

## SYNTHESIS, CHARACTERIZATION AND EVALUATION OF STARCH XANTHATE AS A SUPERDISINTEGRANT IN THE FORMULATION OF FAST DISSOLVING TABLETS

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### ABSTRACT

**Objective:** To synthesize, characterize and evaluate starch xanthate as a superdisintegrant in the formulation of fast dissolving tablets by employing 2<sup>3</sup> factorial design.

**Methods:** Starch xanthate was synthesized by gelatinization process. The physical and micromeritic properties were performed to evaluate the synthesized starch xanthate. The fast dissolving tablet of ibuprofen was prepared by employing starch xanthate as a superdisintegrant in different proportions in each case by direct compression method using 2<sup>3</sup> factorial design. The drug content, hardness, friability, disintegration time and other dissolution characteristics like percent dissolved in 5 min (PD<sub>5</sub>), dissolution efficiency in 5 min (DE<sub>5</sub>%) and first order rate constant (K<sub>1</sub>) were used in the evaluation of prepared fast dissolving tablets.

**Results:** The starch xanthate prepared was found to be fine, free flowing slightly crystalline powder. Starch xanthate exhibited good swelling in water. The study between ibuprofen and starch xanthate was shown the absence of interaction by fourier transform infrared spectra (FTIR) and differential scanning calorimetry (DSC). The drug content (100±5%), hardness (3.6–4 kg/sq. cm), and friability (0.12-0.15%) has been effective with regard to all the formulated fast dissolving tablets employing starch xanthate. The disintegration time of all the formulated tablets was found to be in the range of 12±0.01 to 312±0.02s. The optimized formulation F5 has the least disintegration time i.e., 12±0.01s. The *In vitro* wetting time of the formulated tablets was found to be in the range of 76±0.21 to 217±0.17s. The *In vitro* wetting time was less (i.e., 90s) in optimized formulation F5. The water absorption ratio of the formulated tablets was found to be in the range of 16±0.16 to 174±0.21%. The cumulative drug dissolved in the optimized formulation F5 was found to be 99.83±0.56% in 5 min.

**Conclusion:** The dissolution efficiency of ibuprofen was enhanced when starch xanthate was found to be a superdisintegrant when combined with sodium starch glycolate, croscarmellose sodium and, hence it could be used in the formulation of fast dissolving tablets to provide immediate release of the contained drug within 5 min.

**Keywords:** Fast dissolving, Superdisintegrant, Starch xanthate, Dissolution efficiency

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### INTRODUCTION

Under the category of solid dosage forms, the fast dissolving tablets are containing indicated substances which disintegrate rapidly, usually within a few seconds when placed upon tongue requiring additional water to facilitate swallowing. Fast dissolving tablets contribute immense advantages for the patients having difficulty in swallowing. It has been reported that dysphasia (difficulty in swallowing) is usual among all groups and more specific with pediatric, geriatric population along with patients have nausea, retching, and motion sickness complications [1]. Fast dissolving tablets overcome this problem and provide the advantages for pediatrics, geriatric [2], bedridden, disabled patients and also for who may have difficulty in swallowing tablets, capsules, and liquid orals. Fast dissolving tablets (FDT) will disintegrate rapidly in the mouth without the need of water [3-4]. Fast dissolving tablet formulation provides sufficient strength, quick disintegration/dissolution in the mouth without water [5], 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 [6]. Various techniques can be used to formulate fast dissolving tablets. To achieve fast tablet disintegration, direct compression is one of the techniques used in the incorporation of superdisintegrant or highly water-soluble excipients into the formulation. Direct compression is the ideal method for moisture and heat-labile medication and does not require the use of water or heat during the formulation procedure. The aim of the work was to formulate and characterize fast-dissolving tablets of ibuprofen by utilizing optimization techniques for rapid dissolution of drug and absorption employing a new superdisintegrant i.e., starch xanthate.

The selection of several experimental and manufacturing steps for a given product and to quantitatively select a formulation,

optimization techniques are used which provide both depth of understanding and an ability to explore and define ranges for formulation and processing factors. 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 an approach for optimization of ibuprofen fast dissolving tablets employing starch xanthate, sodium starch glycolate, croscarmellose sodium as superdisintegrants. A 2<sup>3</sup> factorial design was applied 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 within 5 min.

### MATERIALS AND METHODS

#### Materials

Sodium hydroxide, Carbon disulphide, Mannitol was purchased from Finar chemicals Ltd, Ahmedabad. Potato starch, Ibuprofen, 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)

Initially, 35.4 parts of potato starch were slurried in 225 ml distilled water and 8 parts of sodium hydroxide was dissolved in distilled water. Both are stirred continuously for 30 min. To this 5 parts of carbon, disulphide was added and stirred for 16 h at 25 °C. After 16

h, it was filtered and washed with 75 ml of distilled water, 500 ml of acetone and 100 ml of ether. The product was kept in oven at 60 °C for 2 h. The product obtained was ground and sieved.

#### Characterization of starch xanthate

The starch xanthate prepared was evaluated for the following

##### Solubility

Starch xanthate solubility was tested in various solvents like distilled water, aqueous buffers of pH 1,2,3,4,6 and organic solvents such as alcohol, dichloromethane, chloroform, acetone and petroleum ether [6].

##### pH

The pH of 1% w/v slurry was measured by pH meter [6].

##### Melting point

Melting point was determined by using melting point apparatus [6].

##### Viscosity

Viscosity of 1% dispersion in water was measured using Ostwald viscometer [6].

##### 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 ( $S.I$ ) of the material was calculated as follows [6].

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

##### Test for gelling property

Starch and starch xanthate prepared were evaluated for their gelling property by heating a 7% w/v dispersion of each in water at 100 °C for 30 min [6].

##### Particle size

Particle size analysis was done by sieving using standard sieves [7].

##### Density

Density (g/cc) was determined by liquid displacement method using benzene as liquid [7].

##### 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 [7].

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

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

##### Percentage compressibility index

Percentage compressibility of the powder mix was determined by Carr's Compressibility Index calculated by the following formula [8].

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

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

##### Angle of repose

The frictional forces in loose powder or granules can be 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. The angle of repose is calculated by applying the next equation [8];

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

Where  $\theta$ =angle of repose; h=height; r=radius

##### Fourier transform infrared (FTIR) spectroscopy

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

##### 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( $\lambda$ 1.54 Å), 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 [8].

##### Drug-exciptent compatibility studies

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

##### Differential scanning calorimetry (DSC)

DSC thermograms of ibuprofen and their mixtures (1: 1) with starch xanthate were recorded on Perkin Elmer thermal analyser samples (2-5 mg) were sealed into aluminum pans and scanned at a heating rate of 10 °C  $\text{min}^{-1}$  over a temperature range 30-350 °C [8].

##### Infrared spectroscopy

Fourier transform infrared (FTIR) spectra of ibuprofen, and their mixtures (1: 1) with starch xanthate were recorded on a Perkin Elmer, IR Spectrophotometer model: Spectrum RXI, using KBr disc as a reference [8].

##### Preparation of ibuprofen fast dissolving tablets

The tablets were prepared by direct compression method employing 2<sup>3</sup> 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. The composition of the different formulation of ibuprofen fast dissolving tablets is shown in table no 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 croscarmellose 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, croscarmellose sodium, mannitol and microcrystalline cellulose were accurately weighed and mixed using mortar and pestle, and the added to ibuprofen. Finally, talc and magnesium stearate were added to the powder mixture. Finally, the mixed blend was compressed by using eight station rotator press Karnawathi Machinerics Pvt, Ltd., Ahmedabad, India).

##### Evaluation of ibuprofen 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  $\text{kg/cm}^2$  [9].

###### Uniformity of weight

Weight variation test was done with 20 tablets. It is the individual variation of the tablet weighed from the average weight of 20 tablets [10].

**Table 1: Formulae of ibuprofen fast dissolving tablets employing starch xanthate prepared by direct compression method involving mannitol as a diluent**

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Ibuprofen	100	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	---
Mannitol	155	130	130	105	130	105	105	80	180
Micro crystalline cellulose	200	200	200	200	200	200	200	200	200
Talc	10	10	10	10	10	10	10	10	10
Magnesium stearate	10	10	10	10	10	10	10	10	10
Total	500	500	500	500	500	500	500	500	500

**Friability**

The friability of tablets was measured using a Roche friabilator. Tablets were rotated at 25 rpm for 4 min or up to 100 revolutions. The tablets were then reweighed after removal of fines and the percentage of weight loss was calculated [10].

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

**Drug content uniformity**

For content uniformity, ten tablets were weighed and powdered a quantity of powder equivalent to 10 mg of ibuprofen was extracted into 7.2 phosphate buffer and filtered. The ibuprofen content was determined by measuring the absorbance spectrophotometrically at 221 nm after appropriate dilution with 7.2 phosphate buffer. The drug content was calculated as an average of three determinations [10].

**Wetting time**

The wetting time of tablets was measured by placing five circular tissue papers in a petri dish of 10 cm in 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. The time required for water to reach the upper surface of the tablet was noted as wetting time [11, 12].

**Water absorption ratio**

A piece of tissue paper folded was kept in a small petri dish to which 6 ml of water was added. A tablet was kept on the tissue paper and allowed to completely wet. The wetted tablet was then weighed. Water absorption ratio R was determined using the following equation [11, 12].

$$R = \frac{100(W_1 - W_2)}{W_2}$$

Where,

$W_1$  = weight of tablet after water absorption.

$W_2$  = 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 the temperature was  $37 \pm 0.2$  °C. The time taken for complete disintegration of the tablet was measured [13].

**In-vitro dissolution studies**

The *in vitro* dissolution rate study of ibuprofen fast dissolving tablets were performed using 8 stage dissolution test apparatus (Electrolab TDT-08L) fitted with paddles (50 rpm) at  $37 \pm 0.5$  °C, using 7.2 phosphate buffer (900 ml) as a dissolution media. At the predetermined time intervals, 5 ml samples were withdrawn, filtered through a  $0.45 \mu$  membrane filter, diluted and assayed at 221 nm using an 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 ( $n = 3$ ) [13].

**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 found to be  $6.194 \pm 0.001$ .

Starch xanthate exhibited good swelling in water. The swelling index was found to be  $50 \pm 0.003\%$  indicating that it is suitable for superdisintegrant. All micromeritic properties indicated good flow properties needed manufacturing of tablets. The density of starch xanthate was found to be  $0.9848 \pm 0.0004$  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  $1634.10 \text{ cm}^{-1}$  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. 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)	$6.194 \pm 0.001$
Melting point ( °C)	$218 \pm 0.002$
Viscosity(1% w/v aqueous dispersion) (cps)	$1.016 \pm 0.005$
Swelling index (%)	$50 \pm 0.003$
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 (µm)	$80 \pm 0.06$
Density (g/cc)	$0.9848 \pm 0.0004$
Bulk density (g/cc)	$0.625 \pm 0.007$
Angle of repose ( °)	$12.4 \pm 0.07$
Compressibility index (%)	$32.5 \pm 0.07$

\*SD standard deviation from mean,  $n=3$

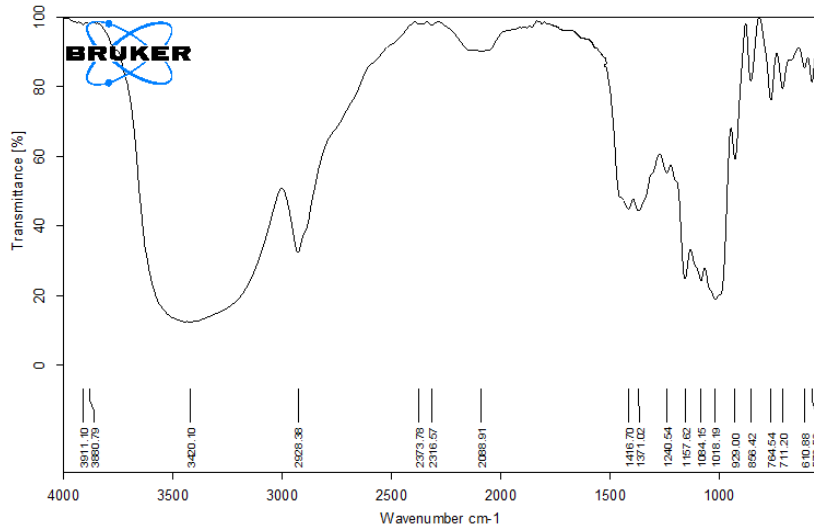


Fig. 1: Fourier transform infrared spectra of potato starch

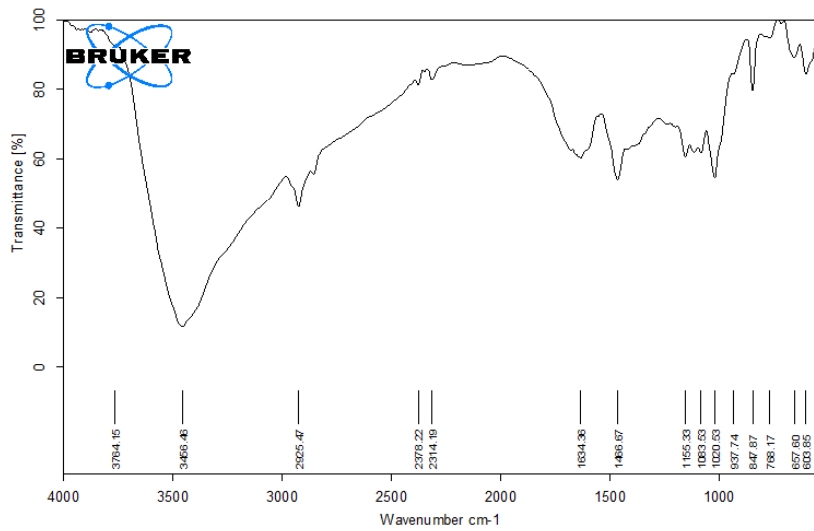


Fig. 2: Fourier transform infrared spectra of starch xanthate

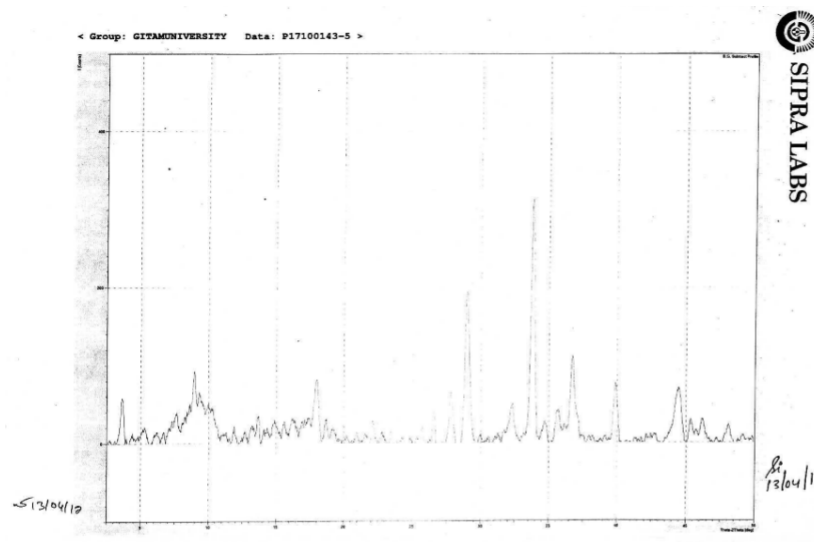


Fig. 3: X-ray diffraction pattern of starch xanthate

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 (Ibuprofen) was evaluated by DSC, FTIR studies. The DSC thermograms of ibuprofen and ibuprofen–starch xanthate are shown in fig. 4 and 5. The DSC thermograms of ibuprofen and ibuprofen–starch xanthate exhibited exothermic peaks at 83.34 °C and 63.13 °C respectively. These melting peaks of ibuprofen and ibuprofen–starch xanthate are nearer to the melting points of ibuprofen (75-78 °C). The peaks observed in the DSC thermograms of ibuprofen and ibuprofen–starch xanthate mixtures correspond to the melting points of the respective drug indicating no interactions between the selected drug and starch xanthate polymer. The DSC

study indicated no interaction between starch xanthate and the selected drug.

The FTIR spectra of ibuprofen and ibuprofen–starch xanthate are shown in fig. 6 and 7. The characteristic FTIR bands of ibuprofen at 1718.78  $\text{cm}^{-1}$  (COOH), and ibuprofen–starch xanthate at 1716.17  $\text{cm}^{-1}$  (COOH) were all observed in the FTIR spectra of both ibuprofen and ibuprofen–starch xanthate. These FTIR spectra observations also indicated no interaction between starch xanthate and the drug selected.

Thus, the results of DSC and 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.

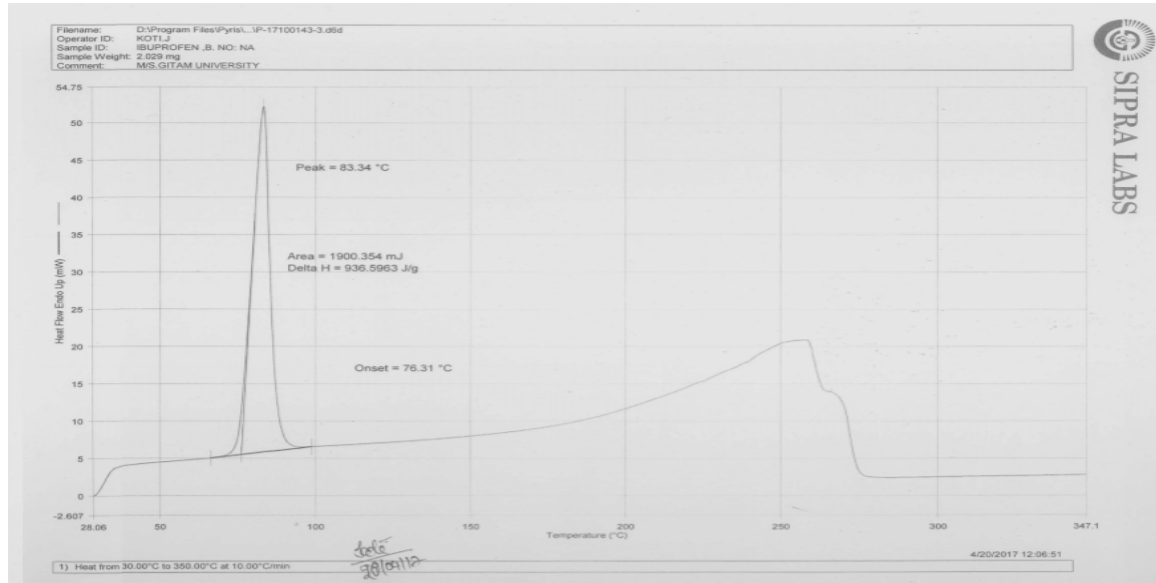


Fig. 4: DSC thermo gram of ibuprofen pure drug

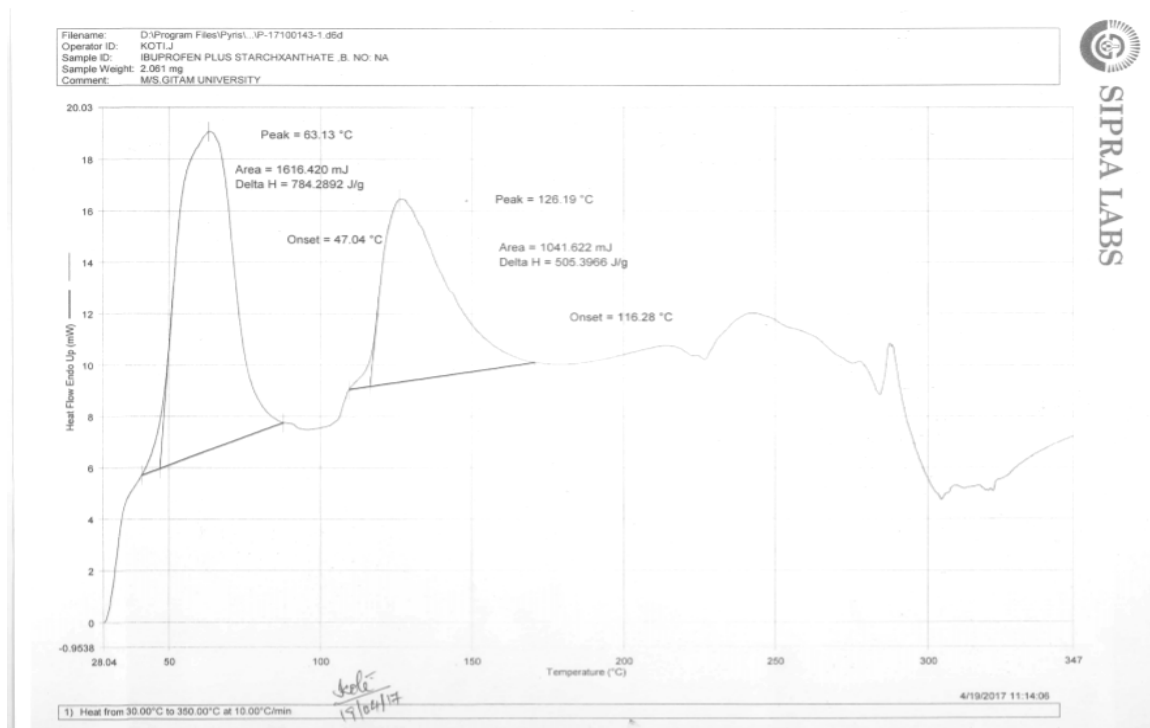


Fig. 5: DSC thermo gram of ibuprofen with starch xanthate

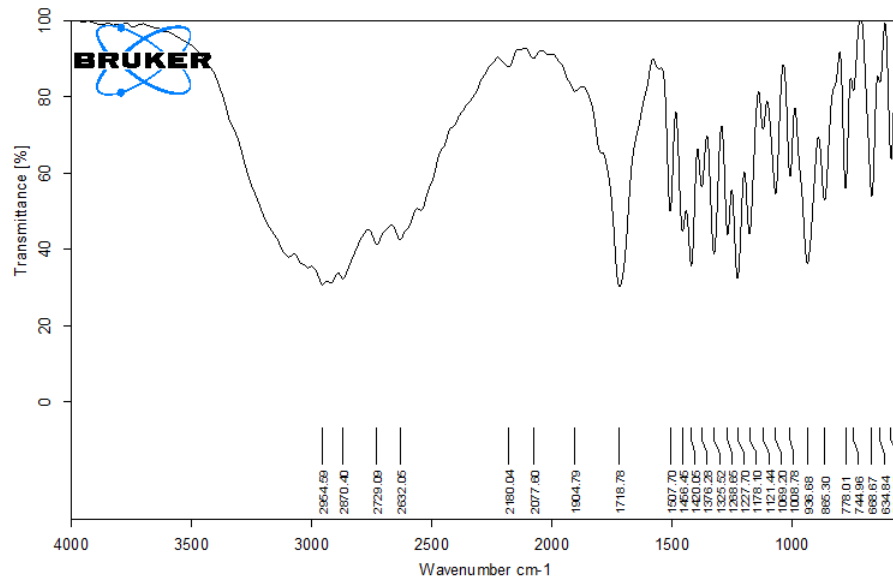


Fig. 6: FTIR spectra of ibuprofen

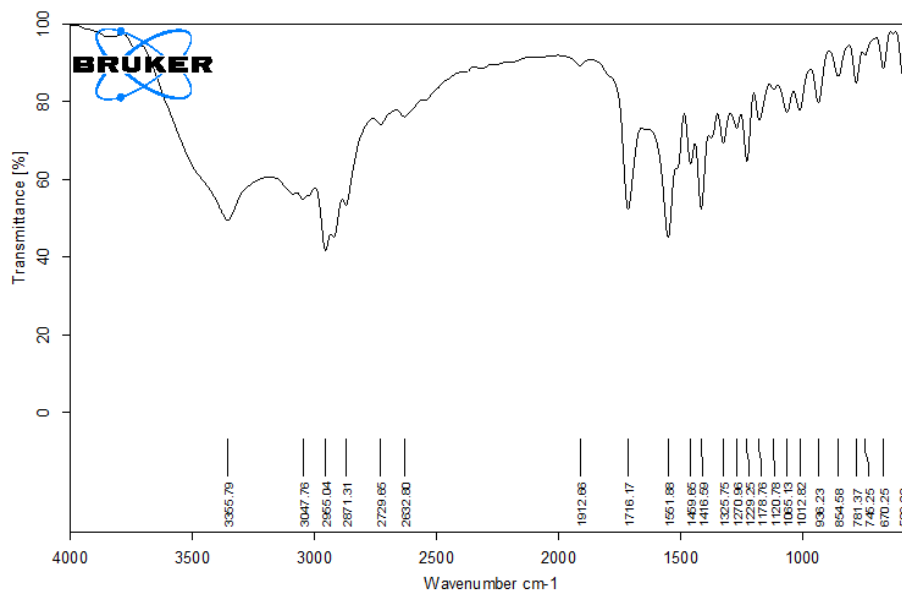


Fig. 7: FTIR spectra of ibuprofen with starch xanthate

### Evaluation of tablets

#### Hardness

The hardness of tablets from all batches was found to be in the range of  $3.6 \pm 0.03$  kg/cm<sup>2</sup> to  $4 \pm 0.01$  kg/cm<sup>2</sup>. All tablets were found hard enough so that they could easily withstand the handling and storage conditions without getting broken.

#### Friability

All the tablets exhibited acceptable friability as none of the tested batches showed percentage friability that exceeded 1%. The percent friability of all batches found in the range of 0.12%-0.15% indicating good mechanical resistance of tablets. Thus, it was proved 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  $97.34 \pm 0.71$  to  $99.83 \pm 0.56$ . 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 115 % 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  $12 \pm 0.02$  to  $312 \pm 0.02$ s. The outcomes were tabulated and data demonstrated in table 3. All the formulation showed disintegration time of less than 180s. It was found that the formulation F5 will show least disintegration time 12s as compare to other formulation. The order for a disintegration time in the fast dissolving tablet was found to be  $F5 < F6 < F7 < F8 < F3 < F4 < F2 < F1 < F9$ . 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 founded from  $16 \pm 0.16$  to  $174 \pm 0.21$ s. This increased behavior due to the water taking the ability of super disintegrants. The wetting time found between  $76 \pm 0.21$  to  $217 \pm 0.17$ s.



The outcomes were tabulated and data demonstrated in table 3 and fig. 8, 8a and 8b. It was found that the formulation F5 containing 5 % starch xanthate and 5 % croscarmellose sodium showed less wetting time i.e.  $76 \pm 0.21$ s as compared to other formulations.

#### In vitro dissolution studies

Dissolution rate depends on the wetting time of the disintegrant, among all the formulations F5 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. 9. In all formulations F5 formulation was selected as the promising formulation containing 5 % starch xanthate and 5 % croscarmellose sodium with 99.84% release in 5 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 (F1–F9) which were made by direct compression method were shown in the table: 4. In all these cases the PD<sub>5</sub> (percent dissolved in 5 min) was more in F5 which consists at 5% starch xanthate, and 5% croscarmellose sodium. The same was in the case of DE<sub>5</sub>% (dissolution efficiency in 5 min). The PD<sub>5</sub> and DE<sub>5</sub>% reveals that starch xanthate was effective at 5% along with 5% croscarmellose sodium when the formulations were made by direct compression using these superdisintegrants. The K<sub>1</sub> decreased in all the formulation when compared to F9

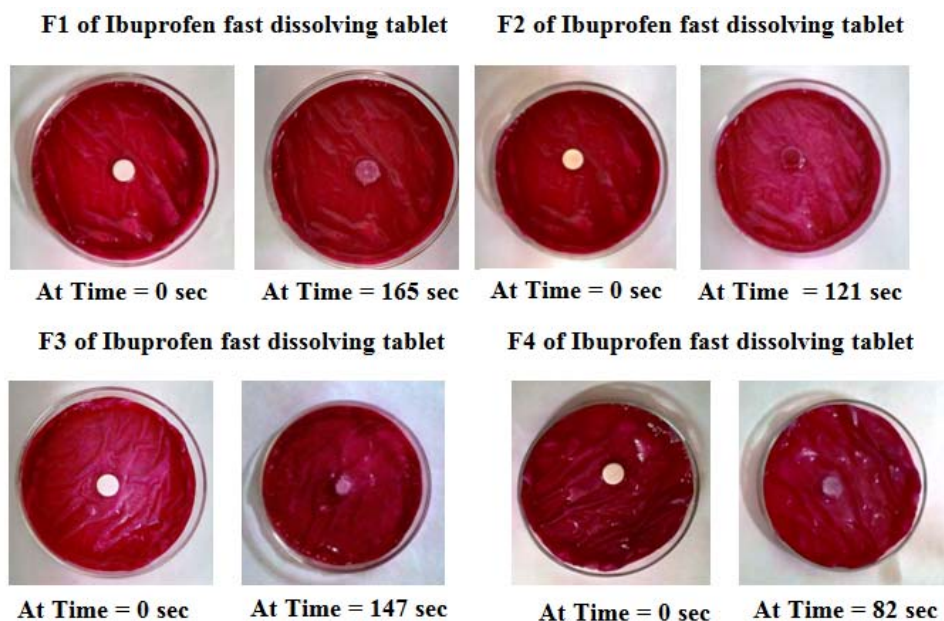
formulation which was given in table 4. The number of folds increases in DE<sub>5</sub>% and number of folds increase in K<sub>1</sub> (min<sup>-1</sup>) were given to the table 4. From the results, it was concluded that starch xanthate (new super disintegrant) could be used as a super disintegrant in the formulation of fast dissolving tablets of ibuprofen. 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<sup>3</sup>-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<sup>3</sup>-factorial design. ANOVA of fast disintegrating times (table 5) 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 (P<0.05) on disintegration time and dissolution efficiency in 5 min of ibuprofen fast dissolving tablets.

Fast dissolving tablets formulated employing starch xanthate (5%), sodium starch glycolate (5%) and croscarmellose sodium (5%) as super disintegrants exhibited in disintegration and dissolution efficiency in 5 min. Formulation F5 gave release of 99.84% in 5 min fulfilling the official specification, based on disintegration time and dissolution efficiency in 5 min. Formulation F5 is considered as a good fast dissolving tablet formulations of ibuprofen which was found to better than the ibuprofen fast dissolving tablets formulated by Purkayastha *et al.* [15].

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

Formulation	Hardness kg/cm <sup>2</sup> n±SD	Friability (%) n±SD	Drug content mg/tab n±SD	Disintegration time (sec) n±SD	Water absorption ratio (%) n±SD
F1	3.9±0.01	0.12±0.013	97.58±0.71	219±0.02	133±0.12
F2	3.6±0.03	0.13±0.015	98.1±0.79	213±0.03	127±0.18
F3	4.0±0.01	0.14±0.012	99.45±0.63	58±0.02	16±0.16
F4	3.8±0.04	0.12±0.014	98.56±0.55	91±0.02	97±0.15
F5	3.7±0.03	0.14±0.012	99.83±0.56	12±0.01	174±0.21
F6	3.9±0.01	0.15±0.012	99.34±0.18	14±0.02	141±0.12
F7	3.7±0.02	0.14±0.014	99.56±0.57	19±0.01	91±0.15
F8	4.0±0.04	0.12±0.013	99.17±0.11	27±0.02	98±0.27
F9	3.6±0.03	0.12±0.013	97.34±0.71	312±0.02	74±0.12

\*SD standard deviation from mean, n=3, mean±SD.



**Fig. 8: Wetting time of ibuprofen fast dissolving tablets prepared employing starch xanthate involving mannitol as a diluents**

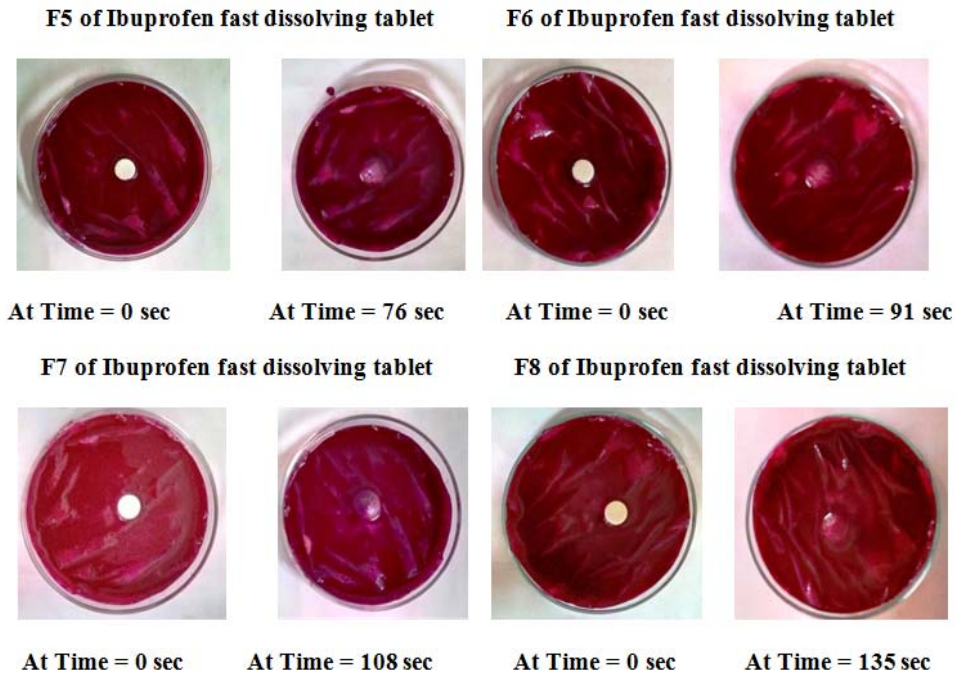


Fig. 8a: Wetting time of ibuprofen fast dissolving tablets prepared employing starch xanthate involving mannitol as a diluents

**F9 of Ibuprofen fast dissolving tablet**

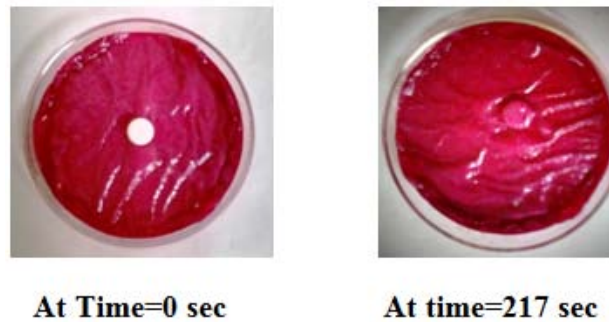


Fig. 8b: Wetting time of ibuprofen fast dissolving tablets prepared employing starch xanthate involving mannitol as a diluents

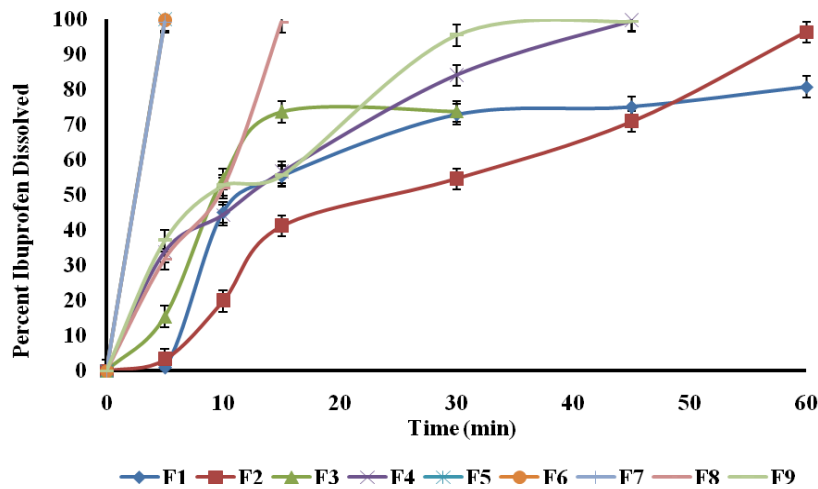


Fig. 9: Dissolution profiles of ibuprofen fast dissolving tablets prepared employing starch xanthate involving mannitol as a diluent (F1-F9) (n=3, mean±SD)



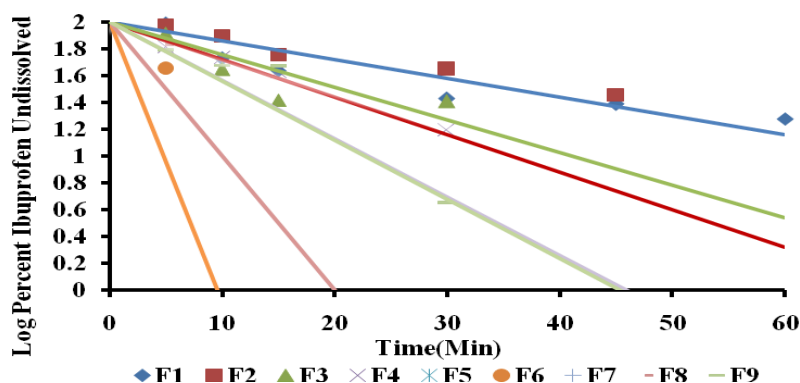


Fig. 10: Time Vs Log percent drug undissolved plots for ibuprofen fast dissolving tablets prepared employing starch xanthate involving mannitol as a diluent (F1-F9) (n=3, mean±SD)

Table 4: Dissolution parameters of ibuprofen fast dissolving tablets formulated employing starch xanthate and other known superdisintegrants prepared by direct compression involving mannitol as a diluent

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
PD <sub>5</sub>	0.93±0.11	3.16±0.63	15.41±0.51	33.85±0.47	99.84±0.19	53.53±0.23	99.17±0.46	31.76±0.28	36.98±0.31
DE <sub>5</sub> %	8.3±0.22	5.9±0.15	12.8±0.32	14.4±0.45	48.6±0.59	48.6±0.59	48.6±0.59	11.3±0.43	3.7±0.19
No of folds increase in DE <sub>5</sub> %	0.60	0.43	0.93	1.05	3.54	3.54	3.54	0.82	-
K <sub>1</sub> (min <sup>-1</sup> )	0.01±0.002	0.02±0.004	0.04±0.007	0.05±0.007	-	0.10±0.008	-	0.07±0.003	0.16±0.009

\*SD standard deviation from mean, n=3, mean±SD, PD<sub>5</sub>-Percent dissolved in 5 min., DE<sub>5</sub>%-Dissolution efficiency in 5 min., K<sub>1</sub> =First order rate constant

Table 5: ANOVA of dissolution efficiency in 5 min of ibuprofen fast dissolving tablets formulated employing starch xanthate involving mannitol as a diluent

Source of variation	d. f.	S. S.	M. S. S.	Variance ratio	Result
Replicates	2	1.73	0.86	01.34	P > 0.05
Treatments	7	8407.59	1201.08	1876.68	P < 0.05
Starch xanthate (5%)	1	14865.30	14865.30	23227.03	P < 0.05
Starch xanthate (10%)	1	559.70	559.70	874.53	P < 0.05
Starch xanthate (5%) X Sodium starch glycolate (5%)	1	219.01	219.01	342.20	P < 0.05
Starch xanthate (10%) X Sodium starch glycolate (5%)	1	434.35	434.35	678.67	P < 0.05
Starch xanthate (5%) X Croscarmellose sodium (5%)	1	5095.42	5095.42	7961.59	P < 0.05
Starch xanthate (10%) X Croscarmellose sodium (5%)	1	506.92	506.92	792.06	P < 0.05
Starch xanthate (5%) X Sodium starch glycolate (5%) X Croscarmellose sodium (5%)	1	923.80	923.80	1443.43	P < 0.05
Starch xanthate (10%) X Sodium starch glycolate (5%) X Croscarmellose sodium (5%)	1	654.17	654.17	1022.145	P < 0.05
Error	14	9.09	0.64	--	--
Total	23	--	--	--	--

\*SD Standard Deviation from mean, n=3, 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, ANOVA= Analysis of Variance

## CONCLUSION

Starch xanthate is an efficient superdisintegrant for fast dissolving tablets. The disintegration and dissolution efficiency of the fast dissolving tablets of ibuprofen was good and depended on the concentration of superdisintegrant employed i.e., starch xanthate (5%), and croscarmellose sodium (5%). The formulated fast dissolving tablets of ibuprofen employing starch xanthate and croscarmellose sodium exhibited good dissolution efficiency in 5 min which can be used for the fast therapeutic action of ibuprofen.

Overall, Starch xanthate was found to be a super-disintegrant when combined with croscarmellose sodium, the dissolution efficiency of ibuprofen was enhanced and hence it could be used in the formulation of fast dissolving tablets to provide immediate release of the contained drug within 5 min.

## ABBREVIATION

FTIR-Fourier transform infrared spectra, DSC-Differential scanning calorimetry, ANOVA-Analysis of variance

## AUTHORS CONTRIBUTIONS

All the author have contributed equally

## CONFLICT OF INTERESTS

Declared none

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