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Optimisation of Aceclofenac Fast Dissolving Tablets Employing Starch Xanthate Using 23 Factorial Design

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ABSTRACT

The present investigation involves in the evaluation of starch xanthate as a superdintegrant in the formulation of fast dissolving tablets of poorly soluble drugs employing 23 factorial design. Starch xanthate was synthesized by gelatinization process. The synthesized starch xanthate was subjected to physical and micromeritic evaluation. To establish as starch xanthate as a superdisintegrant, fast dissolving tablet of aceclofenac was prepared employing starch xanthate in different proportions in each case by direct compression method employing 23 factorial designs. All fast dissolving tablets prepared were evaluated for drug content, hardness, friability, disintegration time and other dissolution characteristics like PD5, DE5 and K1. The starch xanthate prepared was found to be fine, free flowing slightly crystalline powder. Starch xanthate exhibited good swelling in water. The swelling index was 50% all micrometric properties indicated good flow and compressibility needed for solid dosage from manufacturing. All the fast dissolving tablets formulated employing starch xanthate were of good quality with regard to drug content, hardness and friability and fulfilled the official (IP/USP) requirements of compressed tablets with regard to the above mentioned physical properties. Starch xanthate was found to be a superdisintegrant which enhanced the dissolution efficiency when combined with sodium starch glycolate, crosscarmellose sodium, with the aceclofenac and hence it could be used in the formulation of fast dissolving tablets to provide immediate release of the contained drug within 5minutes.

Keywords: Fast dissolving, Super-disintegrant, Starch xanthate, Dissolution efficiency.

Abbreviations: FTIR: Fourier Transform Infrared Spectra; DSC: Differential Scanning Calorimetry**;** ANOVA: Analysis of Variance; PD5: Percent Dissolved in 5 Minutes; DE5%: Dissolution Efficiency in 5 Minutes

INTRODUCTION

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage form. Fast dissolving tablets are solid dosage form containing indicated substances which disintegrate rapidly, usually within few seconds when placed upon tongue requiring additional water to facilitate swallowing. Fast dissolving tablets offer great advantages for the patients having difficulty in swallowing. The elderly constitute a major portion of today's population mainly because of increased life span of individuals. Physiological and neurological conditions, such as dysphasia, a risk of choking, and hand tremors are leading causes of patient non-compliance in the self-administration of conventional solid oral dosage forms [1]. Fast dissolving tablets overcome this problem and provide the advantages for pediatrics, geriatric [2,3], bedridden, disabled patients and also for who may have difficulty in swallowing tablets, capsules and liquid orals. FDT will rapidly disintegrate in the mouth without the need of water [4,5]. Fast dissolving tablet formulation provides sufficient strength, quick disintegration/ dissolution in the mouth without water [6], rapid dissolution and absorption of the drug, which will produce the quick onset of action. Pre gastric absorption of FDT can result in improved bioavailability and as a consequence of reduced dose [7].

Various techniques can be used to formulate fast dissolving tablets. Direct compression one of the techniques which require the incorporation of superdisintegrant or highly water soluble excipients into the formulation to achieve fast tablet disintegration. Direct compression does not require the use of water or heat during the formulation procedure and is the ideal method for moisture and heat-liable medication. The aim of the work was to formulate and characterize fast-dissolving tablets of aceclofenac by utilizing optimization techniques for rapid dissolution of drug and absorption employing a new superdisintegrant i.e., starch xanthate.

Optimization technique

Optimization technique provide both a depth of understanding and an ability to explore and define ranges for formulation and processing factors with a rational approach to the selection of several experimental and manufacturing step for a given product, to quantitatively select a formulation. It is at this point that optimization can become a useful tool to quantitative a formulation that has been qualitatively determined. The present investigation deals with an attempt of systematic formulation approach for optimization of aceclofenac fast dissolving tablets employing starch xanthate, sodium starch glycolate, crosscarmellose sodium as superdisintegrants. A 2^3 factorial design was applied to investigation the main and interaction effects of the three formulation variables i.e., starch xanthate (A), sodium starch glycolate (B), crosscarmellose sodium (C) in each case to find the formula with less disintegration time and more dissolution efficiency 5 min and to permit arbitrary selection of tablets with immediate release of drug within 5 min.

MATERIALS AND METHODS

Materials

Sodium hydroxide, Carbon disulphide, Lactose was purchased from Finar chemicals Ltd, Ahmedabad. Potato starch, Aceclofenac, Sodium starch glycolate, Crosscarmellose sodium was obtained from Yarrow chem. Products, Mumbai.

Microcrystalline cellulose was bought from Qualigens fine chemicals, Mumbai. Talc and Magnesium Stearate was obtained from Molychem, Mumbai.

Preparation of starch xanthate (a novel Superdisintegrant)

Initially 35.4 g of potato starch was slurried in 225ml distilled water and 8g of sodium hydroxide was dissolved in distilled water. Both are stirred continuously for 30 minutes. To this 5ml of carbon disulphide was added and stirred for 16hours at 25°C. After 16 hours, it was filtered and washed with 75ml of distilled water, 500ml of acetone and 100ml of ether. The product was kept in oven at 60°C for 2 hrs. The product obtained was ground and sieved.

Characterization of starch xanthate

The starch xanthate prepared was evaluated for the following:

Solubility: Solubility of starch xanthate was tested in water, aqueous buffer of pH 1,2,3,4, and 6.196 and organic solvents such as alcohol, dichloromethane, chloroform, acetone and petroleum ether.

pH: The pH of 1% w/v slurry was measured by pH meter.

Melting point: Melting point was determined by using melting point apparatus.

Viscosity: Viscosity of 1% dispersion in water was measured using Ostwald viscometer.

Swelling index: Starch xanthate (200 mg) was added to 10 ml of water and light liquid paraffin taken in two Different graduated test tubes and mixed. The dispersion in the tubes was allowed to stand for 12 h. The volumes of the sediment in the tubes were recorded. The swelling index on the material was calculated as follows.

$$S.I\ (\%) = \text{Volume of sediment in water} - \text{volume of sediment in light liquid paraffin} / \text{Volume of sediment in light liquid paraffin} \times 100$$

Test for gelling property: The gelling property (gelatinization) of the starch and starch xanthate prepared was evaluated by heating a 7% w/v dispersion of each in water at 100°C for 30 min.

Particle size: Particle size analysis was done by sieving using standard sieves.

Density: Density (g/cc) was determined by liquid displacement method using benzene as liquid.

Bulk density: Both loose bulk density (LBD) and tapped bulk density (TBD) were determined by transferring the accurate weighed amount of sample in 50 ml measuring cylinder, the granules without any agglomerates and measured the volume of packing and tapped 50 times on a plane surface and tapped volume of packing recorded and LBD and TBD calculated by following formula [8]:

Bulk Density = (TBD-LBD) × 100/TBD;

where, LBD =Mass of powder/Volume of packing; TBD= Mass of powder/Tapped volume of packing.

Percentage compressibility index: Percentage compressibility of powder mix was determined by Carr's Compressibility Index calculated by the following formula [9].

% Carr's Index= (TBD-LBD) × 100/TBD;

Where, TBD=Tapped Bulk Density; LBD=Loose Bulk Density.

Angle of repose: The frictional forces in loose powder or granules can be measured by the angle of repose. This is the maximum angle possible between the surface of a mass of powder or granules and the horizontal plane. Angle of repose is calculated by applying the next equation;

$\tan \theta = h/r$; $\theta = \tan^{-1} (h/r)$, where θ=angle of repose; h=height; r=radius

Fourier Transform Infrared (FTIR) Spectroscopy

FTIR spectra of starch lactate were recorded on samples prepared in potassium bromide (KBr) disks using a BRUKER FT –IR, (Tokyo, Japan). Samples were prepared in (KBr) disks by means of a hydrostatic press at 6-8 tons pressure. The scanning range was 500 to 4000 cm^{-1}.

X– Ray diffraction

Diffraction pattern of starch xanthate was recorded with an x-ray diffractometer (analytical spectra's Pvt. Ltd., Singapore). X-ray diffraction was performed at room temperature (30°C) with a diffractometer; target, Cu (λ 1.54 A), filter, Ni; voltage,40 kV; current 30 mA; time constant 10 mm/s ; scanning rate 2°/min; measured from 2.5-50° at full scale 200.

Drug– excipients compatibility studies

The compatibility of starch xanthate with the selected drug (aceclofenac) was evaluated in DSC and FTIR studies.

Differential scanning calorimetry (DSC)

DSC thermograms of aceclofenac, and their mixtures (1: 1) with starch xanthate were recorded on Perkin Elmer thermal analyser samples (2- 5 mg) were sealed into aluminium pans and scanned at a heating rate of 10°C min^{-1} over a temperature range 30–350°C.

Infrared spectroscopy

Fourier transform infra-red (FTIR) spectra of aceclofenac, and their mixtures (1: 1) with starch xanthate were recorded on a Perkin Elmer, IR Spectrophotometer model: Spectrum RXI, using KBr disc as reference.

Preparation of aceclofenac fast dissolving tablets

The tablets were prepared by direct compression method employing 2^3 factorial designs in which 3 independent variables {superdisintegrants i.e., starch xanthate (A), sodium starch glycolate (B), crosscarmellose sodium (C)} and 1 dependent variable (dissolution efficiency in 5 min) were selected. The composition of different formulation of aceclofenac fast dissolving tablets is shown in Table 1 in which the levels of superdisintegrants were selected at 2 levels i.e., lower and higher level concentrations. For starch xanthate (A), the lower level i.e., 5% concentration and upper level i.e., 10% concentration. For sodium starch glycolate (B) and crosscarmellose sodium (C), the lower level is zero concentration and higher level i.e., 5% concentration. For uniformity in particle size each ingredient was passed through # 100 mesh sized screen before mixing. Starch xanthate, sodium starch glycolate, crosscarmellose sodium, lactose and microcrystalline cellulose were accurately weighed and mixed using mortar and pestle, and the added to aceclofenac. Finally talc and magnesium stearate were added to the powder mixture. Finally mixed blend was compressed by using eight station rotator press Karnawathi Machineries Pvt, Ltd., Ahmedabad, India.

Table: 1: Formulae of aceclofenac fast dissolving tablets employing starch xanthate prepared by direct compression method involving lactose as a diluent.

Ingredients	FL1	FL2	FL3	FL4	FL5	FL6	FL7	FL8
Aceclofenac	100	100	100	100	100	100	100	100
Starch xanthate	25	50	25	50	25	50	25	50
Sodium starch glycolate	---	---	25	25	---	---	25	25
Crosscarmellose sodium	---	---	---	---	25	25	25	25
Lactose	155	130	130	105	130	105	105	80
Micro crystalline cellulose	200	200	200	200	200	200	200	200
Talc	10	10	10	10	10	10	10	10
Magnesium stearate	10	10	10	10	10	10	10	10
Total	500	500	500	500	500	500	500	500

Evaluation of aceclofenac fast dissolving tablets Hardness test

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablet was determined using Monsanto hardness tester and expressed in kg/cm² [10]

Uniformity of weight

Weight variation test was done with 20 tablets. It is the individual variation of tablet weighed from the average weight of 20 tablets.

Friability

The friability of tablets was measured using a Roche fribilator. Tablets were rotated at 25 rpm for 4 minutes or upto 100 revolutions. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated.

$$F = 100 \times W \text{ (initial)}–W \text{ (final)}/W \text{ (initial)}$$

Drug content uniformity

For content uniformity, ten tablets were weighed and powdered a quantity of powder equivalent to 10 mg of aceclofenac was extracted into 7.4 phosphate buffer and filtered. The aceclofenac content was determined by measuring the absorbance spectrophotometrically at 274 nm after appropriate dilution with 7.4 phosphate buffer. The drug content was calculated as an average of three determinations [11].

Wetting time

The wetting time of tablets was measured using a very simple procedure five circular tissue papers of 10 cm diameter were placed in a Petri dish with a 10 cm diameter. Ten ml of water containing a water soluble dye (amaranth) was added to the petri dish. A tablet was carefully placed on the tissue paper. Time required for water to reach the upper surface of the tablet was noted as wetting time [12,13].

Water absorption ratio

A piece of tissue paper folded twice in a small petri dish containing 6 ml of water. A tablet was put in the tissue paper allowed to completely wet. The wetted tablet was then weighed. Water absorption ration R was determined using following equation.

$$R = 100 (W_{a-} W_b)/W_b$$

Where,

W_a = Weight of tablet after water absorption.

W_b = Weight of tablet before water absorption.

***In– vitro* disintegration time**

Disintegration time for FDTs was determined using USP disintegration apparatus 0.1 N HCl buffer. The volume of medium was 900 ml and temperature was 37 ± 0.2°C. The time in second taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured [14].

***In– vitro* dissolution studies**

The *in- vitro* dissolution rate study of aceclofenac fast dissolving tablets were performed using 8 stage dissolution test apparatus (Electrolab TDT-08L) fitted with paddles (50 rpm) at 37 ± 0.5°C, using 7.4 phosphate buffer (900 ml) as a dissolution media. At the predetermined time intervals, 5 ml samples were withdrawn, filtered through 0.45 µ membrane filter, diluted and assayed at 274 nm using a Analytical technology T360 UV/Visible Double beam spectrophotometer. Cumulative percentage release was calculated using standard absorbance from the calibration curve. All the dissolution experiments were conducted in triplicate (n = 3).

RESULTS AND DISCUSSION

The starch xanthate prepared was found to be fine, free flowing slightly crystalline powder. The physical and micromeritics properties of the starch xanthate are summarized in Table 2. It was insoluble in aqueous solvents and insoluble in organic solvents tested (methanol, petroleum ether, dichloromethane, and chloroform) the pH of 0.1% aqueous dispersion was 6.196. Starch xanthate exhibited good swelling in water. The swelling index was 50% all micrometric properties indicated good flow and compressibility needed for solid dosage from manufacturing. The density of starch xanthate was found to be 0.9848 g/cc. The angle of repose and compressibility index showed good flow properties of starch xanthate. The FTIR spectrum of potato starch and starch xanthate is shown in Figures 1 and 2. The presence of peaks absorption at 1634.10 cm^{-1} characteristic peak of ester, so from FTIR studies it was concluded that starch xanthate (ester) was formed when starch was allowed to react with formic acid. The X-ray diffraction pattern (Figure 3) of starch xanthate showed characteristic peaks, which indicates that the structure is slightly crystalline. The disappearance of pink color in the ester test confirmed the presence of ester, i.e., starch xanthate. As the starch xanthate was slightly crystalline powder and it had got all the characteristic of superdisintegrants it was concluded that starch xanthate can be used as novel superdisintegrant in the formulation of fast dissolving tablets.

Table 2: Physical and micromeritic properties of the starch xanthate prepared

Parameters	Observation
Solubility	Insoluble in all aqueous and organic solvents tested
pH (1% w/v aqueous dispersion)	6.194
Melting point	Charred at 218°C
Viscosity (1% w/v aqueous dispersion)	1.016 cps
Swelling index	50%
Gelling property	No gelling and the swollen particles of starch xanthate separated from water whereas in the case of starch, it was gelatinized and formed gel.

Particle Size	80 µm (100 mesh)
Density	0.9848 g/cc
Bulk density	0.625 g/cc
Angle of repose	12.4°
Compressibility index	32.5%

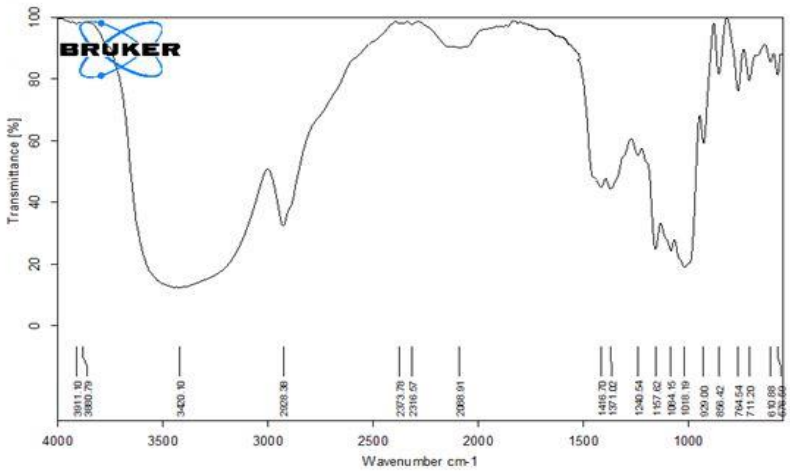


Figure 1: Fourier transform infrared spectra of potato starch.

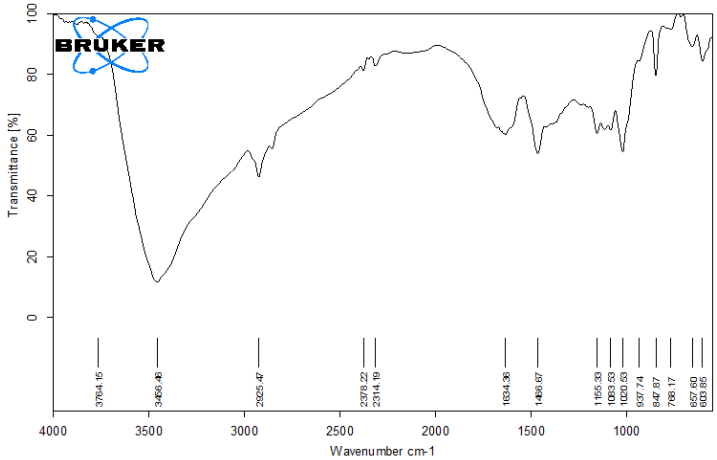


Figure 2: Fourier transform infrared spectra of starch xanthate.

Sample	Frequency of Peak	Functional Group
Starch xanthate	1634.36	(-COOH)

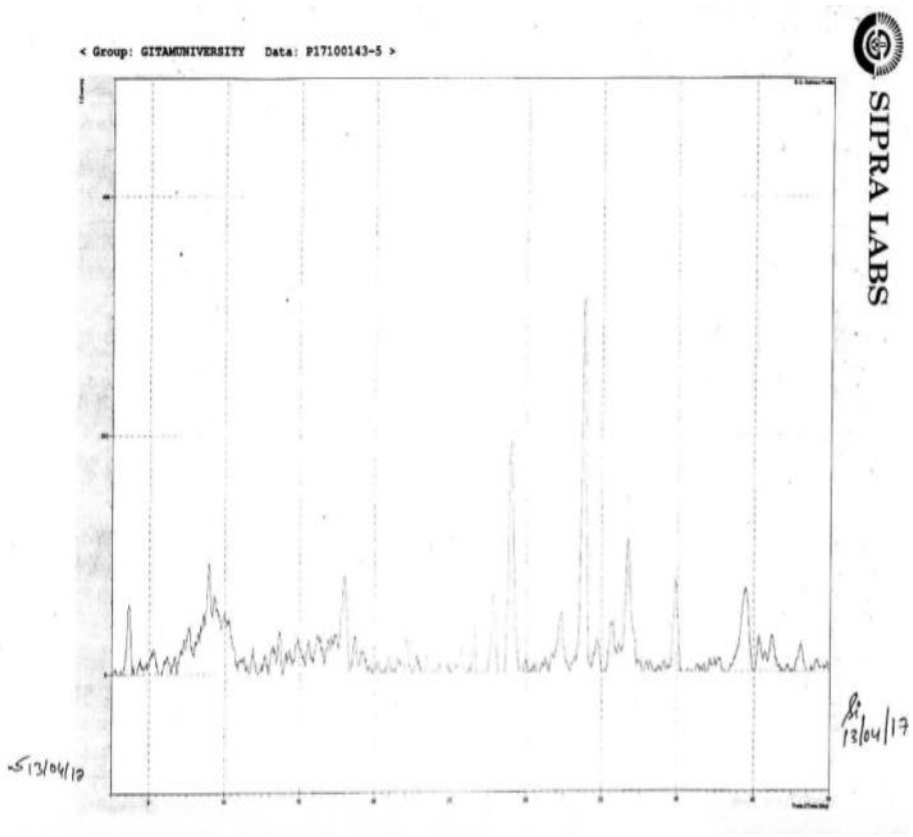


Figure 3: X-ray diffraction pattern of starch xanthate.

The X-ray diffraction pattern of starch xanthate showed 3 charactersistic peaks, which indicates that structure is slightly crystalline. The compatibility of starch xanthate with the selected drug (aceclofenac) was evaluated by FTIR studies. The FTIR spectra of aceclofenac and aceclofenac– starch xanthate are shown in Figures 4 and 5. The characteristic FTIR bands of aceclofenac at 1718.78 cm-1 (COOH), and aceclofenac– starch xanthate at 1716.17 cm-1 (COOH) were all observed in the FTIR spectra of both aceclofenac and aceclofenac– starch xanthate. These FTIR spectra observations also indicated no interaction between starch xanthate and the drug selected. Thus the result of FTIR indicated no interaction between the selected drug and starch xanthate, the new superdisintegrant. Hence, starch xanthate could be used as a superdisintegrant in the design of fast dissolving tablets of the selected drug.

Sample	Frequency of Peak	Functional Group
Aceclofenac	1718.78	(-COOH)

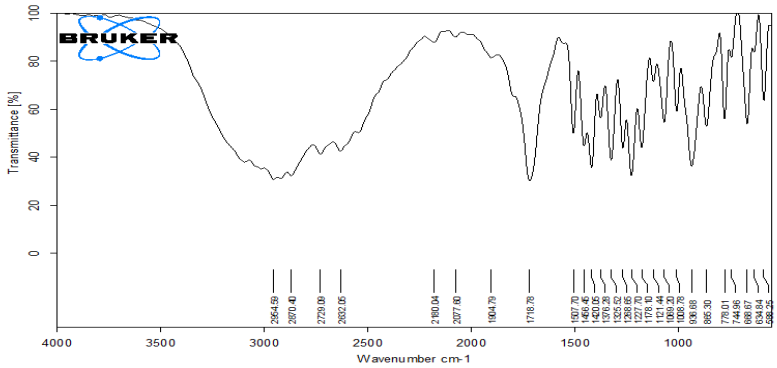


Figure 4: FTIR spectra of aceclofenac

Sample	Frequency of Peak	Functional Group
Aceclofenac + Starch Xanthate	1716.17	(-COOH)

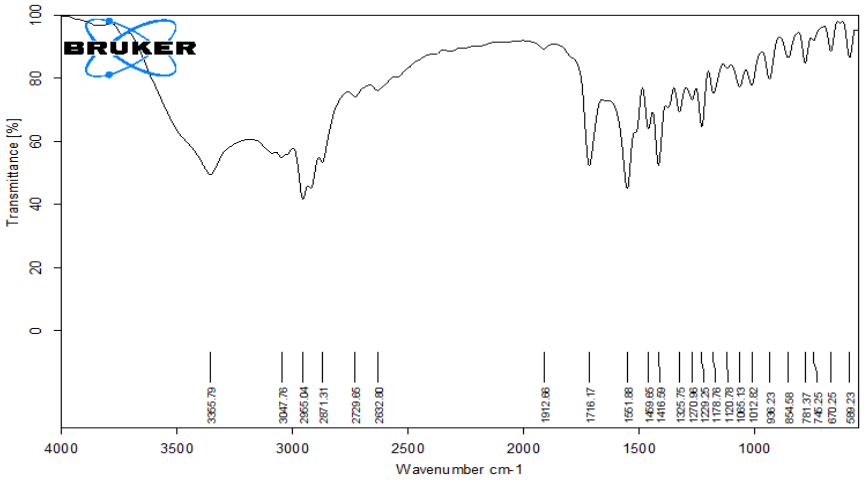


Figure 5: FTIR Spectra of aceclofenac with starch xanthate.

Fast dissolving tablets each containing 100 mg of aceclofenac could be prepared by employing starch xanthate and other known superdisintegrants, sodium starch glycolate and crosscarmellose sodium by direct compression method. Hardness of the tablet was in the range of 3.6– 4 kg/sq.cm. It indicates good strength with a capability to resist physical and pre functionary stress conditions during handling. Weight loss on the friability test was less than 0.15% in all cases. All the fast dissolving tablets prepared contained aceclofenac within 100 ± 5% of the labelled claim. As such the prepared tablets were of good quality with regard to drug content, hardness and friability. The disintegration time of all the formulated tablets was found to be in the range of 05 ± 0. 02 to 121 ± 0.02 seconds as indicated in the Table 3. The result of *In-Vito* wetting time and water absorption ratio was found to be within the prescribed limits and satisfy the criteria of the dissolving tablets (Figure 6). The *In– vitro* wetting time was less in FL5 which consists of combination of 5% starch xanthate, 5% sodium starch glycolate and 5% crosscarmellose sodium.

The drug dissolution from the aceclofenac fast dissolving tablets employing starch xanthate and other known superdisintegrants were in the (Table: 4) and (Figure 7 and 8). The dissolution parameters of the formulation from (FL1–FL8) which were made by direct compression method were shown in the Table 4. In all these cases the PD_5 (percent dissolved in 5 minute) was more in FL5 which consists at 5% starch xanthate, 5% sodium starch glycolate and 5% crosscarmellose sodium. The same was in the case of DE_5% (dissolution efficiency in 5 min). The PD_5 and DE_5% revels that starch xanthate was effective at 5% starch xanthate, 5% sodium starch glycolate, and 5% crosscarmellose sodium when the formulations were made by direct compression using these superdisintegrants. The K_1 also decreased in all the formulations when compared to F1 formulation. From the results it was concluded that starch xanthate (new superdisintegrant) could be used as superdisintegrant in the formulation of fast dissolving tablets of aceclofenac (Tables 4 and 5).

To evaluate the individual and combined effects of the three factors involved, fast dissolving tablets were formulated employing selected combinations of the factors as per 2^3-factorial design. The fast dissolving tablets and release parameters (percent drug released in 5 min) of the fast dissolving formulated were analyzed as per ANOVA of 2^3-factorial design. ANOVA of fast disintegrating times (Table 6) indicated that the individual effects of starch xanthate (A), sodium starch glycolate (B) and crosscarmellose sodium (C) as well as the combined effects of AB, AC, BC and ABC factors were significant on disintegration time and dissolution efficiency in 5 min of aceclofenac fast dissolving tablets.

Fast dissolving tablets formulated employing starch xanthate (5%), sodium starch glycolate (5%) and crosscarmellose sodium (5%) as superdisintegrants exhibited in disintegration and dissolution efficiency in 10 min. Formulation FL5 gave release of 99.28% in 5mins fulfilling the official specification, based on disintegration time and dissolution efficiency in 5 min. Formulation FL5 is considered as a good fast dissolving tablet formulations of aceclofenac.

Table 3: Physical properties: hardness, friability drug content of aceclofenac fast dissolving tablets prepared by direct compression method involving lactose as a diluent

Formulation	Hardness (kg/cm^2)n ± S.D	Friability (%)n ± S.D	Drug Content mg/tab) n ± S.D	Disintegration Time (sec) n ± S.D	Wetting Time (sec) n ± S.D	Water Absorption Ratio (%) n ± S.D
FL1	3.9 ± 0.01	0.12 ± 0.013	97.58 ± 0.71	76 ± 0.02	76 ± 0.02	250 ± 0.12
FL2	3.6 ± 0.03	0.13 ± 0.015	98.10 ± 0.79	93 ± 0.03	107 ± 0.12	229 ± 0.18
FL3	4.0 ± 0.01	0.14 ± 0.012	99.45 ± 0.63	61 ± 0. 02	68 ± 0.09	100 ± 0.16
FL4	3.8 ± 0.04	0.12 ± 0.014	98.56 ± 0.55	48 ± 0. 02	64 ± 0.02	131 ± 0.15
FL5	3.7 ± 0.03	0.14 ± 0.012	99.23 ± 0.56	5 ± 0.01	17 ± 0.21	236 ± 0.21
FL6	3.9 ± 0.01	0.15 ± 0.012	99.34 ± 0.18	17 ± 0.02	83 ± 0.09	135 ± 0.12
FL7	3.7 ± 0.02	0.14 ± 0.014	99.56 ± 0.57	21 ± 0. 01	45 ± 0.15	173 ± 0.15
FL8	4.0 ± 0.04	0.12 ± 0.013	99.17 ± 0.11	121 ± 0.02	246 ± 0.17	183 ± 0.27

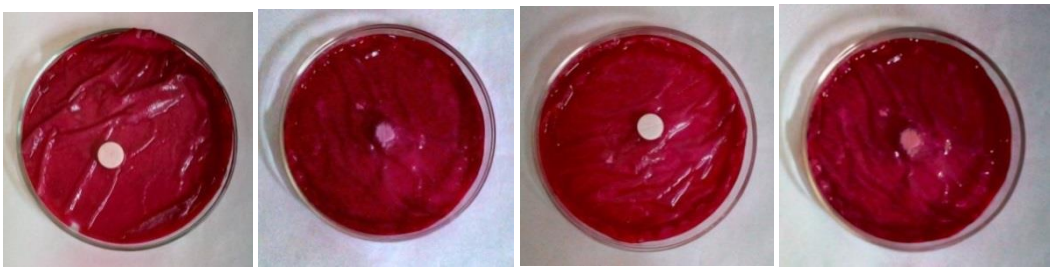
FL1 of aceclofenac fast dissolving tablet **FL2 of aceclofenac fast dissolving tablet**

At Time = 0 sec At Time = 76 sec At Time = 0 sec At Time = 107 sec

FL3 of aceclofenac fast dissolving tablet FL4 of aceclofenac fast dissolving tablet

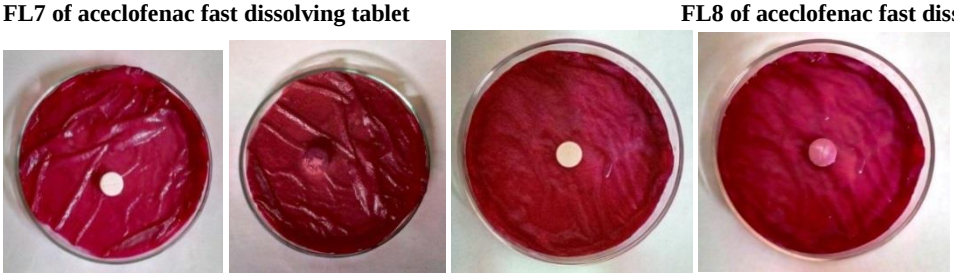
At Time = 0 sec At Time = 68 sec At Time = 0 sec At Time = 64 sec

FL5 of aceclofenac fast dissolving tablet **FL6 of aceclofenac fast dissolving tablet**



At Time = 0 sec At Time = 17 sec **At Time = 0 sec At Time = 83 sec**

FL7 of aceclofenac fast dissolving tablet **FL8 of aceclofenac fast dissolving tablet**



At Time = 0 sec At Time = 45sec **At Time = 0 sec At Time = 246 sec**

Figure 6: Aceclofenac fast dissolving tablets prepared employing starch xanthate involving lactose as a diluent

Table 4: Aceclofenac percent dissolved from dissolving tablets employing starch xanthate prepared by direct compression method involving lactose as a diluent.

Time (mins)	FL1	FL2	FL3	FL4	FL5	FL6	FL7	FL8
5	4.33 ± 0.23	3.98 ± 0.14	18.02 ± 0.12	14.19 ± 0.16	95.43 ± 0.34	8.28 ± 0.45	32.74 ± 0.12	37.78 ± 0.47
10	73.33 ± 0.45	91.55 ± 0.13	49.54 ± 0.29	44.78 ± 0.15	99.28 ± 0.40	15.56 ± 0.39	64.09 ± 0.38	58.77 ± 0.37
15	86.76 ± 0.11	99.89 ± 0.29	98.01 ± 0.45	51.84 ± 0.49	---	27.99 ± 0.19	66.17 ± 0.25	72.33 ± 0.35
30	88.16 ± 0.49	----	---	59.89 ± 0.29	---	28.82 ± 0.37	68.57 ± 0.09	94.32 ± 0.14
45	99.81 ± 0.22	----	---	63.25 ± 0.14	---	40.02 ± 0.45	69.17 ± 0.18	99.16 ± 0.15
60	---	---	---	99.08 ± 0.48	---	49.54 ± 0.38	70.18 ± 0.41	---

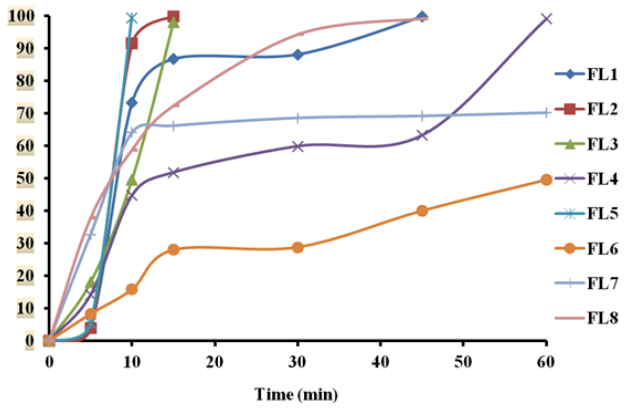


Figure 7: Dissolution profiles of aceclofenac fast dissolving tablets prepared employing starch xanthate involving lactose as a diluent (FL1- FL8).

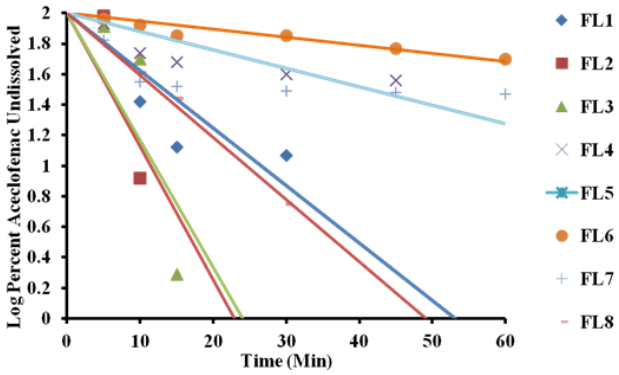


Figure 8: Time vs. log percent drug undissolved plots for aceclofenac fast dissolving tablets prepared employing starch xanthate involving lactose as a diluent (FL1- FL8).

Table 5: Dissolution parameters of aceclofenac fast dissolving tablets formulated employing starch xanthate and other known superdisintegrants prepared by direct compression method involving lactose as a diluent

Time (mins)	FL1	FL2	FL3	FL4	FL5	FL6	FL7	FL8
PD_5	4.33	3.98	18.02	14.19	95.43	8.28	32.74	37.78
$DE_{5\%}$	22.3	27.1	4.1	16.9	36.3	2.4	29.6	14.6
No of folds increase in DE_5%	----	1.21	0.18	0.75	1.17	0.1	1.32	0.65
K_1 (min^{-1})	0.1	0.02	0.07	0.02	0.01	0.01	0.02	0.09

Table 6: ANOVA of dissolution efficiency in 5 min of aceclofenac fast dissolving tablets formulated employing starch xanthate involving lactose as a diluents

Source of Variation	d.f	S.S	M.S.S	Variance ratio	Result
Replicates	2	2.9	1.45	2.36	P>0.05
Treatments	7	2245.76	320.82	524.2	P<0.05
Starch xanthate (5%)	1	7729.27	7729.27	12629.52	P<0.05
Strach xanthate (10%)	1	182.05	182.05	297.46	P<0.05
Starch xanthate (5%) × Sodium starch glycolate (5%)	1	63.05	63.05	103.02	P<0.05
Starch xanthate (10%) × Sodium starch glycolate (5%)	1	103.75	103.75	40.19	P<0.05
Starch xanthate (5%) × Crosscarmellose sodium (5%)	1	2.87	2.87	4.68	P<0.05
Starch xanthate (10%) × Crosscarmellose sodium (5%)	1	1177.4	1177.4	1923.85	P<0.05
Starch xanthate (5%) × Sodium starch glycolate (5%) × Crosscarmellose sodium (5%)	1	63.05	63.05	103.02	P<0.05
Starch xanthate (10%) × Sodium starch glycolate (5%) Crosscarmellose sodium × (5%)	1	247.68	247.68	404.7	P<0.05
Error	14	8.57	0.612	--	--
Total	2	2.9	1.45	2.36	P>0.05
Note: P<0.05 indicate significance; p>0.05 indicate non-significance *d.f– Degree of Freedom * S.S– Sum of Square * M.S.S– Mean Sum of Squares					

CONCLUSION

Starch xanthate is an efficient superdisintegrant for fast dissolving tablets. The disintegration and dissolution efficiency of the fast dissolving tablets of aceclofenac was good and depended on the concentration of superdisintegrant employed i.e., starch xanthate, sodium starch glycolate, crosscarmellose sodium. The formulated fast dissolving tablets of aceclofenac exhibited good dissolution efficiency in 5 min which can be used for the fast therapeutic action of aceclofenac. Overall, Starch xanthate was found to be a superdisintegrant which enhanced the dissolution efficiency when combined with sodium starch glycolate and crosscarmellose sodium, with the aceclofenac and hence it could be used in the formulation of fast dissolving tablets to provide immediate release of the contained drug within 5 minutes.

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