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Original Article

DESIGN, OPTIMIZATION AND EVALUATION OF IBUPROFEN FAST DISSOLVING TABLETS EMPLOYING STARCH PHTHALATE-A NOVEL SUPERDISINTEGRANT

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ABSTRACT

Objective: The objective of the present research was to prepare starch phthalate (a novel super disintegrant) and to optimize and formulate ibuprofen fast dissolving tablets employing 2^3factorial design using starch phthalate as super disintegrant.

Methods: Drug excipient compatibility studies like Fourier-transform infrared spectroscopy (FTIR) and thin-layer chromatography (TLC) studies were carried out to check the drug interaction between ibuprofen and starch phthalate. Direct compression method was used for tablet preparation. Prepared tablets were then evaluated for hardness, friability, drug content, disintegration time, water absorption and wetting time, *in vitro* dissolution studies. Response surface plots and contour plots were also plotted to know the main effects and interaction effects of independent variables (starch phthalate (A), croscarmellose sodium (B) and crospovidone (C)) on dependent variables (disintegration time and drug dissolution efficiency in 1 minute) and stability studies were also done.

Results: Tablets of all formulations were of good quality concerning drug content (100±5%), hardness (3-6 kg/cm2), and friability (less than 0.16%). In all formulations, formulation F5 found to be optimized formulation with least disintegration time 20±0.28 seconds, less wetting time 09±0.12 seconds and enhanced dissolution rate in one minute, i.e., 91.95±0.22 as compared to other formulation.

Conclusion: From the research, it was concluded that on combination with crospovidone, starch phthalate enhanced the dissolution efficiency of the drug. Hence, starch phthalate can be used as a novel disintegrant in the manufacturing of fast dissolving tablets.

Keywords: Fast dissolving, Paediatrics, Geriatric, Superdisintegrant, Starch phthalate, Ibuprofen

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INTRODUCTION

Fast dissolving tablets are new emerged solid dosage forms over conventional tablets having advantages of both solid and liquid dosage systems. It offers convenience in tablet manufacturing, more accurate dosing than the liquid dosage forms [1]. These tablets dissolve fast as it comes in contact with saliva and hence providing the ease of administration which results in patient's compliance for pediatrics, geriatrics, dysphasic, psychic, and bed-ridden, unconscious population [2, 3]. To formulate a fast-dissolving tablet with sufficient hardness that can withstand the pressure handling during transport with the ability to disintegrate quickly as soon it comes in contact with saliva is a challenge [4]. The direct compression method is most preferred method for the preparation of mouth dissolving tablets as it does not involve heat, no requirement of water, less number of processing steps, low cost and thus it is suitable for heat-sensitive drugs [5]. In the direct compression method, super disintegrants were added to achieve quick disintegration with enhanced dissolution (within 5 min). Super-disintegrants are the agents which help in rapid disintegration of tablets when they used in low concentration [6].

In market many superdisintegrants are available and still, there is research going on to find the novel super disintegrant with all the characteristics of super disintegrant for the fast-dissolving tablets. The objective of this present research was the preparation and evaluation of ibuprofen fast dissolving tablets employing starch phthalate as super disintegrant. Starch phthalate was prepared by esterification process by using potato starch and phthalic anhydride. By using 2^3 factorial designs, fast dissolving tablets of ibuprofen were optimized prepared by employing starch phthalate as super disintegrant. Stability studies are conducted to find out the stability of optimized formulation using the novel super disintegrant.

MATERIALS AND METHODS

Materials

Ibuprofen, crospovidone, crosscarmellose sodium, starch and potato starch were purchased from Yarrow chemicals, Mumbai. Phthalic anhydride, dimethyl sulphoxide, acetone and isopropanol were obtained from Finar chemicals Ltd, Ahmedabad. Ethanol was bought from Changshu yangyun chemicals, china. Microcrystalline cellulose was procured from Qualigens fine chemicals, Mumbai. Magnesium stearate and Talc was purchased from Molychem, Mumbai.

Preparation of a novel super disintegrant starch phthalate

Initially 3 parts of phthalic anhydride were dissolved in 2 parts of dimethyl sulphoxide (DMSO). Then, pH of the solution was adjusted to pH 3.5 using 10M sodium hydroxide (NaOH) and finally made up to 50 ml. To this 5 parts of potato starch was added and conditioned for 16 h. After conditioning the dispersion was kept it in an oven at 60 ° C for one hour. Then, the product was mixed with acetone for 15 min and then washed with isopropanol to remove any unwanted phthalic anhydride if present. After washing the resultant product (starch phthalate) was kept in an oven at 60 °C until it gets dried. The product obtained was ground and sieved (# 120).

Characterization of starch phthalate

The starch phthalate prepared was evaluated for the following

Solubility

The solubility of starch phthalate was tested in water, an aqueous buffer of pH 1.2, 4.5, 7.4 and organic solvents like petroleum ether, alcohol, acetone, dichloromethane, chloroform.

pH

By pH meter, pH of 1% w/v slurry was checked.

Viscosity

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

Melting point

The melting point was checked by melting point apparatus.

Swelling index

Starch phthalate (200 mg) was added to two different graduated test tubes containing 10 ml of water and light liquid paraffin and mixed. In the tubes, the dispersion was allowed to stand for 24 h. The sediment volume in the tubes was noted after 24 h. The swelling index of the material was determined as follows [7].

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

Test for gelling property

The gelling property of the starch and starch phthalate was evaluated by heating 7% w/v dispersion of each, in distilled water at 1000 °C for 30 min.

Particle size

By optical microscopy, particle size was determined.

Density

By using benzene as a liquid, the density (g/cc) was measured by liquid displacement process.

Bulk density

For calculation of loose bulk density (LBD) and tapped bulk density (TBD) in 50 ml measuring cylinder accurately weighed the amount of samples was transferred and tapped 50 times on a plane surface. Tapped volume of packing was recorded. LBD and TBD measured by the following formula [8].

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

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

Percentage compressibility index

Carr's compressibility index calculated by the given following formula to check the Percentage compressibility of powder mix.

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

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

Angle of repose

The angle of repose is determined to check the frictional forces in loose powder or granules and calculated by the given equation [9]

$$\tan \theta = \frac{h}{r}$$

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

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

Fourier transform infrared (FTIR) spectroscopy

Fourier transform infrared spectroscopy (FTIR) spectra of starch phthalate were recorded on samples prepared in potassium bromide (KBr) disks using a BRUKER FT–IR, (Tokyo, Japan). Potassium bromide (KBr) disks of samples were prepared at 6-8 tons hydrostatic press and analyzed sample between scanning range 500 to 4000 cm-1.

Drug–Excipients compatibility studies

The compatibility of starch phthalate with the selected drug (ibuprofen) was evaluated in Fourier transform infrared spectroscopy (FTIR) and thin-layer chromatography (TLC) studies.

Fourier transform infrared (FTIR) spectroscopy

Fourier transforms infrared spectroscopy (FTIR) spectra of ibuprofen and their mixtures (1: 1) with starch phthalate were recorded by IR Spectrophotometer (Perkin Elmer model) using Potassium bromide (KBr) disc as a reference.

Thin-layer chromatography (TLC) study

Stationary Phase: Silica gel H (pre-coated TLC plates).

Mobile Phase: n-Hexane: Ethyl Acetate: Glacial Acetic Acid (75:25:5)

Procedure

The mobile phase was prepared and taken in a thin layer chromatography (TLC) chamber. The chamber was allowed to saturate with solvent vapor for 24 h. Standard (pure drug) and test (drug–starch phthalate mixtures) sample were spotted on activated silica plates using narrow capillary tubes. The spotted plates were kept in the thin layer chromatography (TLC) chamber and allowed to run the mobile phase. The plates were dried and kept in Iodine chamber to develop the spots. The retardation factor (Rf) values of standard and test samples were determined by the following formula.

Retardation factor (Rf) = Distance travelled by sample/Distance travelled by solvent front.

Preparation of fast dissolving tablets of ibuprofen

By direct compression method fast dissolving tablets of ibuprofen was prepared by employing 2^3 factorial designs in which super disintegrants i.e., starch phthalate(A), croscarmellose sodium (B), crospovidone (C) are selected as three independent variables and dissolution efficiency in 1 minute as the dependent variable. The composition of different formulation of ibuprofen fast dissolving tablets is given in table no 1. For particle size uniformity each ingredient was flown through #100 mesh sized screen before mixing. Starch phthalate, crospovidone, microcrystalline cellulose, croscarmellose sodium, starch were accurately weighed mixed using mortar and pestle, and then ibuprofen was added. At last to the powder mix talc and magnesium stearate were added. Finally, the mixed blend was compressed by using eight-station rotor press Karnawathi Machineries Pvt, Ltd., Ahmedabad, India).

Table 1: Formulae of ibuprofen fast dissolving tablets employing starch phthalate prepared by direct compression method

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8
Ibuprofen	200	200	200	200	200	200	200	200
Starch phthalate	25	50	25	50	25	50	25	50
Croscarmellose sodium	---	---	25	25	---	---	25	25
Crospovidone	---	---	---	---	25	25	25	25
Starch	50	50	50	50	50	50	50	50
Micro crystalline cellulose	205	180	180	155	180	155	155	155
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 ibuprofen fast dissolving tablets

Hardness test

By using Monsanto hardness tester hardness of tablets was determined and unit for the hardness is kg/cm^2 [10].

Uniformity of weight

Twenty tablets were selected for the weight variation test. It is the individual variation of a tablet weight from the average weight of 20 tablets [11].

Friability

By using Roche friabilator, friability of all tablets was determined. At 25 rpm, tablets were rotated for 4 min or up to 100 revolutions. Tablets were weighed again after the removal of fine dust from the tablet surface, and weight loss percentage was calculated by the given formula [12]

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

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 pH 7.2 phosphate buffer and filtered. The ibuprofen content was determined by measuring the absorbance using the spectrophotometric method at 221 nm after appropriate dilution with pH 7.2 phosphate buffer. The drug content was measured as an average of three determinations [13].

Wetting time and water absorption ratio

In a Petri dish of 10 cm diameter, five pieces of circular tissue paper were placed. Ten ml of water containing a water-soluble dye (amaranth) was added to the Petri dish. Carefully keep the one tablet in between the tissue paper and the time taken to reach the upper surface of the tablet was noted as wetting time.

Water absorption ratio

Fold the tissue paper twice as per the diameter of the Petri dish and 6 ml of water was added to the Petri dish. A tablet was kept on the tissue paper and allowed to wet completely and weighed the wetted tablet. Water absorption ratio is calculated by using the given Equation [14].

$$R = \frac{100(W_d - W_e)}{W_e}$$

Where,

W_d = Tablet weight after water absorption.

W_e = Tablet weight before water absorption.

***In-vitro* disintegration time**

Disintegration time for FDTs was determined using USP disintegration apparatus pH 7.2 phosphate buffer. The volume of medium was 900 ml and the temperature was 37±0.2 °C. The time in seconds taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was determined [15].

***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±0.5 °C, using pH 7.2 phosphate buffer (900 ml) as a dissolution media. At the predetermined time intervals, 5 ml samples were withdrawn, filtered through 0.45µ membrane filter, diluted and assayed at 221 nm using an Analytical technology T360 UV/Visible Double beam spectrophotometer. All the dissolution experiments were conducted in triplicate (n = 3).

Response surface plot study

Optimization of the ibuprofen fast dissolving tablets was done using 2^3 factorial designs in which 3 factors each at two levels were evaluated. To evaluate the individual and combined effects of starch phthalate (factor A), croscarmellose sodium (factor B) and crospovidone (factor C), response surface plot method was conducted.

A polynomial regression algorithm was used to rotate the independent variables to the response variables. The general first-order model and equation they could be constructed from 2^n experimental design is indicated in the following equation.

$$Y = \beta_0+\beta_1A+\beta_2B+\beta_2C+\beta_1\beta_2AB+\beta_1\beta_3AC+\beta_2\beta_3BC+\beta_1\beta_2\beta_3ABC$$

where y is the measured response, β_0 is the arithmetic mean response of 1 min, β_1, β_2, β_3, $\beta_1\beta_2$, $\beta1\beta_3$, $\beta_2\beta_3$, $\beta_1\beta_2\beta_3$ are coefficients for the corresponding factors and A, B, C, AB, AC, BC, and ABC are the percentages of starch phthalate, croscarmellose sodium and crospovidone and interaction terms respectively. The coefficients were calculated accordingly to the general formula given in equation.

$$B = \Sigma XY/2^n$$

Where β is coefficient, X is the corresponding variable (A, B, C) and Y is the response value (dissolution efficiency in 1 minute), n is the level. The two levels of three factors employed in the experimental design are indicated in table 2 and transformed design for analysis of responses of ibuprofen fast dissolving tablets is shown in table 3.

Table 2: Levels of the three factors used in experimental design

S. No.	Factors/Ingredients	Code	Level L1	L2
1	Starch phthalate	A	5	10
2	Croscarmellose sodium	B	0	5
3	Crospovidone	C	0	5

Table 3: Transformed design for analysis of response of ibuprofen fast dissolving tablets

S. No.	Formula code	A (%)	B (%)	C (%)
1	F1	5	0	0
2	F2	10	0	0
3	F3	5	5	0
4	F4	10	5	0
5	F5	5	0	5
6	F6	10	0	5
7	F7	5	5	5
8	F8	10	5	5

Stability studies

As per ICH stability guidelines, stability studies were performed to check the changes in the quality of a drug substance or drug product with time with respect to various environmental factors like temperature, humidity and light stability. Stability studies of F5 formulation were carried out. The tablets were packed in screw-capped HDPE bottles and were stored at 40 °C±2 °C and 75% RH for 6 mo. After storage for 6 mo, the products were tested for drug content and drug release rate.

RESULTS AND DISCUSSION

The starch phthalate prepared was found to be fine, smooth, free-flowing amorphous powder. The physical and micropolitics properties of the starch phthalate are summarized in table 4.

Table 4: Physical and micropolitics properties of the starch phthalate prepared

Parameters	Observation
Solubility	Insoluble in all aqueous and organic solvents tested
pH(1% w/v aqueous dispersion)	2.88%
Melting Point	Charred at 325 °C
Viscosity(1% w/v aqueous dispersion)	1.08cps
Swelling index	65%
Gelling property	No gelling and the swollen particles of starch phthalate separated from water. Whereas in the case of starch, it was gelatinized and formed gel.
Moisture absorption	4.4%
Particle Size	158 µm (80/120 mesh)
Density	0.584 g/cc
Bulk Density	0.555 g/cc
Angle of Repose	27.47 °
Compressibility Index	14.23%

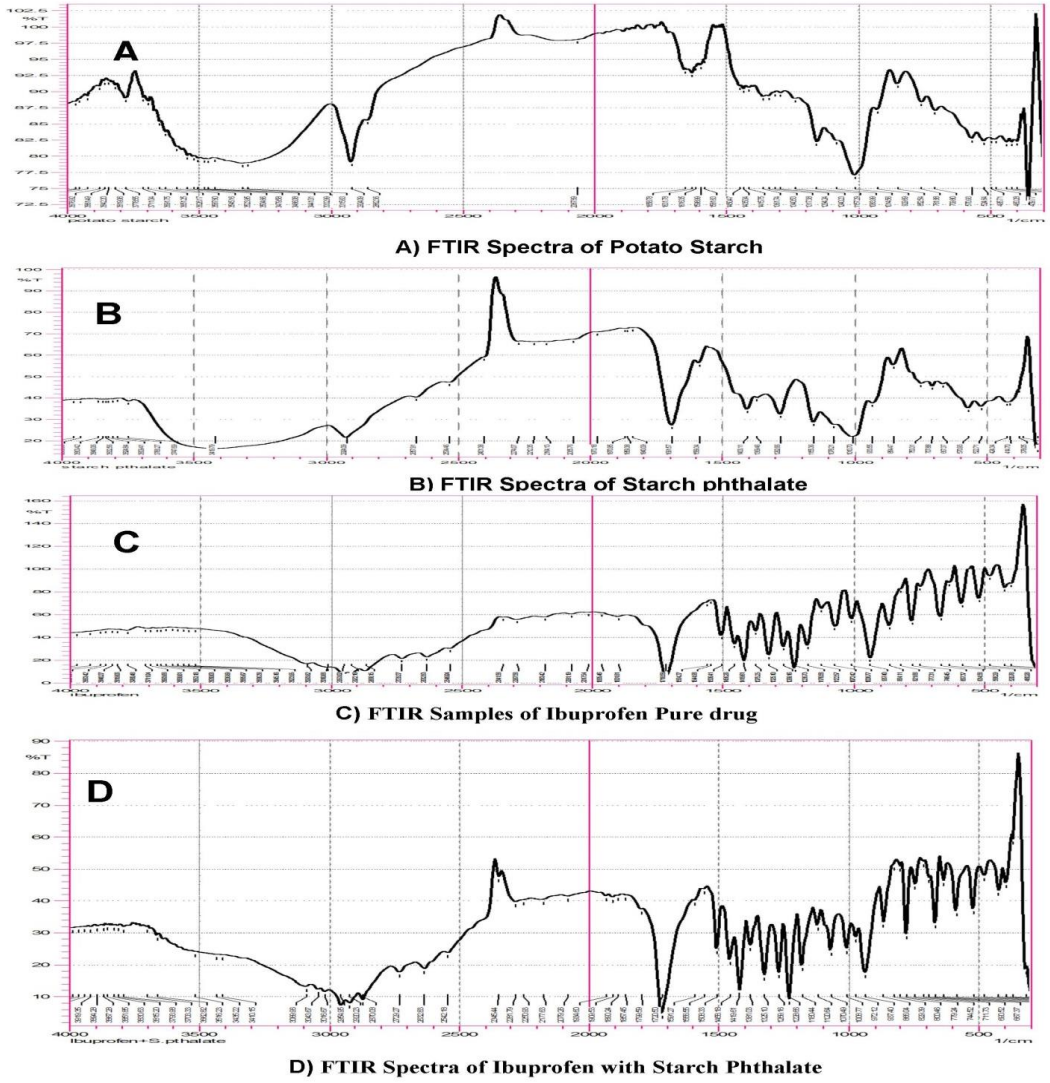


Fig. 1: Fourier transform infrared spectra (FTIR) of (A Potato starch) (B starch phthalate) (C Ibuprofen) (D Ibuprofen and starch phthalate)

The Fourier-transform infrared spectroscopy (FTIR) spectrum of starch and starch phthalate is shown in fig. 1(A and B). The presence of peaks of absorption at 1691.57 cm^{-1} characteristic peaks of ester, so from Fourier-transform infrared spectroscopy (FTIR) studies it was concluded that starch phthalate (ester) was formed when starch was allowed to react with phthalic anhydride. The disappearance of pink colour in the ester test confirmed the presence of ester, i.e., starch phthalate. As the starch phthalate was amorphous, smooth, free-flowing powder and it had got all the characteristic of super disintegrants it was concluded that starch phthalate can be used as novel super disintegrant in the formulation of fast dissolving tablets.

The compatibility of starch phthalate with the selected drug (ibuprofen) was evaluated by Fourier-transform infrared spectroscopy (FTIR) and thin-layer chromatography (TLC) studies.

The FTIR spectra of ibuprofen and ibuprofen–starch phthalate are shown in fig. 1(C and D respectively). The characteristic Fourier-transform infrared spectroscopy (FTIR) band of Ibuprofen at 1718.58 cm^{-1} (-COOH) was observed in the Fourier-transform infrared spectroscopy (FTIR) spectra of both ibuprofen and ibuprofen–starch phthalate. These Fourier-transform infrared spectroscopy (FTIR) spectral observations also indicated no interaction between starch phthalate and drug selected.

In thin-layer chromatography (TLC) plate of ibuprofen and ibuprofen-starch, single spots were observed in the case of pure drug as well as their mixtures with starch phthalate. The close agreement of the retardation factor (Rf) values of the drug (0.76) and its mixture with starch phthalate (0.68) indicated no interaction between the drug and starch phthalate.

The hardness of tablets from all batches was found to be in the range of 3-6 kg/cm^2. All the tablets exhibited acceptable friability as weight loss on the friability test was less than 0.16% in all formulations. Drug content of all the formulation batches was found to be within 100±5% of the labeled amount.

The *in-vitro* disintegration time and water absorption ratio of all the formulations (F1-F8) are given in table 5. Formulation F8 containing 10 % starch phthalate, 5% crospovidone and 5 % croscarmellose sodium showed less wetting time i.e. 05±0.09s as compared to other formulations. *In vitro* dissolution test was carried out in United States Pharmacopeia (USP) type II paddle apparatus and dissolution profile of formulations F1-F4 is shown in fig. 2 (A) and F5-F8 is shown in fig. 2 (B). Percent dissolved in 1 minute ($PD_{1)}$ was found to be more in F5 formulation which consists of 5% starch phthalate, 0% croscarmellose sodium and 5% crospovidone. The same was in the case of dissolution efficiency in 1 min (DE_1%). The Percent dissolved in 1 minute ($PD_{1)}$ and dissolution efficiency in 1 min (DE_1%) reveals that starch phthalate was effective at 5% starch Phthalate, 0% croscarmellose sodium and 5% crospovidone when the formulations were made by direct compression using these super disintegrants given in table 6.

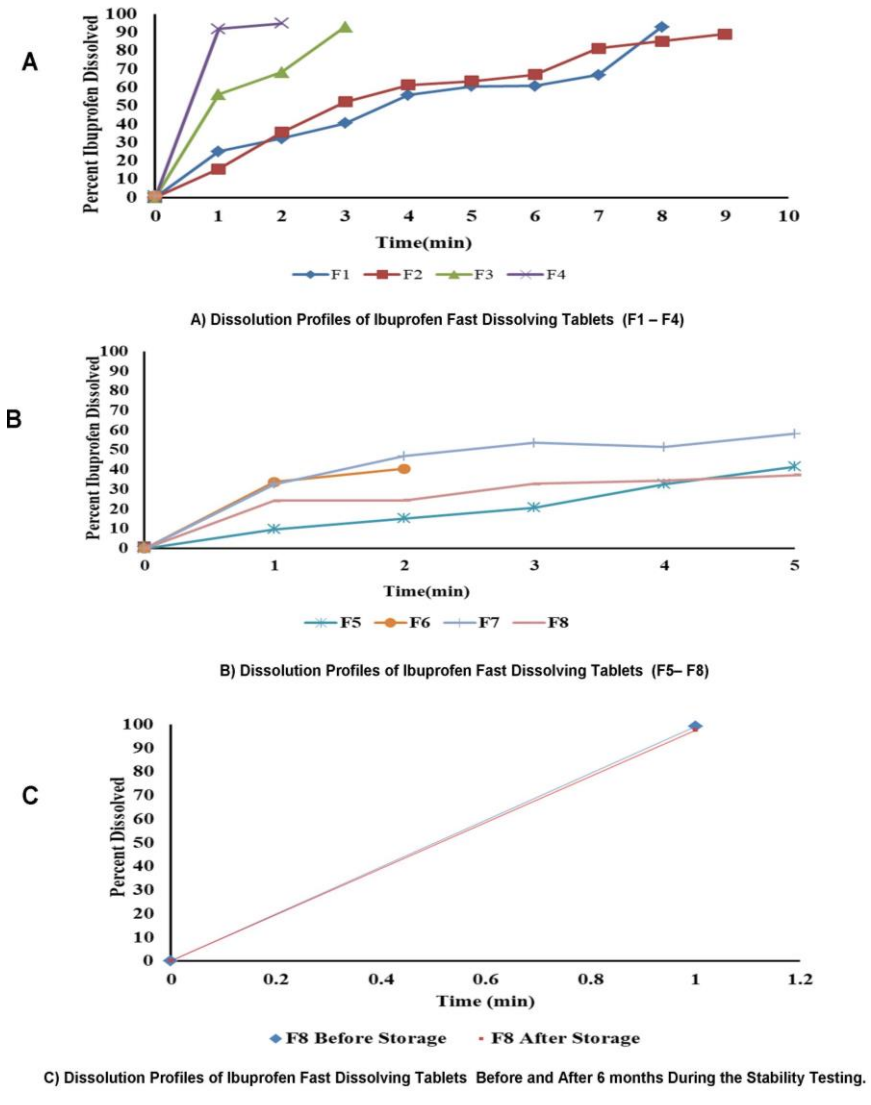


Fig. 2: Dissolution profiles of Ibuprofen fast dissolving tablets employing starch phthalate A) of formulations F1-F4 B) of formulations F5-F8 C) of formulation F5 before and after stability testing

Table 5: Physical properties: hardness, friability, drug content of ibuprofen fast dissolving tablets prepared by direct compression method

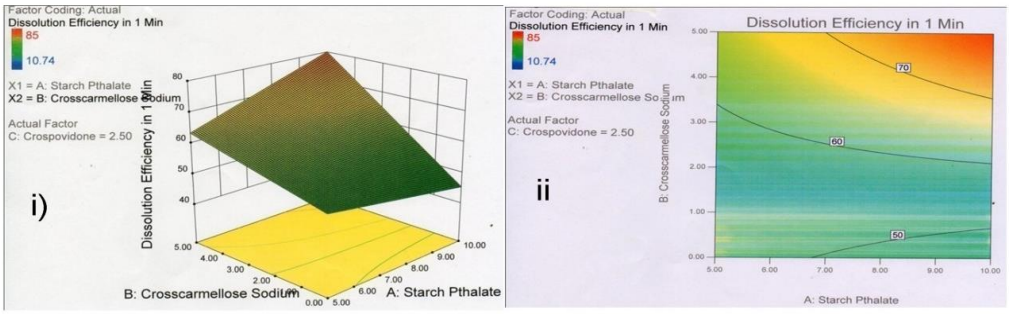
Formulation	Hardness (Kg/Cm^2) n±SD	Friability (%) n±SD	Drug content (mg/tab) n±SD	Disintegration time (sec) n±SD	Wetting time (sec) n±SD	Water absorption ratio (%) n±SD
F1	3.9±0.01	0.12±0.013	198±0.71	45±0.24	17±0.11	50.0±0.15
F2	3.6±0.03	0.13±0.015	199±0.79	27±0.29	16±0.15	54.5±0.19
F3	4.0±0.01	0.14±0.012	198±0.63	24±0.15	16±0.25	56.3±0.11
F4	3.8±0.04	0.12±0.014	198±0.55	38±0.11	22±0.07	51.9±0.23
F5	3.7±0.03	0.14±0.014	199±0.56	20±0.28	09±0.12	54.7±0.25
F6	3.9±0.01	0.15±0.012	198±0.18	14±0.12	08±0.18	57.8±0.18
F7	3.7±0.02	0.14±0.014	198±0.57	12±0.09	07±0.23	60.6±0.13
F8	4.0±0.04	0.12±0.013	198±0.11	09±0.13	05±0.09	60.9±0.22

*SD Standard Deviation from mean, n=3

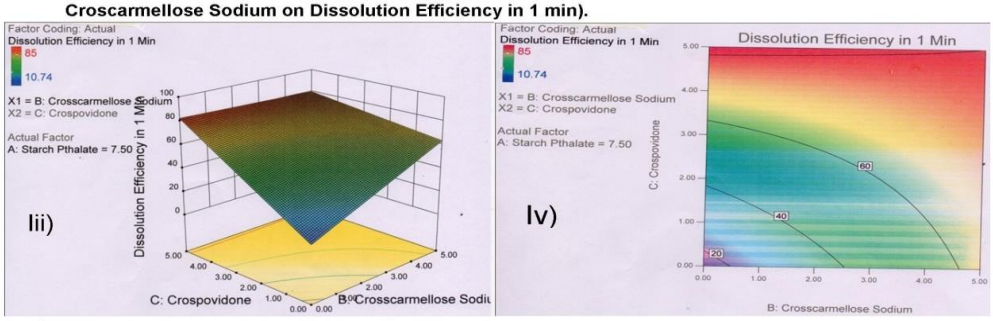
Table 6: Dissolution parameters of ibuprofen fast dissolving tablets formulated employing starch phthalate

Parameters	F1	F2	F3	F4	F5	F6	F7	F8
PD_1	25.04±0.09	15.55±0.11	56.25±0.10	91.95±0.08	91.95±0.10	88.04±0.07	90.97±0.12	81.19±0.07
DE_1 (%)	20±0.07	10.74±0.14	42.19±0.14	85±0.11	85.0±0.11	80±0.10	84.9±0.11	75±0.11
K (min^{-1})	0.18±0.08	0.24 1±0.08	0.573±0.07	2.97±0.13	2.52±0.08	0.99±0.09	2.40±0.08	0.60±0.14

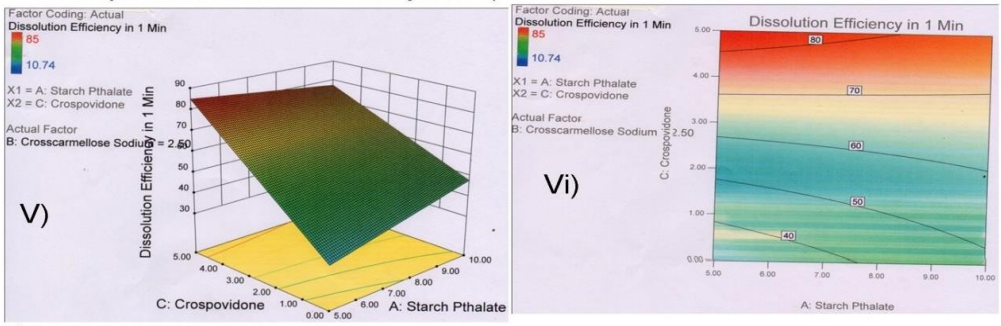
*SD standard deviation from mean, n=3, PD1--percent dissolved in 1 min., DE1%-dissolution efficiency in 1 min., K1 =first order rate constant



(A) Response Plot (B) Contour Plot of Ibuprofen Fast Dissolving Tablets (Effect of Starch Phthalate and Croscarmellose Sodium on Dissolution Efficiency in 1 min).



(C) Response Plot (D) Contour Plot of Ibuprofen Fast Dissolving Tablets (Effect of Croscarmellose Sodium and crospovidone on Dissolution Efficiency in 1 min).



(E) Response Plot (F) Contour Plot of Ibuprofen Fast Dissolving Tablets (Effect of Starch phthalate and crospovidone on Dissolution Efficiency in 1 min).

Fig. 3: Response plot and contour plot of ibuprofen fast dissolving tablets employing starch phthalate showing the effect of starch phthalate, croscarmellose sodium and crospovidone on dissolution efficiency in 1 min

The response surface plot and the contour plot reveal that as a concentration of A (starch phthalate), B (croscarmellose sodium), C (crospovidone) increases dissolution efficiency in 1-minute increases. The effect of A (starch phthalate) and B (croscarmellose sodium) on dissolution efficiency in 1 minute are shown in fig. 3(i). The contour plots were found to be linear to a certain extent. It was determined from the contour plot fig. 3(ii) that more dissolution efficiency in 1 min can be obtained with A (starch phthalate) level range between 7 and 8 % and B (croscarmellose sodium) level range 4 to 5%. The effects of B (croscarmellose sodium) and C (crospovidone) are shown in fig. 3(iii). The contour plots were found to be almost linear indicating the linear relationship between B (croscarmellose sodium) and C (crospovidone). It was determined from the contour plot fig. 3(iv) that more dissolution efficiency in 1 minute can be obtained with B (croscarmellose sodium) level range between 4 and 5% and C (crospovidone) level range 4 to 5%. The effects of A (starch phthalate) and C (crospovidone) are shown in fig. 3(v). The contour plots were found to be linear indicating the linear relationship between A (starch phthalate) and C (crospovidone). It was determined from the contour plot fig. 3 (vi) more dissolution efficiency in 1 min can be obtained in A (starch phthalate) level range between 7 and 8% and C (crospovidone) level range between 4 to 5%.

CONCLUSION

Starch phthalate 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 phthalate (5%) and crospovidone (5%). The formulated fast dissolving tablets of ibuprofen employing starch phthalate and crospovidone exhibited good dissolution efficiency in 1 min which can be used for the fast therapeutic action of ibuprofen.

Overall, Starch phthalate was found to be a superdisintegrant which enhanced the dissolution efficiency when combined with crospovidone and croscarmellose sodium, with the ibuprofen and hence it could be used in the formulation of fast dissolving tablets to provide immediate release of the contained drug within 1 min.

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AUTHORS CONTRIBUTIONS

All the author have contributed equally

CONFLICT OF INTERESTS

The authors confirm that this article content has no conflict of interest.

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