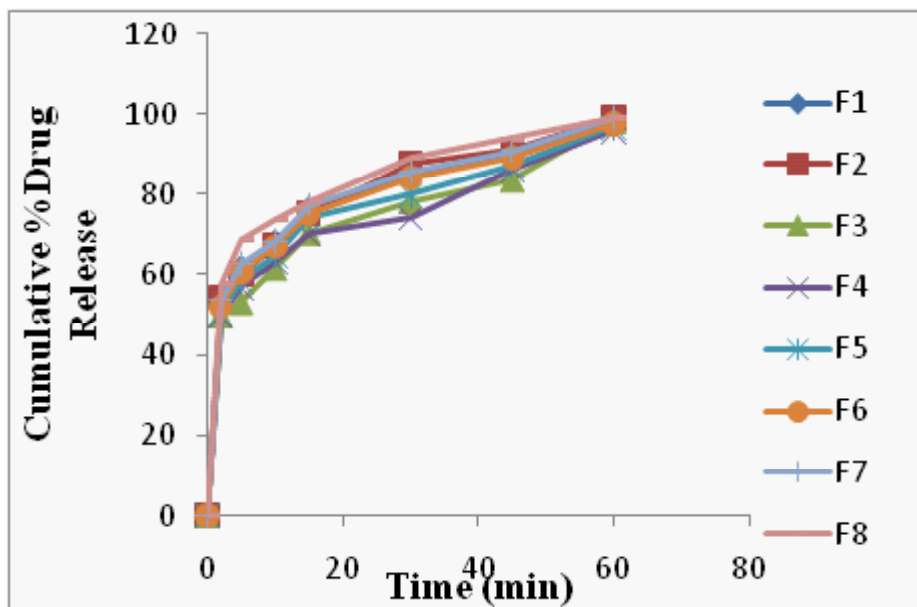


Figure1: drug release study from different formulations

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results obtained it can be concluded that this polymer having good micromeritic properties and flow behavior and so may act as a pharmaceutical excipient.

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