IJPSR (2024), Volume 15, Issue 1 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 15 May 2023; received in revised form, 12 August 2023; accepted, 21 November 2023; published 01 January 2024

FORMULATION, EVALUATION AND COMPARISON OF NATURAL AND SYNTHETIC SUPERDISINTEGRANTS USED IN THE FAST-DISSOLVING TABLET BY DIRECT COMPRESSION TECHNIQUES

V. Barethiya, G. Dixit, S. Deshpande and K. Rajbhar

Department of Pharmaceutics, Priyadarshini J. L. College of Pharmacy, Hingna Road, Nagpur - 440016, Maharashtra, India.

Keywords:

Superdisintegrants, Fenugreek gum, Croscarmellose sodium, Drug release, *In-vitro* dispersion time, Water absorption ratio

Correspondence to Author:
Ms. V. M. Barethiya

Assistant Professor,
Department of Pharmaceutics,
Priyadarshini J. L. College of Pharmacy, Hingna Road, Nagpur - 440016, Maharashtra, India.

E-mail: varshabarethiya@gmail.com

ABSTRACT: Fast-dissolving tablets are a novel drug delivery system that provides the fastest onset of action and rapid pharmacological effects after administration. It can be administered simply by putting the tablets on the tongue, without the need for water. Mostly, this drug delivery system is efficient in emergency situations where an immediate drug response is needed. For the formulation of this kind of dosage form, natural and synthetic superdisintegrants, along with other excipients are required. In the pharmaceutical market, various kinds of synthetic and natural superdisintegrants are available. To find out which superdisintegrants give faster drug release, they are compared in the present research work. The aim of the present study was to formulate and characterise a fast-dissolving tablet using synthetic and natural superdisintegrants. The direct compression technique was used for the formulation of the fast-dissolving tablet. The formulated tablets are evaluated for precompression and postcompression parameters. From the results, it was concluded that among all the formulation batches, F3, F6, F9 and F12 were optimised, and on comparing their drug release profiles, the F3 batch containing synthetic superdisintegrants showed the best results over batches containing natural superdisintegrants. Hence, it was concluded that synthetic superdisintegrants show superior results to natural superdisintegrants.

INTRODUCTION: The lifestyle of an individual varies from person to person with the development of technology. Nowadays, everything is easily available and accessible without wasting much time. But with these changes, individuals are suffering from many serious and complicated health disorders. Health care facilities are furnished and well equipped with a patient-friendly environment, but they are quite expensive and time-consuming, which is unfavourable to many patients.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.15(1).120-30

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.15(1).120-30

Nowadays, an individual wishes that medication should show a faster therapeutic response within a few minutes or seconds. An emergency situation like cardiac arrest, asthma attack, convulsion attack, *etc*. requires an efficient result from medication within a few minutes to save the patient's life.

Hence, formulation scientists have done research and formulated a fast-dissolving drug delivery system that provides a faster onset of action of the drug in emergency conditions. Fast-dissolving tablets are the more popular dosage form than conventional tablets, as they provide advantages like ease of administration, no need for water to administer tablets, high drug loading, faster drug action, palatable taste, *etc*. over conventional tablets. It can be easily accessible for travellers, official personnel, mentally ill people,

uncooperative people, people suffering from nausea and vomiting, *etc* [1]. Fast-dissolving tablets, as per the US FDA, are defined as "a solid dosage form containing medicinal substances that disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue". European pharmacopoeia defined an or dispersible tablet as a "tablet that is to be placed in the mouth where it disperses rapidly before swallowing, despite various terminologies used". Superdisintegrants obtained from natural as well as synthetic sources are added alone or in combination in the formulation of fast-dissolving tablets, which promotes the rapid disintegration of tablets and leads to faster drug release, giving a rapid pharmacological response. Simply put, superdisintegrants are the vital agent of fast-dissolving tablets, which makes them efficient in giving faster responses within a matter of seconds. They are added in 1 to 10% concentration in the formulation, and they help disintegrate a compact mass of tablets into fine dispersible particles when placed in a fluid environment. Objective of the study: In this study, two natural superdisintegrants (fenugreek gum and banana powder) and two synthetic superdisintegrants (croscarmellose sodium and sodium starch glycolate) are screened by formulating a tablet with the incorporation of a model drug. Diclofenac sodium is used as a model drug because it has analgesic, antipyretic, and anti-inflammatory actions. It acts by inhibiting COX-1 and COX-2. Fenugreek gum and banana powder act by swelling mechanisms, which are responsible for drug release, while croscarmellose sodium and sodium starch glycolate act by swelling and wicking actions to facilitate drug release. Thus, the superdisintegrants are compared to find out which gives the best results.

Mechanism of Action of Superdisintegrant:

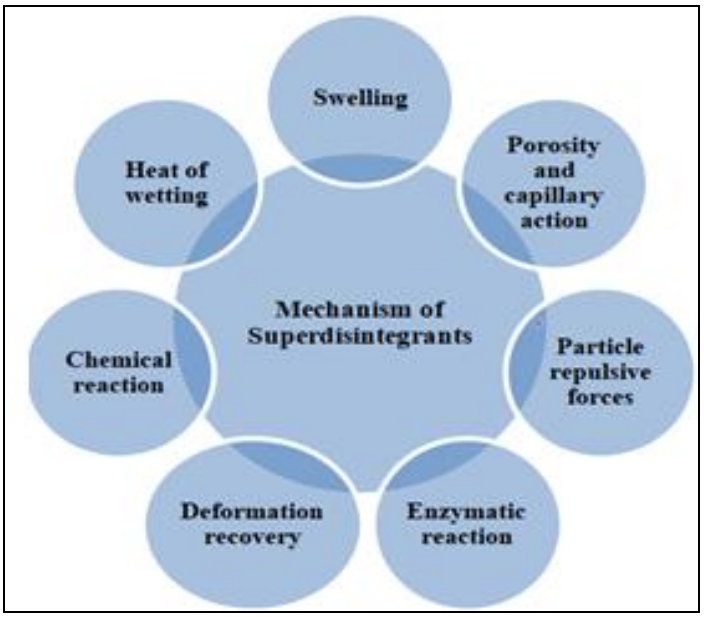

FIG. 1: MECHANISM OF SUPERDISINTEGRANTS

MATERIAL AND METHODS: The drug diclofenac sodium was obtained as a gift sample from Zim Laboratories Pvt. Ltd., Kalmeshwar. Fenugreek gum powder was obtained as a gift sample from Natural Agro Pvt. Ltd., Gujarat. Banana powder was procured from the local market in Nagpur. Croscarmellose sodium and sodium starch glycolate were purchased from Loba Chemie Pvt. Ltd., Mumbai. All the other chemicals and reagents used in the research work are of analytical grade, and experimentation work was performed in the laboratory of Priyadarshini J. L. College of Pharmacy, Nagpur.

Preformulation Parameters:

Physico-chemical Characterization of Synthetic and Natural Superdisintegrants [1]: Swelling index-The study was carried out using a 100-ml stoppered graduated cylinder. The initial bulk volume of 1 g of powder was noted. Water was added in sufficient quantity to ensure 25 ml of uniform dispersion by vigorously shaking every 10

minutes for 1 hour and then being allowed to stand for 24 hours. The dispersion was stored at room temperature, and the sediment volume of the swollen mass was measured after 24 hours.

Swelling index = 100 × (V2 - V1 / V1)

Where V1 is the initial volume of material before hydration; V2 is the volume of hydrated material.

Loss on Drying: The loss-on drying technique is used to determine high levels of moisture or solvents present in the sample. The material sample was weighed (W1) and heated in an oven for 2 hours. It was cooled in the dry atmosphere of desiccators and then finally weighed (W2).

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

Where W1 is the initial weight of the powder; W2 is the final weight of the powder.

pH: One gramme of powder was suspended in 100 ml of distilled water, and the pH was checked using a digital pH meter.

Solubility: Solubility is determined by dissolving a powder sample in aqueous, organic, and inorganic solvents.

Calibration Curve of Diclofenac Sodium:

Method for Preparation of Phosphate Buffer pH 6.8 Solutions: Dissolve 28.80g of disodium hydrogen phosphate and 11.45g of potassium dihydrogen phosphate in sufficient water to produce 1000ml.

TABLE 1: COMPOSITION OF FAST DISSOLVING TABLETS

Composition (in mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Diclofenac sodium	50	50	50	50	50	50	50	50	50	50	50	50
Croscarmellose sodium	4	8	12	-	-	-	-	-	-	-	-	-
Sodium starch glycolate	-	-	-	4	8	12	-	-	-	-	-	-
Fenugreek gum powder	-	-	-	-	-	-	4	8	12	-	-	-
Banana powder	-	-	-	-	-	-	-	-	-	4	8	12
Microcrystalline cellulose	104	100	96	104	100	96	104	100	96	104	100	96
Mannitol	35	35	35	35	35	35	35	35	35	35	35	35
Magnesium stearate	4	4	4	4	4	4	4	4	4	4	4	4
Talc	3	3	3	3	3	3	3	3	3	3	3	3
Total	200	200	200	200	200	200	200	200	200	200	200	200

*All the quantities are in mg and for one tablet.

Evaluation Parameters of Fast Dissolving Tablets [2]:

Precompression Parameter:

Angle of Repose: The angle of repose was determined using the funnel method. The blend was poured through a funnel that can be raised vertically until a maximum cone height (h) is obtained. The radius of the heap was measured, and the angle of repose was calculated using the formula.

ɵ = tan1 h / r

Where, is the angle of repose and h is the height of the pile, r is the radius of the base of the pile.

Bulk Density: The bulk density of a powder is defined as the ratio of the mass of the powder to its bulk volume. It is used to describe the packing of particles. For bulk determination, a weighed quantity of the powder material was introduced into a graduated measuring cylinder, and the volume of powder was determined.

Bulk density = mass of the powder / bulk volume

Tapped Density: For determination of the tapped density, a weighed quantity of the powder was introduced into a graduated measuring cylinder and was tapped mechanically, either manually or using a taping device, till a constant volume was obtained.

Tapped Density = mass of the powder/tapped volume

Carr's Compressibility Index: The simplest way of measuring the free flow of powder is compressibility, an indication of the ease with which a material can be induced to flow. The compressibility index is determined by Carr's index, which is calculated by using the following formula:

C = 100 (1-B / T)

Where, B is bulk density and T is tapped density.

Hausner's Ratio: Hausner's ratio is an index of the ease of powder flow. It is calculated by the following formula:

Hausner's Ratio = Tapped density/bulk density.

Lower Hausner's ratio (1.25) indicates better flow properties than higher ones (> 1.25).

Post Compression Parameter:

Hardness: The hardness of the tablet indicates its tensile strength and is measured in terms of load/pressure required to crush it when placed on its edge. Hardness has influence on disintegration and dissolution times and may affect bioavailability. Monsanto hardness tester was used to measure hardness of the formulated tablet. The tester consists of a barrel containing a compressed spring held between two plungers. The lower plunger was then forced against a spring by turning a threaded bolt until the tablet fractures. As the spring was compressed, a pointer rides along a gauge in the barrel to indicate the force. The force of fracture ease record and the zero force reading was deducted from it. It is expressed in kg/cm^2.

Friability: This test evaluates ability of tablet to withstand abrasion and edge damage during packing, handling and shipping. Friability generally reflects poor cohesion of tablet ingredients. Friability was measured by using Roche friabilator. 10 tablets were weighed and placed in plastic chamber that revolves at 25 rpm for 4 minutes. Tablets were reweighed after removal of fines. The friability was calculated by the formula-

F= w (initial) - w(final) / w(initial)

Weight Variation: Tablets are designed to contain a specific amount of drug in a specific amount of tablet formulation. The weight of the tablet is measured to help ensure that a tablet contain the proper amount of drug. 20 tablets were selected randomly from each formulation were individually weighed using an electronic balance. Average weight of the tablets was calculated. The individual weight of the tablet was compared with average weight. The tablets meet the USP specification if not more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

Weight variation = wavg - winitial / wavg × 100

Disintegration Time: Disintegration time is defined as the process of breakdown of a tablet into smaller fine particles. One tablet was placed in each of 6 tubes of the basket. A disc was added to each tube and the apparatus was run using 6.8 pH phosphate buffer maintained at 37°C as the immersion liquid.

The assembly was raised and lowered between 30 cycles per minute in the 6.8 pH phosphate buffer. The time in second taken for complete disintegration of the tablet with no mass remaining in the apparatus was measured and recorded. The tablet must be disintegrated within 3 minutes.

***In-vitro* Disintegration Time:** It is a modified test of conventional disintegration time test. It is performed in a petri plate containing 6ml of pH 6.8 phosphate buffer. In the petri plate tablet was kept in a centre and the time taken by tablet to get disintegrate was noted. This test is performed because the fast dissolving tablet gets disintegrate in the mouth cavity where the quantity of saliva is less. It is calculated in seconds.

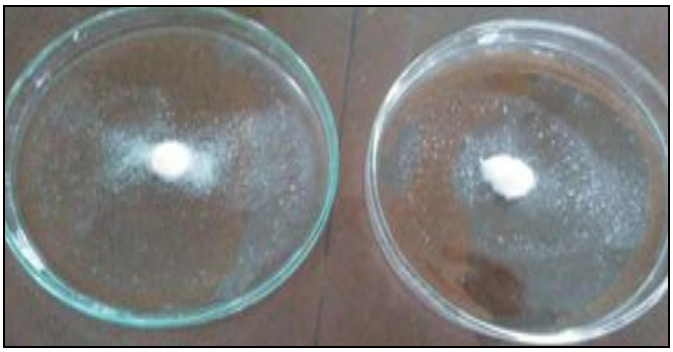

FIG. 2: DIAGRAM SHOWING *IN-VITRO* DISINTEGRATION TIME TEST

Wetting Time: The significant parameters for Fast Dissolving Tablets are the ratio of wetting time and water absorption reported by Yunixia *et al.* A piece of filter paper folded twice (circularly cut) was placed in a small petri plate containing water soluble dye solution (Sorenson‟s buffer pH 6.8).

Tablet was placed in the paper, and the time required for complete wetting of the tablet was determined. Three trials for each batch and the standard deviation were also determined.

FIG. 3: DETERMINATION OF WETTING TIME

Drug Content: Twenty tablets were weighed and powdered. The quantity of powder equivalent to 50 mg of drug was dissolved in phosphate buffer pH 6.8 diluted to 100 ml with the same and the solution was filtered and suitably diluted. The drug content was estimated spectrometrically at required wavelength. Drug content was determined by using formula:

$$y = mx+c.$$

***In-vitro* Dispersion Time:** Three tablets were added to 10 ml of phosphate buffer solution, pH 6.8 at 37+0.5ºC, Time required for complete dispersion of a tablet was measured using stopwatch.

***In-vitro* Dissolution Studies:** *In-vitro* dissolution studies of the tablets were carried out in USP dissolution apparatus type II by employing a paddle stirrer at 50 rpm using 900 ml of pH 6.8 phosphate buffer sat 37± 0.50C as a dissolution medium. One tablet was used in each test. Aliquots of 5 ml each were withdrawn at specified time intervals (0, 2, 6, 8, 10, and 12) and replaced with equal volume of fresh medium. The withdrawn aliquots were analyzed for drug content spectrophotometrically at required ʎmax. Drug concentration was calculated using PCP disso software and expressed as cumulative percent of the drug released.

RESULT AND DISCUSSION:

Identification of Physicochemical Properties of Natural and Synthetic Superdisintegrants: The characterisation of the natural and synthetic superdisintegrants was done by performing the various tests such as pH, swelling index and loss on drying and the results are shown in table .

TABLE 2: CHARACTERIZATION OF NATURAL AND SYNTHETIC SUPERDISINTEGRANTS

Sr. no.	Test	Fenugreek gum	Croscarmellose sodium	Sodium starch glycolate	Banana powder
1	pH	6.05±0.5	5.6±0.1	5.7±0.05	5.2±0.05
2	Swelling index (%)	79.08±0.8	70.16±1.4	61.6±1.6	41.36±0.7
3	Loss on drying (%)	10.85±1.32	7.46±0.45	6.76±0.05	11.96±0.85

±SD= standard deviation; n=3. All the parameters shown above were based on the three replicate and expressed as mean.

Estimation of Diclofenac Sodium by UV spectroscopy:

Determination of λmax: The maximum absorption for λmax was determined by scanning the drug solution in the range of 200nm to 400nm and it was measured at 276nm shown in **Fig. 4** (concentration-10µg/ml).

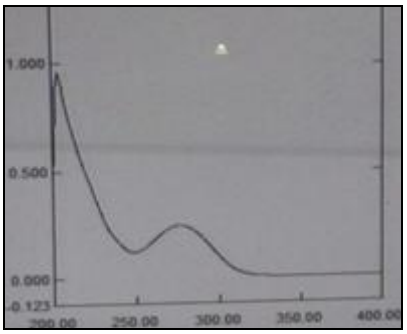

FIG. 4: UV SPECTRA OF DICLOFENAC SODIUM

Calibration Curve of Diclofenac Sodium: The standard calibration curve of Diclofenac sodium was prepared using phosphate buffer solution pH-6.8 and the graph was plotted between concentrations *vs.* absorbance.

The calibration curve of pure Diclofenac sodium was found to be linear and it was found to obey Beer's- Lambert law within the concentration of 2µg/ml - 10µg/ml. The regression co-efficient was found to be 0.997. The result was shown in **Fig. 5.**

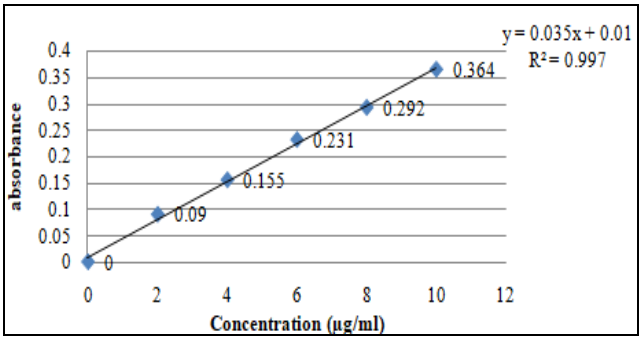

FIG. 5: CALIBRATION CURVE GRAPH OF DICLOFENAC SODIUM

Evaluation of Pre-Compression and Postcompression Parameters of Fast Dissolving Tablet:

TABLE 3: PRE-COMPRESSION PARAMETERS OF ALL THE FORMULATION BATCHES

Formulation code	Tapped density(g/ml)	Bulk density(g/ml)	Carr's index	Hausner's ratio	Angle of repose(θ)
F1	0.51±0.02	0.39±0.02	23.52±1.13	1.30±0.03	31.00±0.5
F2	0.47±0.023	0.37±0.025	21.27±0.05	1.27±0.08	24.16±0.9
F3	0.83±0.07	0.69±0.05	16.86±0.64	1.2±0.009	29.56±1.2
F4	0.7±0.08	0.44±0.04	15.5±0.47	1.5±0.33	30.60±0.9
F5	0.62±0.034	0.43±0.02	16.64±0.5	1.24±0.08	36.59±1.3
F6	0.76±0.05	0.68±0.03	12.82±1.1	1.10±0.06	30.75±0.7
F7	0.48±0.02	0.34±0.011	19.61±1.0	1.21±0.08	24.64±0.15
F8	0.41±0.011	0.33±0.11	19.51±1.04	1.24±0.15	29.68±1.2
F9	0.52±0.07	0.47±0.023	11.61±1.1	1.10±0.15	28.65±0.9
F10	0.60±0.06	0.40±0.011	10.67±0.8	1.25±0.05	25.97±1.05
F11	0.5±0.04	0.35±0.011	13.50±1.04	1.22±0.04	26.97±0.5
F12	0.51±0.02	0.43±0.02	15.68±0.74	1.18±0.09	24.33±1.01

±SD= standard deviation; n=3. All the parameters shown above were based on the three replicate and expressed as mean.

Evaluation of Post-Compression Parameters of Fast Dissolving Tablet:

TABLE 4A: POST-COMPRESSION PARAMETERS

Formulation code	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Weight variation (%)
F1	3.7±0.06	2.8±0.05	0.62±0.012	2.84±1.6
F2	3.19±0.03	2.83±0.1	0.37±0.02	2.07±2.3
F3	3.95±0.03	2.86±0.11	0.62±0.01	3.5±0.3
F4	4.16±0.11	2.8±0.11	0.11±0.12	2.73±1.2
F5	4.21±0.02	3.53±0.11	0.75±0.01	2.27±1.8
F6	4.14±0.01	3.13±0.2	0.36±0.01	4.72±0.9
F7	3.12±0.08	2.96±0.11	0.23±0.01	3.68±0.2
F8	3.16±0.02	2.93±0.15	0.12±0.015	2.86±0.5
F9	4.17±0.02	2.96±0.20	0.11±0.02	2.92±0.3
F10	4.05±0.07	4.6±0.26	0.75±0.01	2.84±1.6
F11	3.82±0.28	3.13±0.40	0.62±0.01	2.07±2.3
F12	3.92±0.06	3.33±0.56	0.36±0.01	2.27±1.8

±SD= standard deviation; n=3 All the parameters shown above were based on the three replicates and expressed as mean.

TABLE 4B: POST-COMPRESSION PARAMETERS OF FAST DISSOLVING TABLET USING SYNTHETIC AND NATURAL SUPERDISINTEGRANTS

Formulation code	Wetting time (sec)	Water absorption ratio (%)	*In-vitro* dispersion time (sec)	Disintegration time (sec)	Drug content (%)
F1	22.01±2	58±0.5	17.66±1.5	16.85±1.5	97.04±1.0
F2	20.33±1.5	57±0.5	14.6±1.5	12.34±2.08	99.07±0.60
F3	16.66±0.5	56±0.5	11.33±1.5	11.25±1.15	104.03±1.7
F4	28.33±2.5	33±0.5	23.33±2.08	29.6±1.5	95.80±0.6
F5	23.33±0.5	40±0.5	19.33±1.5	31.66±2	94.71±0.5

F6	19±3.21	42±0.5	14.32±1.5	26.65±2.08	103.23±1.1
F7	37.33±0.5	39.66±1.0	22.66±1.5	36±0.3	88.02±0.5
F8	37.66±1.5	54.33±1.0	16.66±1.15	34.6±1.2	94.47±1.02
F9	35±1	52±0.5	13.33±1.5	33.00±0.5	101.3±1.2
F10	56.16±1.04	61.53±1.0	47.01±2	55.66±0.7	75.46±0.6
F11	50.3±1.5	50±1.0	45.33±2.08	52.66±0.5	72.26±0.7
F12	52±1.0	69.11±0.5	26.66±3.05	44.33±0.5	82.44±0.9

±SD= standard deviation; n=3. All the parameters shown above were based on the three replicates and expressed as mean.

***In-vitro* Dissolution Studies:** *In-vitro* dissolution studies of all the prepared formulations are studied and the results are shown as follows: An *in-vitro* dissolution study of formulation batches F1, F2 and F3 containing croscarmellose sodium and F4, F5 and F6 containing sodium starch glycolate was studied. The results are shown in **Table 5.**

TABLE 5: CUMULATIVE PERCENTAGE DRUG RELEASE OF FAST DISSOLVING TABLET USING SYNTHETIC SUPERDISINTEGRANTS

Sr. no.	Time (in min)	Cumulative % Drug Release					
		F1	F2	F3	F4	F5	F6
1	0	0	0	0	0	0	0
2	2	20.18±1.1	27.95±1.2	31.93±1.13	19.88±1.02	20.18±1.1	28.71±0.93
3	4	27.45±0.60	41.13±0.74	39.82±1.16	22.59±1.05	39.04±1.2	33.22±1.13
4	6	35.01±0.93	54.48±0.92	45.36±1.03	29.72±0.95	48.1±1.1	37.49±0.60
5	8	39.39±0.93	58.11±0.74	49.54±1.06	32.35±0.87	54.18±0.95	57.97±0.54
6	10	48.44±0.65	60.72±1.0	59.72±1.35	45.99±1.0	57.96±0.35	64.93±1.76
7	12	54.53±1.06	65.40±1.0	66.23±0.68	52.17±1.21	60.27±1.14	70.45±1.02
8	14	58.40±1.76	67.80±1.1	70.42±0.95	54.71±1.0	62.38±1.36	72.57±1.65
9	16	62.40±1.32	71.23±1.1	74.58±0.95	56.59±1.1	64.92±0.65	75.47±1.05
10	18	64.93±0.92	75.39±1.4	78.05±1.05	61.54±0.6	69.35±0.96	78.53±1.05
11	20	69.37±1.02	78.97±0.6	79.54±1.16	67.54±0.8	77.03±1.12	82.02±0.93
12	22	77.05±0.96	82.30±1.13	84.06±1.18	71.94±1.1	81.68±1.13	87.11±0.94
13	24	81.70±1.06	85.50±0.87	86.96±1.2	76.37±0.8	84.27±1.06	89.67±1.02
14	26	86.23±1.12	89.22±0.67	91.61±1.2	80.61±0.76	87.22±1.06	92.03±1.12
15	28	90.06±1.13	92.15±1.16	94.80±1.13	86.76±1.02	90.49±0.74	94.92±1.13
16	30	94.62±0.60	96.77±0.72	99.49±1.03	90.39±1.1	94.55±1.2	96.24±1.15

±SD= standard deviation; n=3. All the parameters shown above were based on the three replicates and expressed as mean.

On studying the drug release profile of the formulation batches F1, F2 and F3, it was observed that the batch F3 shows the faster drug release i.e. 99.49±1.03% shown in **Fig. 6.**

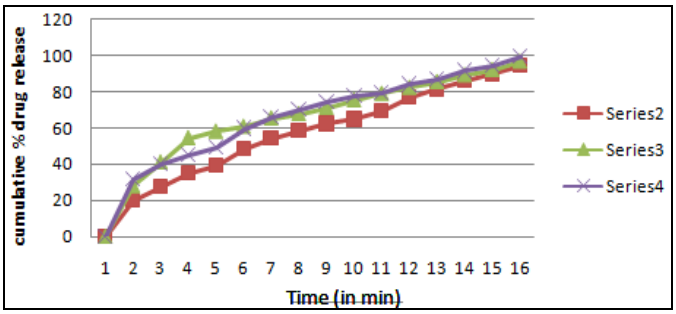

FIG. 6: *IN-VITRO* DISSOLUTION PROFILE OF FORMULATION BATCHES F1, F2 AND F3

On studying the drug release profile of the formulation batches F4, F5 and F6, it was observed that the batch F6 shows the faster drug release *i.e.* 96.24±1.15 % shown in **Fig. 7.**

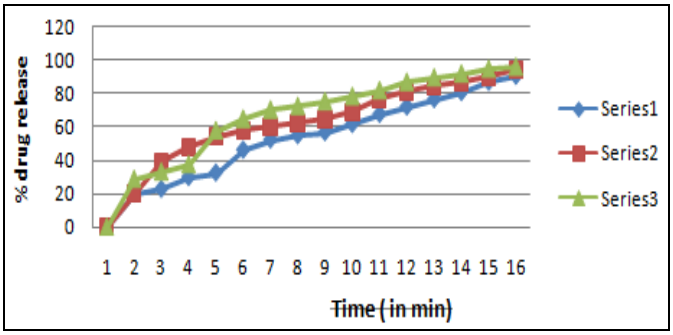

FIG. 7: *IN-VITRO* DISSOLUTION PROFILE OF FORMULATION BATCHES F4, F5 AND F6

An *in-vitro* dissolution study of formulation batches F7, F8 and F9 containing fenugreek gum powder and F10, F11 and F12 containing banana powder was studied. The results are shown in **Table 6.**

TABLE 6: CUMULATIVE PERCENTAGE DRUG RELEASE OF FAST DISSOLVING TABLET USING NATURAL SUPERDISINTEGRANTS

Sr. no.	Time (in min)	Cumulative % Drug Release					
		F7	F8	F9	F10	F11	F12
1	0	0	0	0	0	0	0
2	2	3.02±1.12	9.05±1.3	13.13±1.12	18.50±1.13	14.87±1.3	17.42±1.3
3	4	12.64±1.1	12.21±1.2	16.07±0.97	25.90±1.02	16.28±1.4	22.83±1.10
4	6	18.12±0.96	15.04±1.06	23.87±1.1	30.03±1.01	24.6±1.1	28.53±1.3
5	8	24.01±0.85	18.29±0.74	28.85±1.1	31.58±0.75	29.06±1.2	34.87±1.2
6	10	27.96±1.3	24.11±1.1	32.64±1.35	44.73±0.84	32.86±0.78	37.92±0.64
7	12	31.95±1.1	30.32±1.24	37.47±1.21	50.28±0.91	35.39±0.85	45.69±0.68
8	14	34.37±1.06	35.24±0.5	43.49±1.08	53.83±0.96	39.46±1.1	50.43±0.74
9	16	40.74±0.98	38.19±0.95	48.94±1.54	57.85±1.5	42.8±1.1	55.20±0.74
10	18	42.64±0.86	41.97±0.74	54.11±1.1	59.95±1.11	45.43±1.3	60.66±0.96
11	20	47.42±0.74	45.67±1.1	59.41±1.2	61.55±1.10	50.48±0.98	66.45±1.13
12	22	50.84±1.13	60.22±1.1	65.25±1.2	63.11±1.12	56.06±0.74	73.20±1.4
13	24	58.73±1.25	75.31±1.05	71.27±1.3	64.79±0.74	59.17±0.96	75.12±1.1
14	26	71.36±1.65	82.36±1.32	80.13±0.96	68.39±0.65	67.15±1.3	78.43±1.1
15	28	79.61±1.14	86.4±1.26	88.74±0.87	69.98±0.85	72.26±1.10	80.80±1.32
16	30	87.44±1.04	89.64±1.42	93.15±0.68	73.51±0.96	78.78±1.2	83.78±1.02

On studying the drug release profile of the formulation batches F7, F8 and F9, it was observed that the batch F9 shows the faster drug release i.e. 93.15±0.68% shown in **Fig. 8.**

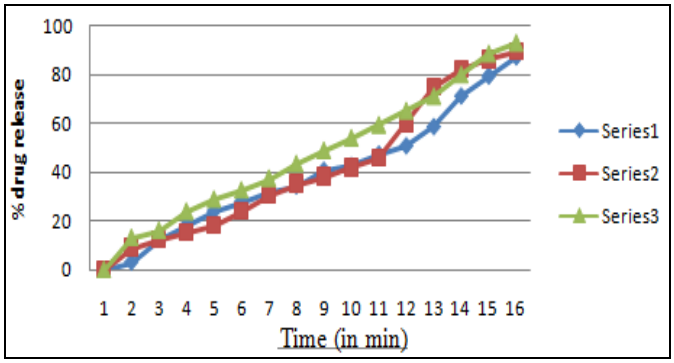

FIG. 8: *IN-VITRO* DISSOLUTION PROFILE OF FORMULATION BATCHES F7, F8 AND F9

On studying the drug release profile of the formulation batches F10, F11 and F12, it was observed that the batch F12 shows the faster drug release i.e. 83.78±1.02 shown in **Fig. 9.**

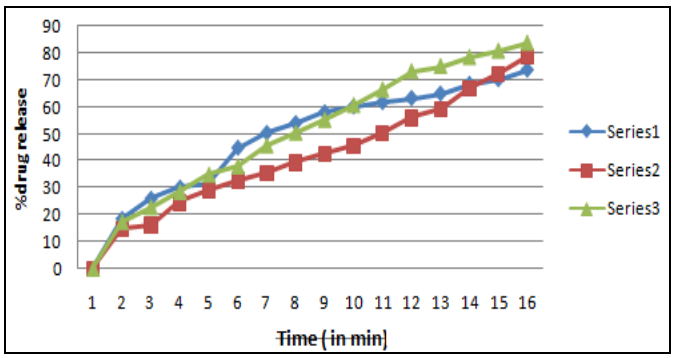

FIG. 9: *IN-VITRO* DISSOLUTION PROFILE OF FORMULATION BATCHES F10, F11 AND F12

Comparison between the Drug Release Profile of all the Optimized batches: On comparing the drug release profile of all the formulations, four batches was optimized which shows the good drug release i.e. F3, F6, F9 and F12. An optimized formulation batches were compared for the maximum drug release and it was found that F3 batch containing CCS shows higher drug release than the other optimized formulations. Hence, it was concluded that the synthetic superdisintegrants shows the superior results than the natural superdisintegrants used in the formulation of fast dissolving tablets. The results were shown in **Fig. 13.**

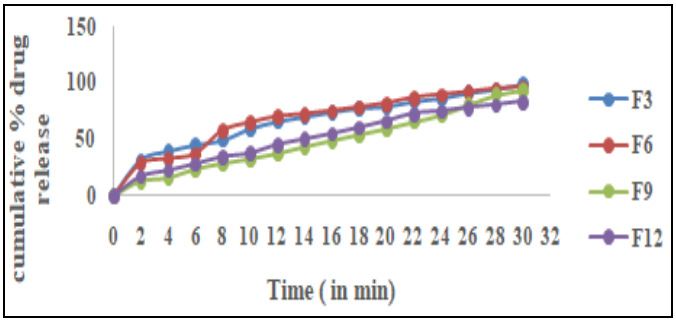

FIG. 10: GRAPHICAL PRESENTATION OF THE DRUG RELEASE PROFILE OF OPTIMIZED BATCHES I.E. F3, F6, F9 AND F12

On comparing the drug release profile of an optimized batch containing synthetic superdisintegrants F3 and F6, it was concluded that the batch F3 containing CCS shows the faster drug release than the F6 batch containing SSG. The results were shown in **Fig. 10.** Hence, it was concluded that CCS gives the best result over SSG.

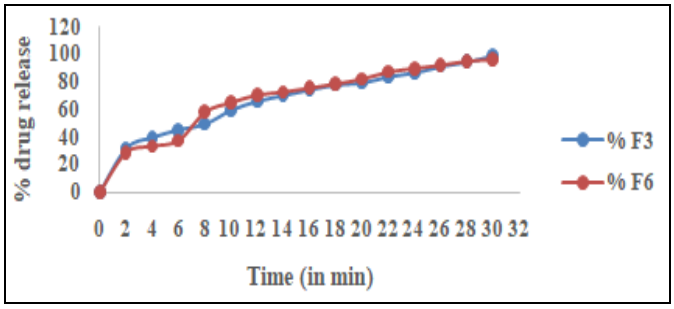

FIG. 11: GRAPHICAL COMPARISON OF THE DRUG RELEASE PROFILE OF AN OPTIMIZED BATCHES I.E. F3 ANDF6 CONTAINING SYNTHETIC SUPERDISINTEGRANTS I.E. CROSCARMELLOSE SODIUM AND SODIUM STARCH GLYCOLATE RESPECTIVELY

On comparing the drug release profile of an optimized batch containing natural superdisintegrants F9 and F12, it was concluded that the batch F6 containing fenugreek gum shows the faster drug release than the F12 batch containing banana powder. The result was shown in **Fig. 11**. Hence, it was concluded that FG gives the best result over BP.

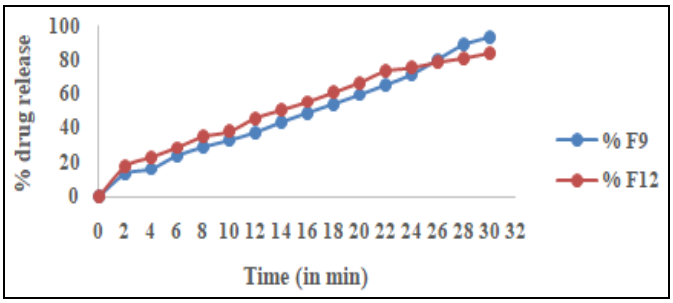

FIG. 12: GRAPHICAL COMPARISON OF THE DRUG RELEASE PROFILE OF AN OPTIMIZED BATCHES I.E. F9 AND F12 CONTAINING NATURAL SUPERDISINTEGRANTS I.E. FENUGREEK GUM AND BANANA POWDER RESPECTIVELY

Stability Studies: An optimized formulation batches F3, F6, F9 and F12 were kept for stability study under the condition at a temperature of $40^{o}C \pm 2^{o}C$ and 75% RH for 1 month.

TABLE 7: STABILITY STUDIES (ZERO DAY READING)

Test parameters	Appearance	Weight variation % (n=3)	Hardness kg/cm^2 (n=3)	*In-vitro* dispersion time sec (n=3)	*In-vitro* disintegration time	*In-vitro* dissolution studies
F3	White	2.85±0.5	3.8±0.5	10±0.1	15.3±0.5	98.2±0.5
F6	White	2.90±0.3	3.2±0.5	16.3±0.5	22.3±0.5	96.5±0.5
F9	White	2.82±1.6	3.8±0.5	22.3±0.5	26±0.1	93.3±0.5
F12	White	2.05±2.3	2.9±0.5	28±0.1	44.3±1.5	86.74±0.5

All the precompression and postcompression parameters of the prepared fast dissolving tablets was performed and evaluated. The FTIR studies revealed that the characteristic peaks of drug appeared in the spectra of the physical mixture at the same wave number indicating no modification or interaction between the drug Diclofenac sodium and the superdisintegrants. The IR spectra showed the absence of any kind of interaction and found compatibility between the model drug and the superdisintegrants.

The micromeritics characteristic of powder was studied and it revealed that the flow properties of all the formulations F1 to F12 are good and found within the acceptable range. The post-compression parameters of the fast dissolving tablets was evaluated and found within the acceptable range limits. The thickness and hardness of the prepared tablets of all formulations batches F1 to F12 was found to be 3.12 to 4.17mm and 2.8 to 4.6kg/cm^2 respectively which indicates the good mechanical properties of all the formulations. Friability test was performed of all the prepared tablets and it was found less than 1% (i.e. prescribed limit in IP). Weight variation test was performed of all the formulation batches which indicate the uniformity in the weight of the prepared tablets and it was found in the range of 2.07 to 4.72%. The prepared tablets were further evaluated for the wetting time, water absorption ratio, *in-vitro* dispersion time, disintegration time and drug content.

The wetting time and water absorption ratio was found in the range of 16.66 to 56sec and 33 to 61.53% respectively fulfilling the criteria of fast dissolving tablet i.e. less than 1minute. Batch F3 shows the wetting time 16.66sec which indicates faster wetting of tablets. Batch F10 shows the wetting time 56.16 sec which is lesser than other formulations. The *in-vitro* dispersion time of all the formulation batches was evaluated and it was found between the ranges 11.33 to 45.33 sec which is in the prescribed limits. Among all the formulation

batches, F3 batch shows the faster *in-vitro* dispersion time i.e. 11.33±1.5sec while batch F10 shows the slower *in-vitro* dispersion time i.e. 47.01±2 sec. The formulation batches F1 to F12 was evaluated for the disintegration time and the drug content which are also found to be 11.25 to 53sec and 82.12 to 104.85% respectively complying with the prescribed limit. Formulation batch F3 shows the faster disintegration time of 11.25±1.15 sec and batch F10 shows the slower disintegration time i.e. 55.66±0.5 sec.

CONCLUSION: The present research work was carried out with the aim of formulation of fast dissolving tablet by using synthetic and natural superdisintegrants along with other excipients. The natural and synthetic superdisintegrant shows variability in their disintegrant time which shows impact on the absorption of drug. Thus, in the present study, the natural and synthetic superdisintegrant will be compared for their superdisintegrant effect on the disintegration time from fast dissolving tablet by incorporating a model drug.

All the prepared tablets were subjected for the evaluation of precompression and postcompression parameters and they were complies with the pharmacopoeial limits. From the present research work, it was concluded that both the natural superdisintegrants (fenugreek gum and banana powder) and synthetic superdisintegrants (croscarmellose sodium and sodium starch glycolate) used in the formulation of fast dissolving tablets shows their promising effect on comparing their *in-vitro* disintegration time and *in-vitro* dissolution studies. Comparatively, formulation containing synthetic superdisintegrants shows better results over the formulation containing natural superdisintegrants used in the formulation of fast dissolving tablets.On comparing the formulation batches F3 and F6 containing synthetic superdisintegrants, it was found that F3 batch shows the best result and hence it was concluded that the tablet containing croscarmellose sodium shows the superior results than the tablet containing sodium starch glycolate as superdisintegrants. On comparing the formulation batches F9 and F12 containing natural superdisintegrants, it was found that F9 batch shows the best result and hence it was observed that tablet containing fenugreek gum shows better results than the tablet containing banana powder as superdisintegrants. The stability study for zero reading was studied and the samples are kept for further readings of stability study.

ACKNOWLEDGEMENT: All the authors of the research work would like to acknowledge Zim laboratories for providing the drug Diclofenac sodium. An authors like to show gratitude to Mr. Himanshu Patel, Director Natural agro for providing the gift sample of superdisintegrants.

Funding source: No

CONFLICT OF INTEREST: No

REFERENCES:

1. Uday KM and Kishore BM: Design and evaluation of fast dissolving tablets containing diclofenac sodium using fenugreek gum as a natural superdisintegrant. Asian Pacific J of Tropical Biomedicines 2014; 4(1): 329-334.
2. Bhore P, Pachpute K, Gadhave MV, Jadhav S and Gaikwad: Formulation and evaluation of diclofenac sodium oro dispersible tablets using superdisintegrant by direct compression technique. International Research Journal of Science & Engg 2018; 3: 43-48.
3. Duppala L, Girinath KS and Kumar DM: Fast dissolving dosage forms: an overview. World Journal of Pharmaceutical Research 2016; 5(10): 1184-1200.
4. Baghel P, Roy A, Chandrakar S and Bahadur S: Fast dissolving drug delivery systems: a brief review. Research Journal of Pharmaceutical Technology 2013; 6(6): 597-602.
5. Deshpande KB and Ganesh NS; Orodispersible tablets: an overview of formulation and technology, International Journal of Pharmaceutical and Biomedical Sciences 2011; 2(1): 72-80.
6. Hirani JJ, Rathod DA and Vadalia KR: Orally disintegrating tablets: a review. Tropical Journal of Pharmaceutical Research 2009; 8(1): 161-172.
7. Chuhan VK, Dr. Rajesh KS, Umalkar DG, Singh LP, Shah K and Pagi K: Mouth dissolving tablets: an overview, Journal of Pharmaceutical and Biomedical Sciences 2011; 5(1): 1-6.
8. Ghosh T, Ghosh A and Prasad D: A review on new generation orodispersible tablets and its future prospective, International Journal of Pharmaceutical Sciences 2011; 3(1): 1-6.
9. Saxena V, Mahavir Pr. K, Gupta MK, Agarwal D and Sharma N: Orally disintegrating tablet: friendly dosage form, International Journal of Research Ayurv Pharma 2010; 10(1): 399-407.
10. Dinesh Kumar, Sharma I and Sharma V; A comprehensive review on fast dissolving tablet technology. Journal of Applied Pharmaceutical Sciences 2011: 1(1): 50-58.
11. Gupta A, Mishra AK, Bansal P, Singh R and Singh AK: Recent trends of fast dissolving tablet: an overview of formulation technology. International Journal Pharma Bio Arch 2010; 1(1): 1-10.
12. Bhardwaj S, Jain V, Sharma S, Jat RC and Jain S: Orally disintegrating tablets: a review. Drug Inv Today 2010; 2(1): 81-88.

13. Daljit M and Rajesh G: Mouth dissolving tablets – a review. UK Journal Pharmaceutical Biosciences 2013; 1(1): 18-24.
14. Madhulika GSSV and Kuber BR: A review on natural and synthetic polymers employed in the formulation of oral disintegrating tablets. Journal of Drug Delivery and Therapeutics 2019; 9(2): 652-658.
15. Gandhi L and Md Akhtar S: Comparative study on effect of natural and synthetic superdisintegrants in the formulation of orodispersible tablets. Journal Drug Delivery Therapeutics 2019; 9(2): 507-513.
16. Parameshwara BP, Md. Rajdar, Rekha MM, Mathappan R. and K. Rekha: Formulation and evaluation of fast dissolving tablets of nislodipine using different superdisintegrants. World Journal of Pharmaceutical Research 2019; 8(7): 1243-1271.
17. Sachan A K, Singh S, Kumar V and Kumari K: Comparative study of natural and synthetic superdisintegrants in orodispersible metformin tablet, Asian Journal Pharmac Research and Development 2019; 7(3): 46-53.
18. Barethiya VM, Dixit GR and Rajbhar K: Fast dissolving tablets- an ongoing trend in pharmaceutical industry, International Journal of Pharma and Chemical Research 2020; 6(3): 31-38.
19. Rajbhar K, Jain Y, Barethiya V, Sahu S and Dixit G: Dissolution - A quality parameter for testing of pharmaceutical dosage form. International Journal of Pharmaceutical Sciences Review and Research 2020; 63(2): 163-172.
20. Joshi R, Garud N and Akram W: Fast dissolving tablets: a review. Int J Pharm Sci & Res 2020; 11(4): 1562-70. doi: 10.13040/IJPSR. 0975-8232.11(4).1562-70.
21. Allam A and Fetih G: Sublingual fast dissolving niosomal films for enhanced bioavailability and prolonged effect of metoprolol tartrate. Drug design, Development and Therapy 2016; 10: 2421.
22. Iurian S, Tomuta I, Bogdan C, Rus L, Tokes T, Barbu Tudoran L, Achim M, Moldovan M and Leucuta S: Defining the design space for freeze-dried orodispersible tablets with meloxicam. Drug Development and Industrial Pharmacy 2016; 42: 1977-89.
23. Naik SB, Venkateswarlu K and Chandrasekhar KB: Formulation and in-vitro evaluation of orodispersible tablets of olanzapine for the improvement of dissolution rate. J Chem Pharm Res 2016; 8: 177-81.

How to cite this article:
Barethiya V, Dixit G, Deshpande S and Rajbhar K: Formulation, evaluation and comparison of natural and synthetic superdisintegrants used in the fast dissolving tablet by direct compression techniques. Int J Pharm Sci & Res 2024; 15(1): 120-30. doi: 10.13040/IJPSR.0975-8232.15(1).120-30.