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Research Article

Optimisation of aceclofenac fast dissolving tablets employing starch xanthate using 2³ factorial design

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ABSTRACT

The present study involves in the evaluation of starch xanthate as a superdisintegrant in the formulation of fast dissolving tablets of poorly soluble drugs employing 2³ factorial design. By using gelatinization process starch xanthate was synthesized. Then the synthesized starch xanthate was evaluated under physical and micromeritic methods. To develop starch xanthate as a superdisintegrant, fast dissolving tablet of aceclofenac was prepared by direct compression method employing starch xanthate in different proportions in each case employing 2³ factorial design. All the prepared fast dissolving tablets were evaluated for drug content, hardness, friability, disintegration time and other dissolution characteristics like PD₁₀, DE₅ and K₁. The prepared starch xanthate was found to be fine, free flowing slightly crystalline powder. Starch xanthate shown good swelling in water. The swelling index was 50% and all micromeritic properties shown good flow and compressibility needed for solid dosage from manufacturing. All the formulated fast dissolving tablets 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 croscarmellose sodium, with the aceclofenac and hence it could be utilized in the formulation of fast dissolving tablets to provide immediate release of the contained drug within 10 minutes.

Keywords: Fast Dissolving, Superdisintegrant, Starch xanthate, Dissolution efficiency

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INTRODUCTION

In total dosage forms, Oral routes of drug administration have wide acceptance up to 50-60%. In solid dosage forms, Fast dissolving tablets are containing indicated substances which disintegrate rapidly, usually within few seconds when placed upon tongue requiring additional water to facilitate swallowing. Fast dissolving tablets give 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, like 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 is one of the methods which require the administration of superdisintegrant or highly water soluble excipients into the formulation to achieve fast tablet disintegration. Direct compression does not need the use of water or heat during the formulation procedure and is the ideal method for moisture and heat-labile medication. The goal 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 give 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 various 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 demonstrated.

The current investigation deals with an attempt of systematic formulation approach for optimization of aceclofenac fast dissolving tablets employing starch xanthate, sodium starch glycolate, and croscarmellose sodium as superdisintegrants. A 2³ factorial design was utilized to investigate the main and interaction effects of the three formulation variables i.e., starch xanthate (A), sodium starch glycolate (B), croscarmellose 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 with in 5 min.

MATERIALS AND METHODS

Materials:

Sodium hydroxide, Carbon disulphide, Lactose was purchased from Finar chemicals Ltd, Ahmedabad. Potato starch, Aceclofenac, Sodium starch glycolate, Croscarmellose 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):

At first, the potato starch of 35.4g 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:

The solubility of starch xanthate was evaluated 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 calculated by pH meter.

Melting point:

The melting point was measured by using melting point apparatus.

Viscosity:

The viscosity of 1% dispersion in water was determined using Ostwald viscometer.

Swelling index:

The starch xanthate (200 mg) was administered to 10 ml of water and light liquid paraffin taken in two Different graduated test tubes and mixed. For 12 h, the dispersion in the tubes was allowed to stand. The volumes of the sediment in the tubes were noted. The swelling index of the material was measured as follows.

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

Test for gelling property:

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

Particle size:

The particle size analysis was done by sieving using standard sieves.

Density:

The 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 demonstrated by transferring the accurate weighed amount of sample in 50 ml measuring cylinder, the granules without any agglomerates and calculated 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].

$$LBD = \frac{\text{Mass of powder}}{\text{Volume of packing}}$$

$$TBD = \frac{\text{Mass of powder}}{\text{Tapped volume of packing}}$$

Percentage compressibility index

The percentage compressibility of powder mix was determined by Carr's Compressibility Index calculated by the following formula⁹.

$$\% \text{ Carr's Index} = \frac{(TBD - LBD)}{TBD} \times 100$$

Where, TBD= Tapped bulk density; LBD= Loose bulk density.

Angle of repose

The frictional forces in loose powder or granules can be determined 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 determined by applying the next equation;

$$\tan \theta = \frac{h}{r} \quad \theta = \tan^{-1} \frac{h}{r}$$

Where θ = angle of repose; h = height of pile; r = radius of pile.

Fourier Transform Infrared (FTIR) Spectroscopy:

The FTIR spectra of starch xanthate 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:

The 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 30mA; time constant 10mm/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):

The 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:

The 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:

By direct compression method, the tablets were prepared employing 2³ factorial design in which 3 independent variables {superdisintegrants i.e., starch xanthate (A), sodium starch glycolate (B), croscarmellose sodium (C)} and 1 dependent variable (dissolution efficiency in 5 min) were selected. In Table 1, the composition of different formulation of aceclofenac fast dissolving tablets is shown in which superdisintegrants were selected at 2 levels i.e., lower and higher. For starch xanthate (A), the lower level i.e., 5% concentration and upper level i.e., 10% concentration. For sodium starch glycolate (B) and croscarmellose sodium (C), the lower level is 0 concentration and higher level i.e., 5% concentration. For uniformity in particle size each ingredient was flown through # 100 mesh sized screen before mixing. Starch xanthate, sodium starch glycolate, croscarmellose sodium, lactose and microcrystalline cellulose were accurately weighed mixed using mortar and pestle, and then aceclofenac was added. Finally, talc and magnesium stearate were administered to the powder mixture. Then the, 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
Croscarmellose 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 calculated using Monsanto hardness tester and expressed in kg/cm² ¹⁰.

Uniformity of weight:

Weight variation test was performed 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 friabilator. Tablets were rotated at 25 rpm for 4 minutes or up to 100 revolutions. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated.

$$F = \frac{100 \times W(\text{initial}) - W(\text{final})}{W(\text{initial})}$$

Drug content uniformity:

For content uniformity, ten tablets were weighed and powdered a quantity of powder equivalent to 10mg of

aceclofenac, which was extracted into 7.4 phosphate buffer and filtered. The aceclofenac content was calculated by measuring the absorbance spectrophotometrically at 274 nm after appropriate dilution with 7.4 phosphate buffer. The drug content was determined as an average of three determinations ¹¹.

Wetting time:

The wetting time of tablets was calculated 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 recorded 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 ratio R was determined using following equation.

$$R = \frac{100(W_x - W_y)}{W_y}$$

Where,

W_x = weight of tablet after water absorption.

W_y = 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 $37 \pm 0.2^\circ\text{C}$. The time in second taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was calculated 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 $37 \pm 0.5^\circ\text{C}$, 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 micromeritic 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 micromeritic 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 Fig: 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 (Fig: 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. Where as 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 $^\circ$
Compressibility index	32.5%

Figure 1: Fourier transform infrared spectra of potato starch.

Figure 2: Fourier transform infrared spectra of starch xanthate

Figure 3: X-Ray diffraction pattern of starch xanthate

The X-ray diffraction pattern of starch xanthate showed 3 characteristic 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 Figs.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.

Figure 4: FTIR spectra of aceclofenac

Figure 5: FTIR Spectra of aceclofenac with starch xanthate

Evaluation of tablets

Hardness

Hardness of the tablet was in the range of 3.6 ± 0.02 kg/cm² to 4.0 ± 0.05 kg/cm². It indicates good strength with a capability to resist physical and pre functional stress conditions during handling.

Friability

All the tablets exhibited acceptable friability as none of the tested batches showed percentage friability that exceeded 1%. As per IP, percent friability below 1% is an indication of good mechanical resistance of the tablets. Percent friability of all batches found in the range of 0.11%-0.15 %. Thus, it was resulted that tablets could withstand the pressure, mechanical shocks during handling, transportation, storage and manufacturing processes.

Drug content

Drug content of all the formulation batches was found to be between 97.58 ± 0.71 to 99.56 ± 0.57 . Hence, it can be concluded that all the formulations are having an accurate amount of drug distributed uniformly in powder mass and followed acceptable limits as per IP [14]. i.e. 85 to 110 % of average content table 3.

Disintegration studies

In vitro disintegration time was done by the USP dissolution apparatus. The disintegration rate has a correlation with water absorption capacity of disintegrate and The *In vitro* disintegration time was found between 12 ± 0.02 to 76 ± 0.02 s. The outcomes were tabulated and data demonstrated in table 3. It was found that the formulation FL5 will show least disintegration time 12s as compare to other formulation. The order for a disintegration time in fast dissolving tablet was found to be FL5<FL8<FL6<FL7<FL4<FL3<FL1<FL2. The order of disintegration time may be due to the interaction and main effects of the super disintegrants used in the fast dissolving tablets.

Water absorption ratio and wetting time

The water absorption ratio was in between 29 ± 0.18 - 183 ± 0.27 . The wetting time found between 57 ± 0.21 - 246 ± 0.15 . The outcomes were tabulated and data demonstrated in table 3 and Fig. 6 and 6a. It was found that the formulation FL5 containing 5 % starch Xanthate, 5% and 5 % croscarmellose sodium showed less wetting time i.e. 57 ± 0.21 s as compared to other formulations.

In vitro dissolution studies

Dissolution rate depends on the wetting time of the disintegrant, among all the formulations FL5 has less wetting time and has greater dissolution rate and then this is the other conformance test for correct selection of desirable. *In*

vitro dissolution studies of all the formulation were done and depicted in fig. 7 and 7a. Log Percent drug undissolved studies of all the formulation were done and depicted in fig. 8 and 8a. In all formulations FL5 formulation was selected as the promising formulation containing 5 % starch xanthate, and 5 % croscarmellose sodium with 99.28% release in 10 min which may be due to the interaction effect between the two super disintegrants i.e., starch xanthate, and croscarmellose sodium at a concentration of 5 % each. 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 PD₁₀ (percent dissolved in 10 minute) was more in FL₅ which consists at 5 % starch xanthate, and 5 % croscarmellose sodium. The same was in the case of DE₅ % (dissolution efficiency in 10 min). The PD₁₀ & DE₅ % reveals that starch xanthate was effective at 5%, along with 5 % croscarmellose sodium when the formulations were made by direct compression using these superdisintegrants. From the results, it was concluded that starch xanthate (new super disintegrant) could be used as a super disintegrant in the formulation of fast dissolving tablets of aceclofenac. 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 2³-factorial design. ANOVA of fast disintegrating times (Table 6) indicated that the individual effects of starch xanthate (A), sodium starch glycolate (B) and croscarmellose 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. ANOVA of dissolution efficiency in 10 min (Table 6) indicated that the individual effects as well as combined effects of the three factors (i.e., starch xanthate, sodium starch glycolate and croscarmellose sodium) were all significant ($p < 0.05$). The ANOVA results thus indicated that the three factors have significantly influence on the disintegration time and dissolution efficiency in 5 min.

Fast dissolving tablets formulated employing starch xanthate (5%) and croscarmellose sodium (5%) as superdisintegrants exhibited in disintegration and dissolution efficiency in 10 min. Formulation 5 gave release of 99.28% in 10 min fulfilling the official specification, based on disintegration time and dissolution efficiency in 10 min. Formulation FL5 is considered as a good fast dissolving tablet formulations of aceclofenac which was found to better than the aceclofenac fast dissolving tablets formulated by Manohara P et al ¹⁵.

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) $\pm$ S.D	Friability (%) $\pm$ S.D	Drug Content mg/tab) $\pm$ S.D	Disintegration Time (sec) $\pm$ S.D	Water Absorption Ratio (%) $\pm$ S.D
FL1	3.9 $\pm$ 0.01	0.12 $\pm$ 0.013	97.58 $\pm$ 0.71	76 $\pm$ 0.02	50 $\pm$ 0.12
FL2	3.6 $\pm$ 0.02	0.13 $\pm$ 0.015	98.10 $\pm$ 0.79	93 $\pm$ 0.03	29 $\pm$ 0.18
FL3	4.0 $\pm$ 0.01	0.14 $\pm$ 0.012	99.45 $\pm$ 0.63	61 $\pm$ 0.02	100 $\pm$ 0.16
FL4	3.8 $\pm$ 0.04	0.12 $\pm$ 0.014	98.56 $\pm$ 0.55	48 $\pm$ 0.02	131 $\pm$ 0.15
FL5	3.7 $\pm$ 0.03	0.14 $\pm$ 0.012	99.56 $\pm$ 0.56	12 $\pm$ 0.01	183 $\pm$ 0.21
FL6	3.9 $\pm$ 0.01	0.15 $\pm$ 0.012	99.34 $\pm$ 0.18	17 $\pm$ 0.02	135 $\pm$ 0.12
FL7	3.7 $\pm$ 0.02	0.14 $\pm$ 0.014	99.23 $\pm$ 0.57	21 $\pm$ 0.01	173 $\pm$ 0.15
FL8	4.0 $\pm$ 0.05	0.12 $\pm$ 0.013	99.17 $\pm$ 0.11	15 $\pm$ 0.02	176 $\pm$ 0.27

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

FL-5 of Aceclofenac fast dissolving tablets

At Time = 0 sec

At Time = 45 sec

FL-6 of Aceclofenac fast dissolving tablet

At Time = 0 sec

At Time = 83 sec

FL-7 of Aceclofenac fast dissolving tablets

At Time = 0 sec

At Time = 246 sec

FL-8 of Aceclofenac fast dissolving tablet

At Time = 0 sec

At Time = 57 sec

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

Figure 7: Dissolution profiles of aceclofenac fast dissolving tablets prepared employing starch xanthate involving lactose as a diluent (FL1- FL4)

Figure 7a: Dissolution profiles of aceclofenac fast dissolving tablets prepared employing starch xanthate involving lactose as a diluent (FL5- 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- FL4)

Figure 8a: Time Vs Log Percent drug undissolved plots for aceclofenac fast dissolving tablets prepared employing starch xanthate involving lactose as a diluent (FL5- 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)	FL-1	FL-2	FL-3	FL-4	FL-5	FL-6	FL-7	FL-8
PD ₁₀	73.33	91.55	49.54	44.78	99.28	15.56	64.09	58.77
DE ₅ %	18.1	25.2	20.7	16.4	48.6	7.8	17.4	21.8
No of folds increase in DE ₅ %	----	1.39	1.14	0.90	2.68	0.43	0.96	1.20
K ₁ (min ⁻¹)	0.10	0.02	0.07	0.02	0.01	0.01	0.02	0.09

Table 6: ANOVA of dissolution efficiency in 10 min of aceclofenac fast dissolving tablets formulated employing starch xanthate involving lactose as a diluent

Source of Variation	d.f	S.S	M.S.S	Variance ratio	Result
Replicates	2	2.90	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
Starch xanthate (10%)	1	182.05	182.05	297.46	P < 0.05
Starch xanthate (5%) X Sodium starch glycolate (5%)	1	63.05	63.05	103.02	P < 0.05
Starch xanthate (10%) X Sodium starch glycolate (5%)	1	103.75	103.75	40.19	P < 0.05
Starch xanthate (5%) X Croscarmellose sodium (5%)	1	2.87	2.87	4.68	P < 0.05
Starch xanthate (10%) X Croscarmellose sodium (5%)	1	1177.40	1177.40	1923.85	P < 0.05
Starch xanthate (5%) X Sodium starch glycolate (5%) X Croscarmellose sodium (5%)	1	63.05	63.05	103.02	P < 0.05
Starch xanthate (10%) X Sodium starch glycolate (5%) X Croscarmellose sodium (5%)	1	247.68	247.68	404.70	P < 0.05
Error	14	2.90	1.45	2.36	P > 0.05
Total	23	2245.76	320.82	524.2	P < 0.05

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, croscarmellose sodium. The formulated fast dissolving tablets of aceclofenac exhibited good dissolution efficiency in 10 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 croscarmellose 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 10 minutes.

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

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