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FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS OF ACECLOFENAC USING NATURAL SUPERDISINTEGRANT

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ABSTRACT: On contact with saliva, FDTs (Fast dissolving tablets) which are designed to disintegrate rapidly, enables tremendous oral administration without contact with water. Also chewing these formulations produces an increased convenience and ease of administration with a significant potential efficacy to improve the patient compliance, predominantly in certain populations who were facing difficulties for swallowing the conventional solid oral dosage forms. In our present study, the effect of a natural superdisintegrant namely, Fenugreek and some synthetic superdisintegrants such as SSG (Sodium Starch Glycolate), MCC (Micro Crystalline Cellulose), CP (Cross Povidone) and CCS (Cross Carmaellose sodium) were employed for this study to produce the formulations of FDTs. By direct compression method, FDTs of Aceclofenac were prepared and evaluated as per IP standards. From our study it was confirmed that Fenugreek showed excellent swelling index than the synthetic superdisintegrants. Hence the present study reveals that this natural superdisintegrants showed significant disintegration

INTRODUCTION:

The Fast Dissolving tablets from the desire to provide patient with conventional means of taking their medication. Because of physiological changes associated with, especially, elderly and pediatrics are quite unable to swallow (Dysphasia); rather, this is a common problem of all age groups patients. Some fast dissolving tablets dosage forms which can be disintegrated, dissolved, or suspended with saliva in the mouth resulting in easy swallowing can provide distinguishable benefits to the pediatric and elderly population, as well as other patients who prefer the convenience of easy swallowing able dosage forms. This tablet disintegrates quickly when placed on tongue, fast releasing of the drug that dissolves or disperses in the saliva pH 6.8. [1] Recently, pharmaceutical preparations used for elderly patients have been investigated to improve the treatment compliance and quality of life of such patients. Fast dissolving tablets can fast disintegrate in saliva (pH 6.8). Fast disintegrating tablet is an attractive dosage form and a patient-oriented pharmaceutical preparation. These Fast -dissolving tablets have attracted the

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interest of many researchers. Many elderly patients have difficulty swallowing tablets, capsules, or powders. To reduce this problem, these tablets are expected to dissolve or disintegrate in the oral cavity without drinking water. The disintegrated mass can slide down smoothly along the esophagus with the help of saliva, so even people who have swallowing or chewing difficulties can take it with ease. There are two different types of dispersible tablets which have to be distinguished: One dosage form disintegrates instantaneously in the mouth, to be swallowed without the need for drinking water, while the other tablet formulation can readily be dispersed in water, to form dispersion, easy to ingest by the patient.[2] Fast dissolving tablets are tablets which disintegrate and dissolve rapidly in saliva within seconds even if water is not available. In spite of tremendous development of fast dissolving drug delivery system or technology, oral route remains perfect route for administration of therapeutic reagents because of low cost of therapy, ease of administration, accurate dose, self medication, pain avoidance, leading to high level of patient compliance. According to European pharmacopoeia, fast dissolving tablets are those which disintegrate on tongue before swallowing and it should disperse in less than 3 min.

MATERIALS AND METHOD: Aceclofenac was obtained as Yarrow chem. pvt. Ltd. Sodium Starch Glycolate, Croscarmellose Sodium, Microcrystalline cellulose, Magnesium Stearate, Talc, PVP - K- 30 was obtained from loba chemicals.

METHODS:

Extraction and purification of fenugreek gum: Fenugreek seed 100 g were ground to 100 mesh using laboratory mill. The fine powder was extracted with boiling hexane in soxhlet apparatus for 80 min. The obtained extract was treated with 95% ethanol (maintaining its boiling points) 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 if necessary. The residue was filter through sintered glass at room temperature. The filtered residue was subject to mechanical stirring at 700 rpm. with addition of water for 8 hrs. The obtained mixture was centrifuged at 5000 rpm. for 12 min. at 100C. The supernatant contained crude fenugreek gum, which was decanted and precipitated by adding of ethanol 70 %. Thus the gum precipitate was washed with acetone, diethyl ether and water. The pure fenugreek gum was oven dried

Physicochemical characterization of fenugreek gum:

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

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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 theswollen mass was measured after 24 h.

Swelling index = $100\ [(V_2-V_1) / V_1]$

Where,

V_1=Initial volume of material before hydration.
V_2=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 (W_1) and heated in an oven for 2 h.at temperature $40^0C \pm 2^0C$. It was cooled in the dry atmosphere of desiccators and then finally weighed (W_2).

% Loss on drying= $[(W_1-W_2)/W_1]\ 100$

Where

W_1=Initial weight of the powder.
W_2=Final weight of the powder.

PREFORMULATION STUDY:

Identification of Drug: Authentication of drug sample by U.V. Spectrophotometer:

When the drug Aceclofenac was examined in the range 220 nm to 370 nm, the 0.002 % w/v solution in methanol show an absorption maximum at 275 nm. [3]

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Authentication of drug sample by FTIR:

Fourier Transform Infrared spectroscopy (FTIR) Spectrum was recorded of pure drug. The sample were analysed 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 4000 -400 cm^{-1} .[4]

Differential Scanning Calorimetry:

The DSC of aceclofenac is the thermogram of pure aceclofenac obtained by using DSC (mettle star 8.10) at heating rate 10^0C/minutes over a temperature range of 35- 300^0C. Accurately weight 2.0 mg of sample was hermetically sealed in an aluminum pan. Nitrogen gas was purged rate 10 ml / minutes for maintaining inert atmosphere.

Determination of Melting Point:

Melting point of drug sample was determined by using melting point apparatus. The drug sample was taken and placed in a thin walled capillary tube; the tube was approximately 10-12 cm in length with 1mm in diameter and closed at one end. The capillary was placed in melting point apparatus and heated and when drug sample was melted the melting point of sample powder was recorded.[5]

Determination of solubility:

Preparation of calibration curve of Aceclofenac:

The calibration curves of Aceclofenac were prepared in distilled water and phosphate buffer pH 6.8 by using Shimadzu 1800 UV visible spectrophotometer. Accurately weighed 50 mg of Aceclofenac was transferred into a 50 ml volumetric flask and the volume was made up with distilled water to obtain a 1000µg/ml stock solution of Aceclofenac. From the stock solution 1 ml was taken and transferred into a 10 ml volumetric flask and rest of the volume was made up with solvent to obtain a 100µg/ml of solution from which further dilutions were prepared. Same procedurewas followed for phosphate buffer pH 6.8 to prepare calibration curve.[6]

Determination of solubility of Aceclofenac in various medium: The solubility of Aceclofenac in various medium 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 put on mechanical stirrer at 37 ± 2^0C 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 (UV-1800 Shimadzu ,japan) at 273 nm, the studies was performed in triplicate.[36]

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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.[7]

Table No. 1: Selection of excipients:

S.No.	Excipients	Purpose
01	P.V.P. –K-30	Disintegrants
02	Fenugreek gum	Superdisintegrant
03	Sosium starch glycolate	Superdisintegrant
04	Croscarmellose Sodium	Superdisintegrant
05	Microcrystalline Cellulose	Diluent
06	Mannitol	Sweetening agents
07	Magnesium Stearate	Lubricants
08	Talc	Glidant

FORMULATION AND DEVELOPMENT:

Preparation of solid dispersion: The solid dispersion prepared by physical mixture

Preparation of physical mixture: Accurately weight quantity of Aceclofenac and PVP K-30 in the ratio of (1:1) were weight and taken in a glass mortar, were mixed thoroughly. It has the mixture pass through sieve number 100# and stored in a vacuum desiccator for the completed removal of moisture. [8]

Preparation of Aceclofenac Fast dissolving tablets by Direct Compression

Method:

- Weighed all Ingredients as per the quantities defined in below given Table No. 1.
- Pass all the ingredients through sieve #80 and collected individuals in polybags.

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- 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 No. 2: Composition of Aceclofenac Fast Dissolving Tablets.

S.No	Ingredients	Formulation Code (quantity in mg)								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	SD * Aceclofenac (Equivalent to 100 mg ACF)	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**

*Solid Dispersion

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EVALUATION PARAMETER:

Evaluation of Precompression Parameter of Fast Dissolving Tablets: [9]

- Angle of repose:

The angle of repose of powder blend was determined by the funnel method. The accurately weighed powder blend were taken in 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 used the following equation.

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

Where,

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

Table No. 3: Flow Properties of Angle of Repose.

Flow properties	Angle of repose (^{0})
Excellent	25-35
Good	31-35
Fair and not needed	36-40
Passable	41-45
Poor	46-55
Very Poor	56-65
Very, Very Poor	>66

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- **Bulk Density:**

Bulk density ρb is defined as the mass of the powder divided by the bulk volume and is expressed as g/cm^3. Accurate the weighed quantity of powder blend from each formulation was taken in a measuring cylinder and the initial volume of the powder blend(V_b) in the measuring cylinder was noted. This was calculated by using below given formula.

$$\mathbf{P_b = M / V_b}$$

Where,

ρb - Bulk density

M - Weight of the sample in gV_b- volume of the blend in ml

- Tapped Density:

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

$$\mathbf{P_t = M / V_t}$$

Where,

ρ**t** - Tapped density,

M - Weight of the sample in g

V_t - Tapped volume of blend in ml

- Compressibility index and hausners 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

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Hausner's Ratio = Tapped density / Bulk density

Carr's compressibility index (%) =

[(Tapped density-Bulk density/Tapped density)× 100]

Table 4: Scale of flow ability:

Compressibility Index (%)	Flow Character
<10	Excellent
11-15	Good
16-20	Fair
21-25	Passable
26-31	Poor
32-37	Very Poor
>38	Very, Very Poor

Table No. 5: Flow properties of Hausner Ratio:

Hausner Ratio	Flow Character
1.00-1.11	Excellent
1.12-1.18	Good
1.19-1.25	Fair
1.26-1.34	Passable
1.35-1.45	Poor
1.46-1.59	Very Poor
>1.60	Very, Very Poor.

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Evaluation of solid dispersion:

- Solubility Determination:

  The samples of physical mixtures equivalent to 10 mg of ACF was 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 in used of spectrophotometric at 273 nmusing UV-1800 spectrophotometer (Shimadzu, Japan) after suitable dilution. [10]

- Drug content of solid dispersion:

  The Aceclofenac solid dispersions prepared were tested for drug content. From the physical mixture equivalent to 100 mg of Aceclofenac were taken and analyzed for drug content. An accurately weighed quantity of Aceclofenac Solid dispersion were 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.[11]

Evaluation of Post compression Parameter of Fast Dissolving Tablet:

- **Thickness:** Twenty tablets were randomly selected from formulation and thickness was measured individually by screw gauge. The result was expressed in millimeters. [3]
- **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

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adjusted to zero. The screw knob was moved forward until the tablet breaks and the force required breaking the tablet was noted. Three tablets of each formulation batch were tested randomly and the average reading was recorded.[12]

- **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. [13]

Table No. 6: Criteria for percent deviation from average weight:

Dosage form	Average Weight	% Deviation
Fast dissolving tablets or uncoated tablets	80 mg or less	10 %
	More than 80 but less than 250 mg	7.5 %
	250 mg or more	5 %

- **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 minute (100 revolutions) the tablet were dusted and reweighed. The percentage friability was determining using this formula.

  Percentage friability = Initial weight - Final weight / Initial weight ×100 [13]

- **Wetting time:**

  The tablet was placed at the center of two layers of tissue adsorbent paper fitted into a petridish. After the paper was thoroughly wetted with distilled water, excess water was completely drained out of the dish. The time

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required for the water to diffuse from the wetted absorbent paper throughout the entire tablet was then recorded usinga stopwatch. [13]

- **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 tocompletely wetting. The wetted tablet was the again weighed. Water absorption ratio, R was determined using following equation

$$R = 100 \times (W_a - W_b)/W_a$$

Where,

W_a = Weight of tablet after water absorption

W_b = Weight of wetted tablet before water absorption [14]

- **Drug contents:** Twenty tablets were taken and amount of drug present in each formulation was determined. The tablet was crushed in a mortar and the powder equivalents to 100 mgdrug were transferred to 100 ml standard flask. The powder was dissolve 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 Test:**

The USP disintegration test apparatus was used to determine disintegration time. Six tablets from each formulation were tested in 900 ml of water at 37^0C. The study was done in triplicate. [16]

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- **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) (50 rpm , 37±0.5 ^{0}C ,and 900 ml of medium). A temperature of 37±0.5 ^{0} C was maintained throughout the study. the dissolution medium was phosphate buffer (900 ml pH 6.8) for the experiment. Five milliliter 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 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. [17]

- **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 withdrawnperiodically with an interval of 30 days and analyzed for Hardness, Disintegration, Dissolution, Wetting time, drug content etc.[18]

6. RESULT AND DISCUSSION:

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 no.10.

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Table No. 7: 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	19.20^0
9	Percentage Yield	27 %

PREFORMULATION STUDY:

Identification and Drug Characterization

- **Determination of Maximum wavelength using UV spectrophotometer :**

  The maximum wavelength of Aceclofenac was found to be 273.30.nm which matches thereported wavelength

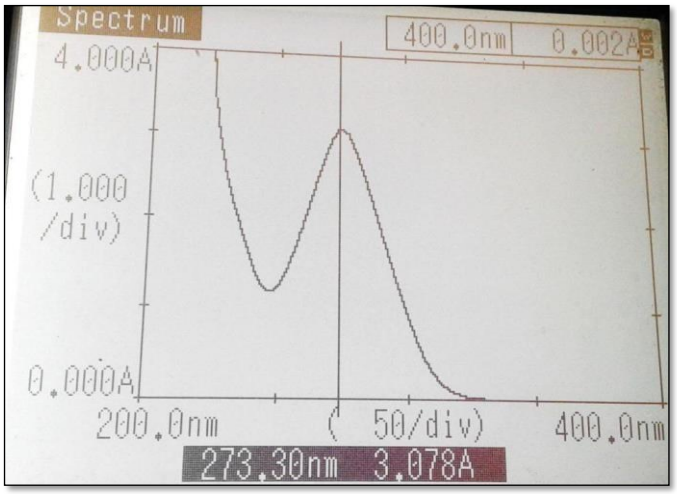

Figure: 1 UV

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Authentication of drug sample by I.R. Spectroscopy:

FTIR: (Fourier Transform Infrared Spectroscopy) The prominent IR absorption peak of Aceclofenac at 3319.60 and 3240.52 that these broad peaks may be due to OH hydrogen bonding. 1766.76 and 1720.56 carbonyl group vibration. 1587.47 indicate the presence of C=C ring stretching and 1510.31 N-H bending presence in the FTIR of Aceclofenac.

Table No. 8: FTIR Spectra of Aceclofenac

S. No.	IR Absorption peak	Chemical group
01	3319.60	OH hydrogen bonding
02	3340.52	OH hydrogen bonding
03	1766.76	Carbonyl group
04	1720.56	Carbonyl group
05	1510.31	NH group
06	1587.47	C=C group

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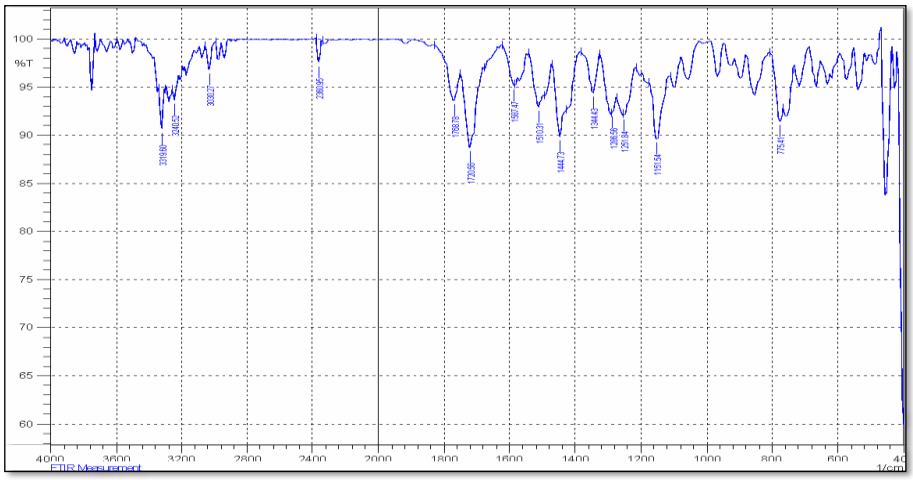

Figure: 2 FTIR

Differential Scanning Calorimetry: the DSC thermogram of Aceclofenac exhibited endothermic peak at 155.07 ^{0} C which corresponds to the melting point of Aceclofenac.

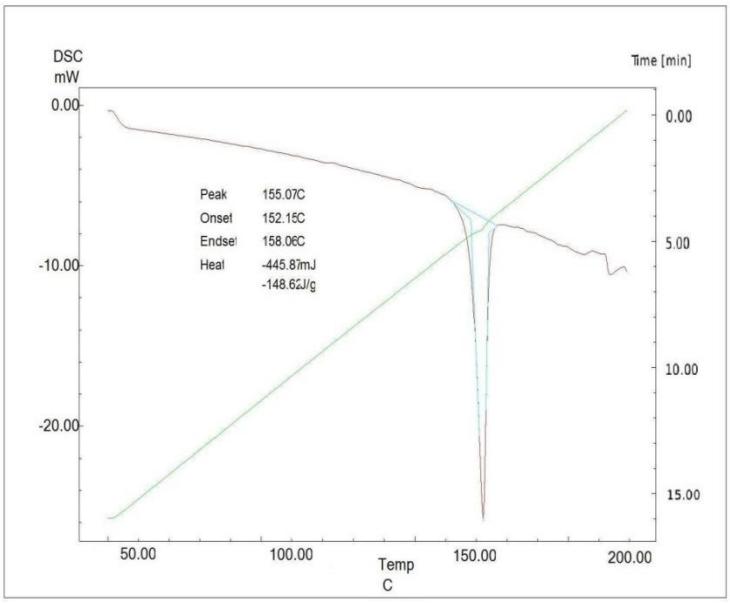

Figure.3 DSC graph of Aceclofenac.

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- **Melting point determination:**

The melting point of Aceclofenac was found to be 150^0C which is same as reported inliterature**.**

Determination of solubility:

- **Preparation of calibration curves:**

The calibration curves of Aceclofenac in various solvents e.g. Distilled water, 6.8 pH phosphate buffers were prepared and shown in Table No. 12

Table No. 9: Absorbance data of Aceclofenac in distilled water for preparation ofcalibration curve, at 273 nm.

S. No.	concentration (µg/ml)	Absorbance
1	2	0.066
2	4	0.125
3	6	0.198
4	8	0.256
5	10	0.331

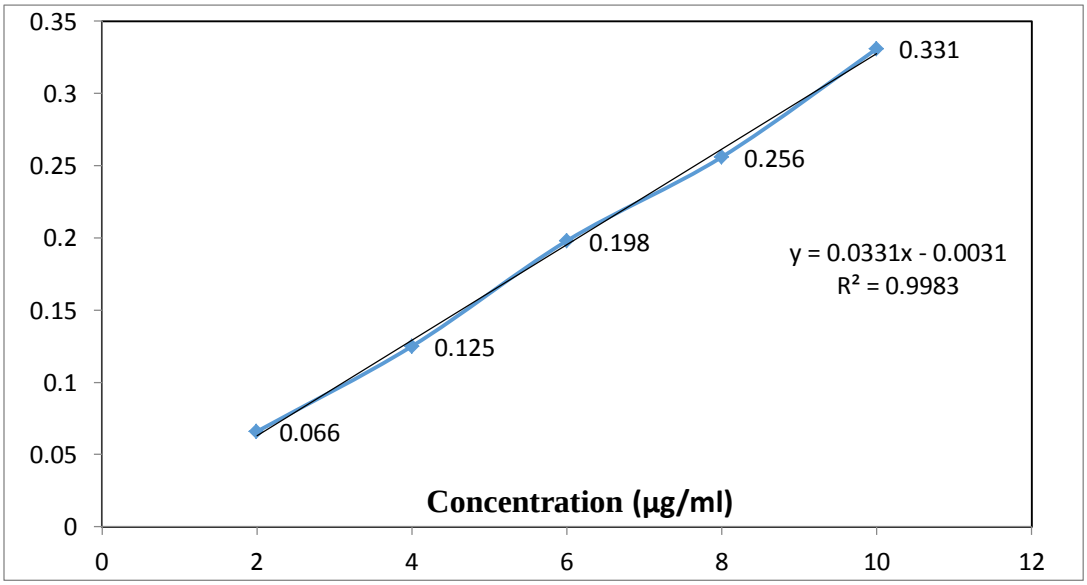

Figure 7.4: Calibration curve of Aceclofenac in distilled water

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Table No. 10: Absorbance data of Aceclofenac in phosphate buffer pH 6.8 for preparation of calibration curve, at 273 nm

S. No.	Concentration (µg/ml)	Absorbance
1	2	0.145
2	4	0.296
3	6	0.443
4	8	0.641
5	10	0.765

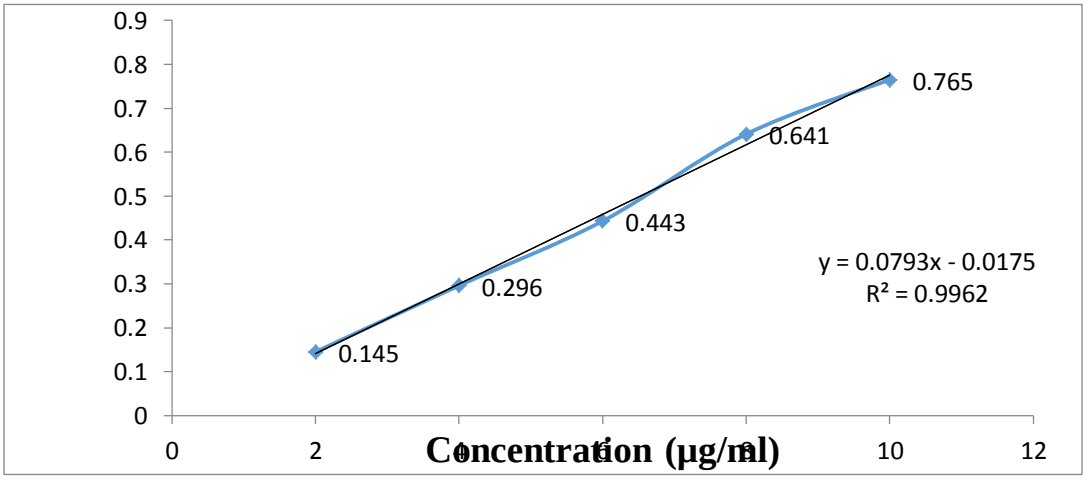

Figure 7.5: Calibration curve of Aceclofenac in Phosphate Buffer pH 6.8

- **Determination of solubility of Aceclofenac in various medium:**

The solubility of Aceclofenac in various mediums was studied and the results of studywere shown in below table no.14.

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Table No. 11: Solubility study data of Aceclofenac in different mediums:

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: 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 found similar.

Table No.12: Data of drug-excipient interaction study

S.No.	Drug/ drug+ ExcipientRatio (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 + Croscarmellosesodium	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 Sterate	0.583	0.583	No Change
9	Drug + Talc	0.591	0.591	No Change

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Determination of various flow properties:

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 no.-16. All the results show that the final formulations possess a good flow property.

Table No. 13: Various flow properties of formulation F1– F9:

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 (^{0})	26 ^{0}	30 ^{0}	25 ^{0}	24 ^{0}	29 ^{0}	27 ^{0}	28 ^{0}	30 ^{0}	29 ^{0}

Data are represented as mean ±SD (n=3).

FORMULATION AND DEVELOPMENT:

- **Preparation of Solid dispersion:**

It was attempted to improve the aqueous solubility of ACE 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

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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 FDTs:

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 contents:

Percent drug content of solid dispersion formulation were found to be 80.5%.

S. No.	Sample	Absorbance	Concentration (µg/ml)	Dilution Factor	% Drug content
1.	Phosphate buffer pH6.8	0.621	8.05	1000	80.5

Solubility studies of solid dispersion

Table No. 14: Solubility of solid dispersion of Aceclofenac

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

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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 were shown in below table:

Table No.15: Weight Uniformity, Thickness, Hardness, and Percentage Friabilityand of Batch F1-F9

Batch	Weight Variation Mean ± SD	Thickness Mean ± SD	Hardness Mean ± SD	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 No. 16: Wetting time, Drug Content Uniformity, Water Absorption Ratio,Disintegration Time and In-vitro dissolution of Batch F1-F9.

Batch	Wetting Time (Sec)±SD	(%) Drug Content Uniformity ±SD	Water Absorption Ratio (%)	Disintegrationtime (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

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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

All value expressed in Standard deviation (n=3)

In-vitro drug release study for fast dissolving tablet:

The percentage drug release from formulations F1 to F9 was found to be more than 95% drug within 30 minutes.

Table-No. 17: Percentage drug release data of F1 to F9 formulation of Fastdissolving tablets.

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

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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± 036	91.01± 0.63	94.54± 0.56

Stability studies: The stability studies F-3 Formulation were carried out for a period of 1 month in the stability chamber. The tablet were stored under the following condition as prescribed by the ICH guidelines (40^0C±2^0Cand 75±5%RH, Q1C).The tablet were withdrawn periodically with an interval of 30 days and analyzed for Weight variation, Hardness, Disintegration, Wetting time, Drug contents etc. Results are presented in table no.

Table No. 18: 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

SUMMARY AND CONCLUSION: The present study was carried out in order to develop fast dissolving drug delivery system of Aceclofenac using fenugreek gum as a natural superdisintegrants. Fast dissolving tablet are successfully developed for the delivery of poorly water soluble drugs. The fenugreek gum was extracted and evaluated for the physicochemical characterization of fenugreek gum. Aceclofenac solid dispersion using PVP-K-30 were successfully prepared by physical mixture technique. The

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solubility and drug content studies showed a remarkable increase in both solubility and drug content of Aceclofenac solid dispersion using PVP-K-30 as hydrophilic carrier compared with pure Aceclofenac and physical mixtures. The solubility studies of prepared solid dispersion shows the improved solubility. Using fenugreek gum as a natural superdisintegrants Increased concentration of fenugreek gum leads to significant effect on disintegration and dissolution properties. It can be concluded that solid dispersion of Aceclofenac with fenugreek gum as a natural super disintegrants shows promising result of solubility and in vitro drug release of FDT of Aceclofenac.

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