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OPTIMIZATION & EVALUATION OF FAST- DISSOLVING TABLETS USING NATURAL AND SYNTHETIC SUPERDISINTEGRANTS

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ABSTRACT

A novel drug delivery method that offers the quickest onset of action and quick pharmacological effects after administration is the fast-dissolving tablet. It can be taken without the need for water by just placing the tablets on the tongue. This medication delivery method works best in emergency scenarios where a quick medication response is required. Other excipients, as well as synthetic and natural superdisintegrants, are needed for the formulation of this type of dosage form. The pharmaceutical industry offers a range of artificial and natural Superdisintegrants can be found. In the current study, superdisintegrants are compared to determine which one releases drugs more quickly. The current study's objective was to create and evaluate a fast-dissolving tablet with both artificial and natural superdisintegrants. The fast-dissolving tablet was formulated using the direct compression technique. Pre- and post-compression parameters are assessed for the prepared tablets. According to the results, formulation batches F9 is the most preferred optimized batch. When drug release profiles were compared, the F9 batch—which contained combination of natural and synthetic superdisintegrants performed better than batches that contained only natural superdisintegrants. As a result, it was determined that combined natural and synthetic superdisintegrants perform better than alone natural ones.

KEYWORDS: Superdisintegrants, Fenugreek mucilage powder, Crospovidone, Drug release, In-vitro dispersion time, Direct compression.

INTRODUCTION

As technology has advanced, people's lifestyles have become more individualistic. In this day and age, everything can be found quickly and easily. However people are experiencing a wide range of severe and intricate health issues as a result of these changes. Although medical facilities are attractively designed and offer a comfortable and convenient setting for patients, many patients find them to be costly and time-consuming. These days, a patient wants their medication to take effect more quickly in a matter of minutes or seconds. In an emergency, such as a cardiac arrest, asthma attack, convulsion attack, etc., the patient needs an effective medication response in a matter of minutes in order to survive. As a result, formulation scientists have conducted research and developed a fast-dissolving drug delivery system that enables the medication to take effect more quickly in emergency situations. Because they have more advantages over conventional tablets such as ease of administration, no need for water when administering tablets, high drug loading, faster drug action, palatable taste, etc. fast-dissolving tablets are the more widely used dosage form. Travelers, government employees, mentally ill persons, irrational people, people experiencing nausea and vomiting, etc. can all easily access it.[1] The US FDA defines "fast-dissolving tablets as a solid dosage form containing medicinal substances that disintegrates." quickly, typically in a few seconds, when pressed against the tongue." Despite the use of different terminology, the European Pharmacopoeia defined an or dispersible tablet as a "tablet that is to be placed in the mouth where it disperses rapidly before swallowing." In the formulation of fast-dissolving tablets, superdisintegrants derived from both natural and synthetic sources are added either alone or in combination. This promotes the rapid disintegration of tablets and results in faster drug release, resulting in a rapid pharmacological response. In a nutshell, superdisintegrants are the key component of fast-dissolving tablets, which enables them to provide quicker results in a matter of seconds. When a compact mass of tablets is placed in a fluid environment, they aid in the disintegration of the tablets into fine, dispersible particles and are added to the formulation at concentrations ranging from 1 to 10%. The goal of this study is to use one natural superdisintegrant (fenugreek mucilage powder), one synthetic superdisintegrants (crospovidone) and combination of both natural superdisintegrant and synthetic superdisintegrantsare examined by creating a tablet that contains a model medication. Diclofenac sodium has analgesic, antipyretic, and anti-inflammatory properties, making it a model drug. By suppressing COX-1 and COX-2, it works.[2] While crospovidone acts by swelling and wicking actions to facilitate drug release, fenugreek mucilage powder

acts by swelling mechanisms that are responsible for drug release. Consequently, the superdisintegrants are compared to determine which produces the best outcomes.

MATERIALS AND METHODS

Diclofenac sodium, fenugreek mucilage powder, Crospovidone, Mannitol, talc, Magnesium stearate, Microcrystalline cellulose (MCC).

Extraction of mucilage from fenugreek seeds

The seeds are powdered using mortar and pestle and soaked 100g of the powder in 500ml solvent and incubate at 37 ^{0}C for 3-5 days. Filtered with muslin cloth. Collected filtrate and evaporated solvent at 37 ^{0}C and collected dried extract.

Formulation composition was optimized by taking different amount of natural and synthetic superdisintegrant in alone as well as in combination.

Preparation of Fast Dissolving Tablets

Fast dissolving tablets was prepared by direct compression method. The drug and excipients were passed through sieve no. 80 to ensure better mixing, natural superdisintegrants fenugreek mucilage powder and synthetic superdisintegrants crospovidone and combination of both were used in different proportions.[3] The powders were compressed into tablets by using 9 mm punch and weight of the tablet is 200 mg [Table 1].

Table 1: Composition of Fast Dissolving Tablets.

Ingredients (mg)	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
Diclofenac sodium	50	50	50	50	50	50	50	50	50
sweetener	50	50	50	50	50	50	50	50	50
Crospovidone	2	4	6	-	-	-	2	2	2
Fenugreek mucilage powder	-	-	-	2	4	6	2	4	6
Microcrystalline cellulose	52	50	48	52	50	48	50	48	46
Mannitol	40	40	40	40	40	40	40	40	40
Magnesium stearate	3	3	3	3	3	3	3	3	3
Talc	3	3	3	3	3	3	3	3	3
Total	200	200	200	200	200	200	200	200	200

EVALUATION

Pre-compressionparameters

Physico-chemical Characterization of Synthetic and Natural Superdisintegrants

The swelling index was calculated using a 100-ml graduated cylinder with stoppers. One gram of powder's initial bulk volume was recorded. After an hour of vigorous shaking every

ten minutes, enough water was added to ensure 25 ml of uniform dispersion, and the mixture was left to stand for 24 hours. After a day, the sediment volume of the swollen mass was measured while the dispersion was kept at room temperature.

Swelling index = 100 × (V2 - V1 / V1)

Where,

V_1= initial volume of material before hydration.

V_2= volume of hydrated material.

Loss on Drying: This method is employed to ascertain whether a sample contains excessive amounts of moisture or solvents. After being weighed (W1), the material sample was heated for two hours in an oven.[4] After cooling in the desiccator's dry atmosphere, it was weighed in the end (W2).

% loss on drying = [(W1 - W2) / W1] × 100

Where,

W_1= initial weight of the powder

W_2= final weight of the powder.

pH: A digital pH meter was used to measure the pH of one gram of powder suspended in 100 ml of distilledwater.

Solubility: A powder sample is dissolved in aqueous, organic, and inorganic solvents to ascertain its solubility.

Calibration Curve of Diclofenac Sodium

Method for Preparation of Phosphate Buffer pH 6.8 Solutions: Sufficient water to make 1000ml, dissolve 11.45g of potassium dihydrogen phosphate and 28.80g of disodium hydrogen phosphate.

Angle of Repose: The funnel method was used to calculate the angle of repose. A vertically adjustable funnel was used to pour the mixture through until the desired maximum cone height (h) was reached. Using the formula, the angle of repose was computed after the heap's radius was determined.

ɵ = tan1 h / r

Where, ɵ = the angle of repose

h =the height of the pile,

r =the radius of the base of the pile.

Bulk Density: The bulk density of a powder is determined by dividing its mass by bulk volume. It is employed to explain how particles are arranged.[5] The volume of powder was calculated for bulk determination by adding a weighed quantity of the powder material into a graduated measuring cylinder.

Bulk density = mass of the powder / bulk volume

Tapped Density: To find the tapped density, a measured amount of powder was added to a graduated measuring cylinder, the powder was then mechanically tapped, either by hand or with the aid of a taping device, until a consistent volume was reached.

Tapped Density = mass of the powder/tapped volume

Carr's Index: The simple way to measure the free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow. Carr's index, which is derived using the following formula, determines the compressibility index.[6]

C = 100 (1-B / T)

Where, B = bulk density

T= tapped density

Hausner's Ratio: It is used to measure how easily powder flows through a material. The formula used to calculate hausner's ratio is,

Hausner's Ratio = Tapped density/bulk density.

Post compression parameters

Appearance: From every formulation were chosen at random, and organoleptic characteristics like colour, flavor, and shape Pills were assessed.

Weight variation: From each batch, twenty tablets were chosen at random and weighed separately on an electronic balance (Shimadzu). The weight variation is then compared between the weighed individual and the average weight.[7]

Hardness: The Monsanto hardness tester was used to measure the tablet hardness for each formulation.[8]

Wetting Time: A double-folded piece of tissue paper (10.75 x 12 mm) was put in a culture dish (d = 6.5 cm) with 6 ml of water. The amount of time it took for a tablet to completely wet the paper was measured.[9]

Disintegration Time: The same methodology used for the wetting time was applied to the test. The tablet was weighed for this test before it was put on a Petri dish. The tablet was taken out and weighed after it had been thoroughly wetted.[10]

$R=100(Wb-Wa) / Wa$

is the formula used to calculate the ratio of water absorption, or R.

Where,

W_a = the weight of the tablet before it absorbs water.

W_b = the weight of the tablet after it has been absorbed.

Table 2: Evaluation parameters of Fast dissolving tablets using fenugreek and cross povidone as natural and synthetic superdisintegrants.

Parameters	F1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
Angle of repose (ɵ)	29.00±0.4	23.16±0.8	28.56±1.0	23.60±0.13	28.68±1.0	27.90±1.0	23.47±0.4	21.80±0.6	25.7±.08
Carr's Index%	22.50±1.10	20.25±0.03	15.84±0.60	18.61±0.9	19.49±1.0	11.59±1.0	16±1.1	14±0.9	17±0.6
Thickness (mm)	3.7±0.06	3.19±0.03	3.95±0.03	3.12±0.08	3.16±0.002	4.17±0.02	4.05±0.06	4.02±0.08	4.02±0.03
Hardness (kg/cm^2)	2.8±0.05	2.83±0.1	2.86±0.11	2.96±0.11	2.93±0.15	2.96±0.20	4.2±0.26	4.5±0.25	4.1±0.24
Weight variation (mg)	2.80±1.3	2.05±2.0	3.5±0.3	3.66±0.1	2.84±0.4	2.90±0.2	2.84±1.5	2.08±2.2	2.28±1.7
Friability %	0.60±0.010	0.35±0.01	0.60±0.01	0.20±0.01	0.10±0.014	0.10±0.01	0.75±0.01	0.36±0.01	0.62±0.01
Wetting time (sec)	20.01±1	19.33±1.4	15.60±0.4	35.33±0.4	35.66±0.4	34.01±0.9	22.60±0.4	23.05±0.6	22.02±0.8
Disintegration time (sec)	14.85±1.5	13.34±2.08	11.35±1.15	35±0.3	33.6±1.2	32.00±0.5	11.85±0.6	10.68±1.1	11.23±0.9

RESULT AND DISCUSSION

The fast dissolving tablets are playing major role in different types of attacks of various diseases in the market. Many patients are feeling difficult in swallowing tablets, fluids and capsules out this new drug delivery system called fast dissolving tablets are better. The values of pre-formulation parameters (Table 2) are prescribed within the limits and these are showing good free flowing property. The values from post –compression parameters such as thickness, hardness, weight variation, friability, wetting time and disintegration time as shown in (Table2). from all these formulations, hardness test indicated good mechanical strength as it ranges from 2.8 to 4.5 kg/cm^2. Friability was found to be less than 1% it shows good mechanical resistance. The fast dissolving tablets were subjected for in vitro disintegration time for all the formulation varies from 10 to 35 sec. it was observed that the combination of these both natural and synthetic disintegrants showing better activity (F7to

F9) the fast dissolving tablets disintegrants within less time. Due the swelling property in fenugreek mucilage powder than compare to the individual it was observed that the disintegration time as decreased.

Results were shown in table 2 which shows rapid disintegration is due the penetration of saliva into the pores of tablet, it leads to swelling of tablet and create pressure for quick and complete disintegration of tablet.

CONCLUSION

In the present study the superdisintegrants property of fenugreek mucilage powder and crospovidone and combination has been explored. Extensive swelling action of natural material in fast dissolving tablets were found to be having superdisintegrant action in combination of natural and synthetic superdisintegrants showing fast disintegration compare to the individual.

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