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ORIGINAL ARTICLE

Comparative study on the effect of natural and synthetic superdisintegrant in fast dissolving tablets by using model drug for anti-inflammatory and analgesic action

Ravi Sharma*, Beerendra Vishwakarma, Shraddha Mahajan, Ashish Gupta, Pravin Kumar Sharma, G.N. Darwhekar
Acropolis Institute of Pharmaceutical Education and Research, Indore, M.P., India
Corresponding Author:
Ravi Sharma
Associate Professor, Acropolis Institute of Pharmaceutical Education and Research, Indore
Email address: s.ravi11588@gmail.com

ABSTRACT
In the research, the effects of a natural superdisintegrant fenugreek gum isolated from fenugreek seed and synthetic super disintegrants like sodium starch glycolate and croscarmellose sodium were compared in the formulations of fast dissolving tablets (FDT). The fast disintegrating drug delivery system offers a solution for patients having difficulty in swallowing tablets/ capsules etc. The objective of the study was to extract the fenugreek gum and compare its disintegration efficiency with widely used synthetic superdisintegrants. Aceclofenac (anti-inflammatory and analgesic) was selected as the model drug, which has a powerful inhibitory effect on pain and inflammation. Aceclofenac causing gastric irritation, low bioavailability because of poor aqueous solubility and due to this it also has delayed onset of action. FDT increases bioavailability, and as the absorption site is mouth, it reduces the gastric irritation. Solid dispersion's of Aceclofenac were prepared by using PVP-K30 were by physical mixing and it showed remarkable increase in aqueous solubility. The fenugreek gum was extracted and evaluated for the physicochemical characterization of fenugreek gum. Fast dissolving tablets were evaluated on the basis of thickness (3.99±0.2), hardness (4.0±0.15), weight variation (350.1±0.39 mg), friability (0.561±0.02), wetting time (15±1 sec), water absorption ratio (63.00±0.19%), drug content (99.64±0.24%), in-vitro disintegration test (21±3 sec), in-vitro dissolution study (90.23±0.40% upto 30 min) and stability studies. Results of in-vitro disintegration and dissolution studies revealed improved and fast dissolution of Aceclofenac. It was concluded that fast dissolving tablet containing solid dispersion of poor soluble drug using natural superdisintegrant showing enhanced dissolution rate.
Keywords: *Aceclofenac, Fenugreek gum, Fast Dissolving Tablet, Solid Dispersion, Bioavailability*

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INTRODUCTION

Conventional solid dosage forms such as tablet and capsules are the most popular dosage forms for many drugs but elderly patient face difficulty in swallowing (dysphasia) it. Moreover, these are not suitable for drugs which have low oral bioavailability due to poor aqueous solubility. Solid dispersion method is most successfully used technique to improve the aqueous solubility, dissolution rates and subsequently the bioavailability of poorly soluble drugs [1]. Likewise, fast dissolving tablet offers accuracy of dosage, an alternative to the liquid dosage forms and is ideal for geriatric patients with a rapid onset of action [2]. In addition, fast-dissolving tablets disintegrate and dissolve rapidly in saliva without need of water [3].
Superdisintegrants are agents added to tablets and some encapsulated formulations to promote moisture penetration and dispersion of the tablet matrix [4]. Natural superdisintegrant like fenugreek gum, have evoked tremendous interest due to their pharmaceutical applications. Plant products are therefore an attractive alternative as compared to synthetic products because of biocompatibility, low toxicity, and low

price [2]. Fenugreek (*Trigonella foenum graecum*) is an annual plant and its seeds are used in food as well as in medicinal application. Fenugreek seed has a central hard and yellow embryo which is surrounded by a corneous and comparatively large layer of white and semi-transparent endosperm [5].
Aceclofenac is a NSAID which has effective anti-inflammatory and analgesic properties. Aceclofenac belongs to BCS Class II , thus it has very low bioavailability due to poor aqueous solubility and rapid first-pass metabolism [1]. Present investigation was aimed to compare the effect of natural and synthetic superdisintegrant in the fast-dissolving tablet of solid dispersion of Aceclofenac to overcome the drawbacks of synthetic superdisintegrant as well as drug such as poor solubility, slow onset of action, first pass metabolism, low bioavailability and dysphasia.

MATERIAL AND METHODS

Aceclofenac was received as a gift sample from Mariya Pharmaceuticals Pvt. Ltd., Indore (M.P.) for analysis purpose. Fenugreek gum was extracted in the laboratory of Acropolis Institute of Pharmaceutical Education and Research, Indore (M.P.). All other chemicals were purchased from Loba Chemie, Mumbai (Maharashtra).

EXTRACTION AND PURIFICATION OF FENUGREEK GUM:

Fenugreek seeds were ground to 100 mesh using a laboratory mill. The fine powder was extracted with boiling hexane in soxhlet apparatus for 80 min. The obtained extract was treated with 95% ethanol for 130 min in a conical flask to remove the unwanted saponins. Further enzymes deactivation was initiated by refluxing the extract with 70 % ethanol for 180 min. The refluxing mixture was repeatedly treated with ethanol to remove undissolved traces. The residue was filtered through sintered glass at room temperature. The filtered residue was subject to mechanical stirring at 700 rpm with the addition of water for 8 hrs. The obtained mixture was centrifuged at 5000 rpm for 12 min at 10°C. The supernatant contained crude fenugreek gum, which was decanted and precipitated by adding 70% ethanol. Thus the gum precipitate was washed with acetone, diethyl ether and water. The pure fenugreek gum was oven dried [6].

PHYSICOCHEMICAL CHARACTERIZATION OF FENUGREEK GUM:

The purified and dried extracted gum powder was evaluated for its solubility, swelling index and loss on drying.

Solubility Study:

Solubility of fenugreek gum powder was determined in aqueous medium (different temperature) and organic solvent.

Swelling Index:

The study was carried out by using a 100 ml stoppered graduated cylinder. The initial bulk volume of 1 g of fenugreek gum was noted. Water was added in sufficient quantity to ensure 25 ml of uniform dispersion by vigorously shaking every 10 min for 1 h and then allowed to stand for 24 h. The dispersion was stored at room temperature and the sediment volume of the swollen mass was measured after 24 h.

Swelling index = 100 [(V2-V1) / V1]

Where,

V1 = Initial volume of material before hydration.

V2 = Volume of hydrated material.

Loss on Drying:

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 2h at a temperature of 400C±20C. It was cooled in the dry atmosphere of desiccators and then finally weighed (W2).

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

Where,

W1 = Initial weight of the powder.

W2 = Final weight of the powder.

PREFORMULATION STUDIES:

Identification of drug samples by U.V. Spectrophotometer:

The 0.002 % w/v solution Aceclofenac in methanol was scanned at 400 to 200nm, the using double beam UV visible spectrophotometer (Shimadzu 1800, Japan) [7].

Identification of drug samples by FTIR:

FTIR Spectrum was made of pure drug .The sample were analyzed by KBr pellet method using FTIR spectroscopy. About 10 mg of Aceclofenac mixed with potassium bromide of equal weight. The spectra were scanned over a frequency range of 4000 -400 cm -1[8].

Differential Scanning Calorimetry:
The DSC of aceclofenac is the thermogram of pure Aceclofenac obtained by using DSC (mettle star 8.10) at heating rate of 100C/minute over a temperature range of 35-3000C. Accurately weight 2.0 mg of sample was hermetically sealed in an aluminum pan. Nitrogen gas was purged rate of 10 ml / minute to maintain inert atmosphere [9].

Determination of solubility of Aceclofenac in various medium:
The solubility of Aceclofenac in various mediums was determined by equilibrium solubility method. In this method, 5 ml of each solvent was taken into a separate vial and excess amount of Aceclofenac was added in to vials containing distilled water and phosphate buffer pH 6.8. The vials are put on a mechanical stirrer at 37±20C for 12 hrs. The solutions were allowed to equilibrate for next 24 h. The solution was transferred into eppendroff tubes and centrifuged for 5 min. at 2000 rpm. The supernatants of each vial were filter through 0.45-micron membrane filter, make appropriate dilutions and analyzed by UV visible spectrophotometer (Shimadzu 1800, Japan) at 273nm, the studies were performed in triplicate [10].

Drug-excipient interaction study:
The compatibility of the drug was assessed by drug-excipient interaction study. The drug was mixed with various excipients in a 1:1 ratio in glass vials which were properly sealed and kept undisturbed at 40°C temperature for 14 days. After 14 days, incompatibility (if any) was confirmed by TLC [11].

FORMULATION AND DEVELOPMENT:

Preparation of solid dispersion by physical mixing method:
Accurately weighted quantity of Aceclofenac and PVP K-30 in the ratio of (1:1) were weighted and taken in a glass mortar, were mixed thoroughly. It has the mixture passed through a sieve number 100# and stored in a vacuum desiccator for the completed removal of moisture[12].

Preparation of aceclofenac fast dissolving tablets by direct compression method:
Weighed all ingredients as per the quantities defined in below given Table 1. Pass all the ingredients through sieve #80 and collected individuals in polybags. Mixed measured quantity of solid dispersion, fenugreek gum, sodium starch glycolate, croscarmellose sodium, microcrystalline cellulose and mannitol. Magnesium stearate and talc was added to it and blend for 5 min in pestle mortar. Compress final blend using D-Tooling, multiple rotatory compression machine using 10 mm round shaped punches and corresponding dies.

Table 1: Composition of Aceclofenac fast dissolving tablets

S. No	Ingredients	Formulation Code (quantity in mg)								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Solid dispersion of Aceclofenac (Equivalent to 100 mg Aceclofenac)	200	200	200	200	200	200	200	200	200
2	Fenugreek Gum	7.5	10	12.5	-	-	-	-	-	-
3	Sodium Starch Glycolate	-	-	-	7.5	10	12.5	-	-	-
4	Croscarmellose Sodium	-	-	-	-	-	-	7.5	10	12.5
5	Microcrystalline cellulose	86.5	84	81.5	86.5	84	81.5	86.5	84	81.5
6	Mannitol	50	50	50	50	50	50	50	50	50
7	Magnesium stearate	3	3	3	3	3	3	3	3	3
8	Talc	3	3	3	3	3	3	3	3	3
Total Weight (in mg)		**350**	**350**	**350**	**350**	**350**	**350**	**350**	**350**	**350**

EVALUATION OF PRE COMPRESSION PARAMETER OF FAST DISSOLVING TABLETS:[13]

Angle of repose:
The angle of repose of powder blend was measured by the funnel method. The accurately weighed powder blend was taken in glass funnel. That is the height of the funnel was maintained in the funnel touches the heap of the powder blend. The powder blend was to flow through the funnel freely onto the surface. The diameter of the powder cone was determined and angle of repose was calculated using the following equation.

$$\theta = \tan^{-1}(h/r)$$

Where,
h= height of the cone.
r = radius of the cone.

Bulk Density
Bulk density ρb is defined as the mass of the powder divided by the bulk volume and is expressed as g/cm3. Accurate weighed quantity of powder blend from each formulation was taken in a measuring

cylinder and the initial volume of the powder blend (Vb) in the measuring cylinder was noted. This was calculated by using the below given formula.

ρb= M / Vb

Where,

ρb - Bulk density

M - Weight of the sample in g

Vb- volume of the blend in ml

Tapped Density

It is the ratio of total weight of the powder to the tapped volume of powder. The volume was measured by tapping the powder blend 50 times. Then the tapping was done 50 times and the tapped volume was noted. Tapped density was calculated by using the following formula

ρt= M / Vt

Where,

ρ**t**-Tapped density,

M - Weight of the sample in g

Vt - Tapped volume of blend in ml

Compressibility Index and Hausner's Ratio

It is a compressibility index of the powder blend was measured by Carr's compressibility index and the Hausner's ratio is calculated by using the formula

Hausner's Ratio = Tapped density / Bulk density

Carr's compressibility index (%) = [(Tapped density-Bulk density/Tapped density) × 100]

EVALUATION OF SOLID DISPERSION OF ACECLOFENAC

Solubility determination:

The samples of physical mixtures equivalent to 10 mg of Aceclofenac were added to 10 ml each of distilled water and phosphate buffer pH 6.8. It is shaken well and kept for 24 h. The solution was filtered and analyzed at 273nm using UV-1800 spectrophotometer (Shimadzu, Japan) after suitable dilution [14].

Drug content of solid dispersion:

The Aceclofenac solid dispersions prepared were tested for drug content. The physical mixture equivalent to 100 mg of Aceclofenac was taken and analyzed for drug content. An accurately weighed quantity of Aceclofenac Solid dispersion was taken in a 100 ml volumetric flask and dissolved in methanol. The stock solutions were filtered, suitably diluted and assayed for drug content using a Shimadzu 1800 UV visible spectrophotometer [12].

EVALUATION OF POST COMPRESSION PARAMETERS:

Thickness:

Twenty tablets were randomly selected from formulation and thickness was measured individually by a screw gauge. The result was expressed in millimeters [15].

Hardness:

The crushing strength of tablet was measured using a Monsanto Hardness Tester. Tablets to be place are held between a fixed and a moving jaw of Monsanto hardness test apparatus and reading of tablets is indicated is adjusted to zero. The screw knob was moved clockwise until the tablet broke and the force required to break the tablet was noted. Three tablets of each formulation batch were taken randomly, tested and the average reading was recorded [13].

Weight Variation:

Twenty tablets were randomly taken from each batch and the weight of their average weight was determined. Then individual weight was compared with average weight. The weight was measured using weighing balance [15].

Friability:

Friability test was performed by using Roche friabilator. Ten tablets were weighed and place in the friabilator, which was then operated for 25 revolutions per minute. After four minutes (100 revolutions) the tablet was dusted and reweighed. The percentage friability was determining using this formula [13].

Friability (%) = Initial weight - Final weight / Initial weight ×100

Wetting Time:

The tablet was placed at the center of two layers of tissue adsorbent paper fitted into a petri dish. After the paper was wetted with distilled water, excess water was completely drained out of the dish. The time required for the water to diffuse from the wetted absorbent paper throughout the entire tablet was then recorded using a stopwatch [15].

Water Absorption Ratio:
The piece of tissue adsorbent paper was folded twice was placed in a small petri dish containing 6 ml of water. A tablet was put on the tissue paper and allowed to get completely wet. The wetted tablet was again weighed. Water absorption ratio, R was determined using the following equation

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

Where,
Wa = Weight of tablet after water absorption
Wb = Weight of wetted tablet before water absorption. [15].

Drug Content:
Twenty tablets were taken and the amount of drug present in each formulation was determined. The tablet was crushed in a mortar and the powder equivalents to 100 mg drug were transferred to a 100 ml standard flask. The powder was dissolved in 5 ml of methanol and made up to volume with phosphate buffer pH 6.8 .The sample was mixed thoroughly the filtered through 0.45-micron membrane filter paper. The filter solution was diluted suitably and analyzed for drug content by U.V. Spectrophotometer at 273 nm [15].

***In-vitro* Disintegration Time:**
The USP disintegration test apparatus was used to determine disintegration time. Six tablets from each formulation were tested in 900 ml of water at 37°C. The study was done in triplicate [15].

***In-Vitro* Drug Release Study:**
The *in-vitro* dissolution study of formulated fast dissolving tablets F1-F9 was carried out using USP dissolution apparatus type II(Electro Lab Dissolution Tester USP II) (50rpm, 37±0.5°C, and 900 ml of medium). A temperature of 37±0.5°C was maintained throughout the study. The dissolution medium was phosphate buffer (900 ml, pH 6.8) for the experiment. Five milliliters of the sample was withdrawn at specified time intervals and analyzed by UV spectrophotometer (Shimadzu 1800, Japan) at 273.30 nm. The amount of drug released at each time point was calculated and summed to give the cumulative amount of drug. In order to the study the effect of drug release in fast dissolving tablet were carried out in USP paddle type dissolution apparatus at 50 rpm sample were predetermined interval and analyzed by UV spectrophotometer (Shimadzu 1800, Japan) at 273.30 nm[10].

Stability Studies:
The stability studies were carried out for a period of 1 month in the stability chamber. The tablets were stored under the following conditions as prescribed by the ICH guidelines (40°C±2°C and 75±5% RH,Q1C). The tablets were withdrawn periodically at an interval of 30 days and analyzed for Hardness, Disintegration, Dissolution, Wetting time, drug content etc [15].

RESULTS AND DISCUSSIONS

Extraction and purification of fenugreek gum:
The fenugreek gum was extracted from fenugreek seed.

Characterization of fenugreek gum:
The purified and dried extracted gum powder was evaluated for its micromeritic properties preformulation studies, solubility studies, swelling index and loss on drying show in Table 2.

Table 2: Physicochemical characterization of fenugreek gum

S. No.	Parameters	Result
1	Loss on drying	5%
2	Swelling index	133%
3	Solubility	Slightly soluble in cold water and insoluble in organic solvents
4	Bulk density	0.769g/ml
5	Tapped density	0.909g/ml
6	Compressibility index	15.40 %
7	Hausner's ratio	1.18
8	Angle of repose	19.200
9	Percentage yield	27 %

PREFORMULATION STUDY:

Determination of maximum wavelength using UV Spectrophotometer:
The maximum wavelength of Aceclofenac is shown in figure 1 and was found to be 273.30 nm which matches the reported wavelength.

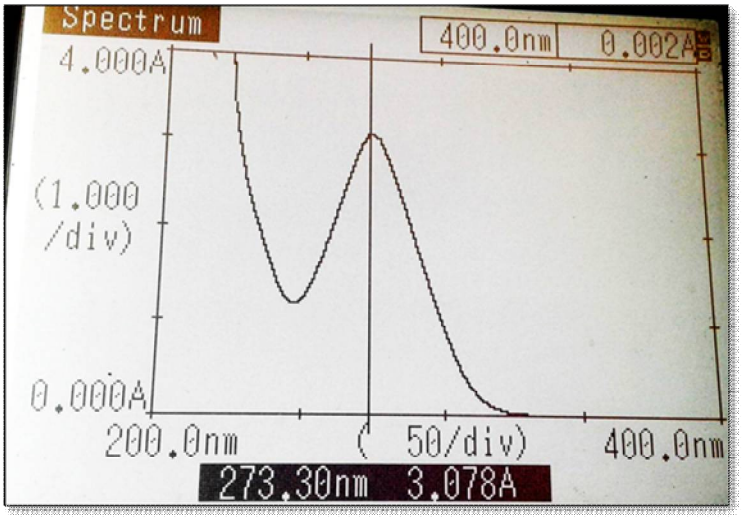

Figure 1: UV Spectrum of Aceclofenac

Identification of drug samples by FTIR Spectroscopy:

The prominent FTIR peak of Aceclofenac is shown in table 3 and the FTIR spectrum is shown in figure 2. Results indicated that all the peaks matched with that of standard FTIR of Aceclofenac.

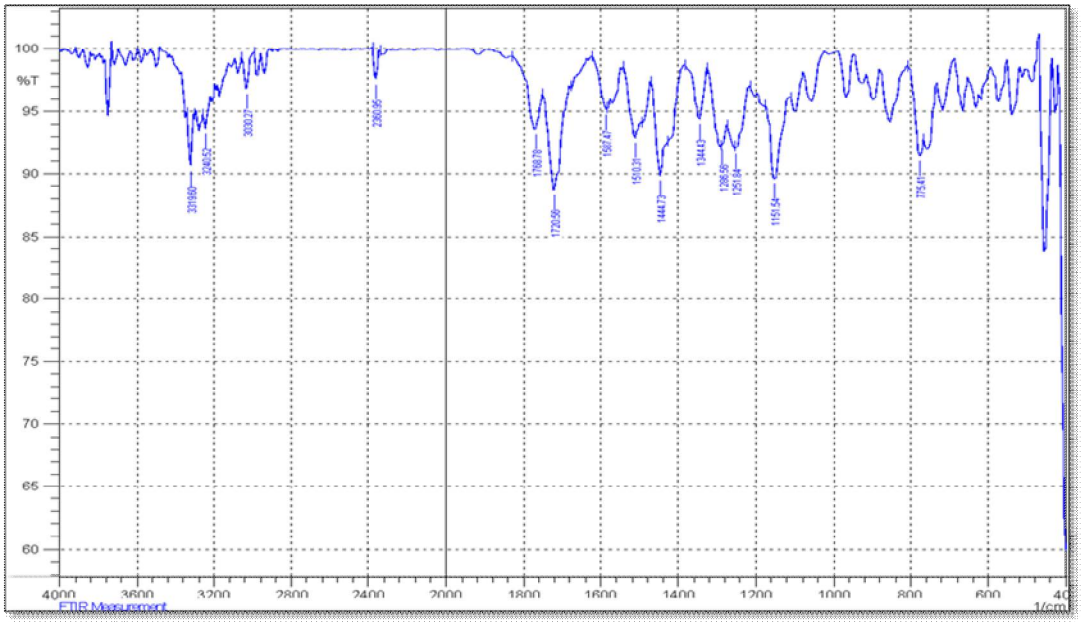

Figure 2: FTIR Spectrum of Aceclofenac

Table 3: Prominent peaks of FTIR Spectrum of Aceclofenac

S. No.	IR Absorption peak	Chemical group
1	3319.60	OH hydrogen bonding
2	3340.52	OH hydrogen bonding
3	1766.76	Carbonyl group
4	1720.56	Carbonyl group
5	1510.31	NH group
6	1587.47	C=C group

Differential Scanning Calorimetry:

The DSC thermogram of Aceclofenac is shown in figure 3 and it exhibited endothermic peak at 155.07°C which corresponds to the melting point of Aceclofenac.

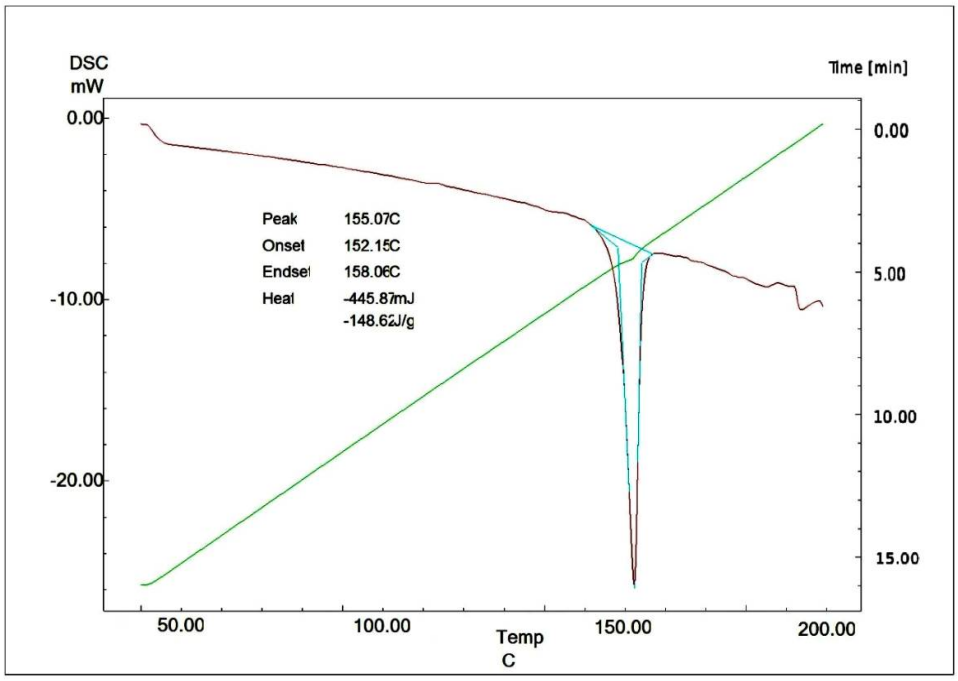

Figure 3: DSC thermogram of Aceclofenac

Determination of solubility of aceclofenac in various solvents:

The solubility of Aceclofenac in various solvents was studied and the results of the study were shown in table 4.

Table 4: Solubility study data of Aceclofenac in various media

S. No.	Solvent	Absorbance	Concentration (µg/ml)	Dilution factor	Solubility of Aceclofenac (µg/ml)
1	Distilled water	0.131	4.06	-	4.06µg/ml
2	Phosphate buffer (pH) 6.8	0.161	5.74	100	574.19µg/ml

Drug-Excipient Interaction Study:

Results of drug-excipient interaction study are shown in table 5. The drug (Aceclofenac) was found to be compatible with various excipients which were selected for formulation of fast dissolving tablets. The compatibility was assessed by TLC and the retention factors of all ratios were found similar.

Table No.5: Data of drug-excipient interaction study

S. No.	Drug/ drug+ Excipient Ratio (1:1)	Present Day (Rf)	After 8 Days (Rf)	Inference
1	Drug (Aceclofenac)	0.531	0.531	No Change
2	Drug + PVP-K 30	0.541	0.541	No Change
3	Drug + Fenugreek gum	0.730	0.730	No Change
4	Drug + Croscarmellose sodium	0.508	0.508	No Change
5	Drug + Sodium Starch glycolate	0.510	0.510	No Change
6	Drug + Micro Crystalline Cellulose	0.566	0.566	No Change
7	Drug + Mannitol	0.616	0.616	No Change
8	Drug + Magnesium Stearate	0.583	0.583	No Change
9	Drug + Talc	0.591	0.591	No Change

Determination of various flow properties such as Bulk density, Tapped density, Carr's index, Hausner's ratio, Angle of repose

The bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose of selected formulations were performed and shown in table 6. All the results show that the final formulations possess a good flow property.

Table 6: Various flow properties of formulation (n=3)

Characterization	F1	F2	F3	F4	F5	F6	F7	F8	F9
Bulk density (g/ml)	1.35± 0.23	1.33± 0.14	1.31± 0.21	1.36± 0.40	1.37± 0.41	1.39± 0.28	1.37± 0.26	1.37± 0.44	1.36± 0.08
Tapped density (g/ml)	1.58± 0.14	1.60± 0.24	1.62± 0.23	1.58± 0.08	1.58± 0.19	1.58± 0.22	1.56± 0.16	1.58± 0.20	1.58± 0.26
Carr's index (%)	14.55	16.87	19.13	13.92	13.29	12.02	12.17	13.29	13.92
Hausner's ratio	1.17	1.20	1.23	1.16	1.15	1.13	1.13	1.15	1.16
Angle of Repose(°)	26°	30°	25°	24°	29°	27°	28°	30°	29°

FORMULATION AND DEVELOPMENT

Preparation of solid dispersion:

It was attempted to improve the aqueous solubility of Aceclofenac by solid dispersion technique. PVP-K-30 was used as a carrier for preparation of solid dispersion with Aceclofenac due to their characteristics i.e. easily soluble in water, physiologically, non-toxic, lack of absorption, thermally stable at melting temperature, and improve compound wettability. Binary solid dispersion using drug and carrier were prepared by 1:1 ratio of PVP-K-30. The drug and carrier were used for preparation of solid dispersion by physical mixture method to enhance the solubility of Aceclofenac.

Formulation of Fast Dissolving Tablets

The different formulation of Aceclofenac FDTs were prepared by direct compression method using fenugreek gum as a natural superdisintegrants, and solid dispersion of Aceclofenac +PVP-K-30 were compared with various standard synthetic superdisintegrants like SSG, Croscarmellose Sodium. The tablets were prepared.

EVALUATION OF SOLID DISPERSION

Drug Content:

The percent drug content of solid dispersion formulation was found to be 80.5%.

Solubility studies of solid dispersion:

Results of solubility studies are shown in table 7 and it revealed a remarkable increase in the aqueous solubility of Aceclofenac.

Table 7: Solubility of solid dispersion of Aceclofenac

S. No.	Solvent	Absorbance	Concentration (µg/ml)	Dilution factor	Solubility of Solid Dispersion (µg/ml)
1	Distilled water	0.542	16.51	10	165.1µg/ml
2	Phosphate buffer (pH) 6.8	0.362	12.22	100	1222.58µg/ml

EVALUATION OF FAST DISSOLVING TABLETS

The various physicochemical properties were evaluated like thickness, hardness, weight variation, friability, drug content, disintegration time, wetting time and the results of the study are shown in table 8 and table 9.

Table 8: Weight Uniformity, Thickness, Hardness and Friability (n=3)

Batch	Weight Variation Mean ± SD (mg)	Thickness Mean±SD (mm)	Hardness Mean ±SD (Kg/Cm2)	Friability Mean ±SD (%)
F1	350.0±0.81	3.99±0.2	4.3±0.1	0.845±0.01
F2	350.1±0.26	3.98±0.2	4.2±0.1	0.704±0.01
F3	350.1±0.39	3.99±0.2	4.0±0.15	0.561±0.02
F4	348.4±0.89	3.98±0.02	4.3±0.15	0.702±0.1
F5	348.6±0.93	3.98±0.02	4.6±0.1	0.571±0.02
F6	350.1±0.32	3.99±0.2	4.2±0.15	0.568±0.01
F7	350.1±0.29	3.98±0.2	4.3±0.1	0.842±0.02
F8	349.1±0.43	3.99±0.2	4.2±0.05	0.560±0.02
F9	349.6±0.28	3.98±0.2	4.5±0.05	0.835±0.01

Table 9: Wetting time, Drug Content Uniformity, Water Absorption Ratio and *In-vitro* Disintegration Time (n=3)

Batch	Wetting Time (Sec)±SD	(%) Drug Content Uniformity ±SD	Water Absorption Ratio (%)	Disintegration time (sec)±SD
F1	33±1	99.23±0.53	66.10±0.25	41±3
F2	25±2	99.34±0.44	61.15±0.90	32±2
F3	15±1	99.64±0.24	63.00±0.19	21±3
F4	46±2	99.56±0.14	69.70±0.20	51±2
F5	35±1	99.05±0.65	66.65±1.01	43±3
F6	23±1	98.62±0.61	62.30±0.90	31±1
F7	41±3	99.23±0.40	70.00±0.32	47±2
F8	30±2	99.11±0.56	66.10±0.20	36±3
F9	22±3	99.17±0.26	62.00±0.30	27±3

***In-vitro* drug release study for fast dissolving tablet:**

Results of *In-vitro* drug release study are shown in table 10 and comparative dissolution plot is shown in figure 4. The percentage of drug release from formulations F1 to F9 was found to be more than 95% within 30 minutes.

Table 10: Percentage drug release data of F1 to F9 formulation of Fast dissolving tablets (n=3)

S. No.	Time (in min)	% Drug Release data								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1	0	0	0	0	0	0	0	0	0	0
2	1	11.67 ± 0.56	12.44 ± 0.60	14.54 ± 0.80	12.95± 0.89	16.62 ± 0.53	15.01± 0.90	13.56± 0.92	14.55± 0.58	17.25± 0.20
3	2	22.25 ± 0.50	24.55± 0.58	27.01± 0.14	24.65± 0.53	20.08± 0.56	27.86± 0.60	22.45± 0.53	26.42± 0.80	27.91± 0.83
4	3	34.93± 1.30	36.42± 0.56	38.94± 0.58	36.82± 0.56	32.25± 0.80	30.21± 0.30	34.56± 1.40	37.14± 0.60	35.65± 0.82
5	5	45.55± 0.58	47.14± 0.56	50.57± 0.59	47.91± 1.20	44.56± 0.80	42.54± 0.56	47.95± 0.72	49.95± 0.80	50.15± 0.56
6	10	67.5± 0.50	69.95± 0.63	72.98± 0.53	59.98± 0.32	67.98± 0.78	54.99± 0.40	59.78± 0.54	54.17± 0.80	66.45± 0.60
7	15	72.45± 0.60	74.17± 0.63	82.52± 0.40	71.54± 0.56	79.78± 1.56	76.98± 0.76	66.66± 0.56	73.02± 0.20	81.26± 0.56
8	20	79.45± 2.30	83.02± 1.20	88.24± 0.30	79.56± 0.58	86.56± 0.30	89.84± 0.45	75.84± 0.73	86.23± 0.23	86.21± 0.60
9	25	81.21± 1.20	90.23± 0.40	98.05± 0.45	85.23± 0.40	90.34± 0.12	93.29± 0.50	86.01± 0.36	91.01± 0.63	94.54± 0.56

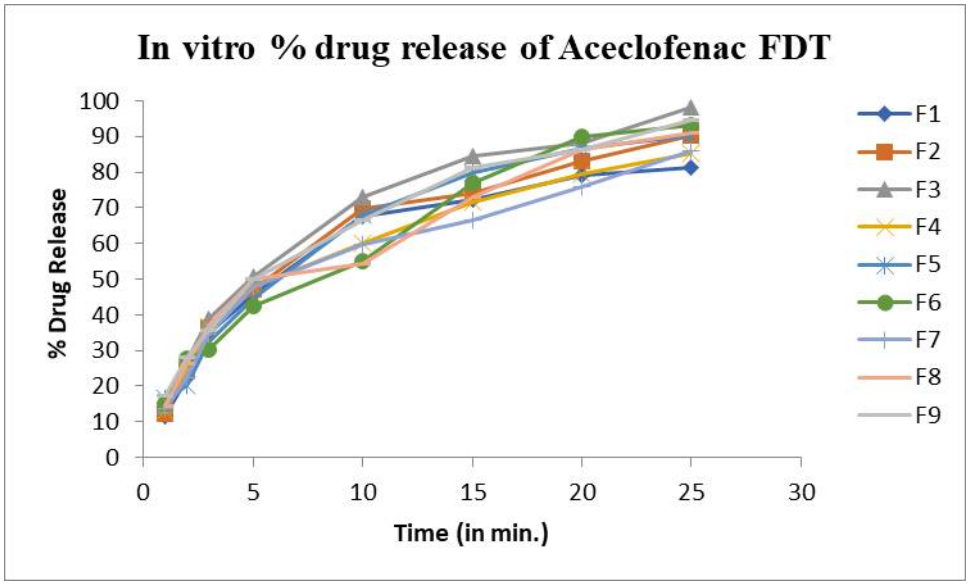

Figure 4: Percentage of drug release from fast dissolving tablets formulation

Stability Studies:

Results of the stability studies are shown in table 11. The stability studies F-3 Formulation were carried out for a period of 1 month in the stability chamber. The tablets were stored under the following conditions as prescribed by the ICH guidelines (40°C±2°Cand 75±5%RH, Q1C). The tablets were withdrawn periodically at an interval of 30 days and analyzed for weight variation, Hardness, Disintegration, Wetting time, drug contents etc.

Table 11: Stability study for fast dissolving tablet of Formulation batch (F-3)

S. No.	Parameter	0 days	15 days	30 day	Result
1	Weight Uniformity	350.1±0.39	350.1±0.39	350.1±0.39	No change
2	Hardness	4.0±0.15	4.0±0.15	4.0±0.15	No change
3	Drug content	99.64±0.24	99.64±0.24	99.62±0.20	Some change
4	Wetting time	15±1	15±1	15±1	No change
5	Disintegration	21±3	21±3	21±3	No change

CONCLUSION

It was concluded that the fast-dissolving tablets of the poor soluble drug can be made by direct compression technique. Powder blend was evaluated and the values were found to be within prescribed limit. The values obtained from the post compression parameters were also evaluated. Formulation (F3) using natural superdisintegrant shows enhanced dissolution rate as compared to synthetic superdisintegrant and hence better patient compliance and used as an effective therapy.

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