

2³ Full Factorial Designs for Formulation and Evaluation of Non-Steroidal Anti-inflammatory Drug

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ABSTRACT

This study aimed to formulate ibuprofen fast-dissolving tablets using a natural super-disintegrant to enhance their anti-inflammatory activity. In this survey, three factors in a two-level (2³) factorial design were employed to examine the effects of three factors, i.e., effects of *Ocimum gratissimum* mucilage [A], sodium starch glycolate [B], and croscarmellose sodium [C] on dependent variables such as in vitro method, in water absorption, and percent drug release at 5 minutes. The pH range for all formulations was 7.2 ± 0.24 to 7.2 ± 0.25. The drug content percentages ranged from 198.92 ± 0.78 to 201.5 ± 10.55%. The in vitro relationship is that after transient administration of the system, it remains intact for an extended period of time. Water absorption was in the range of 45.9 ± 0.15 to 99.9 ± 0.25%; optimized formulation water absorption was estimated to be approximately 55 ± 0.05% to 195 ± 0.040%. Formulations F2 and F4 reflected rapid drug release within 5 minutes, and all formulations except F3, F6, and F7 exhibited approximately 90% drug release within 10 minutes. Experience has shown that the independent variables chosen to have a significant effect on the dependent variable, demonstrating the robustness and adaptability of the design implied by optimization. The developed system could be a promising alternative strategy to increase ibuprofen retention in the stomach, thereby enhancing its therapeutic efficacy. It even offers the added benefit of reducing stomach irritation, tissue damage, and ulcers by avoiding direct contact of the drug with the gastric mucosa.

Keywords: Factorial design, Ibuprofen, Mucilage, pH.

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INTRODUCTION

When placed on the tongue, fast dissolving tablets are defined as a solid dosage form containing medicinal substances that disintegrates rapidly, usually within seconds. Physical problems with swallowing (dysphagia) can occur at any age with traditional tablets but are more common in the elderly and those with dementia, whereas refusal to swallow is common in geriatric, paediatric, and psychiatric patients.¹ Tablet-taking difficulties and resistance are common in all patient groups. Fast-dissolving tablets have been developed in recent years to help people with swallowing problems. The tablet's orally disintegrating property is due to the rapid ingress of water into the matrix, which creates a porous structure and causes rapid disintegration. These tablets dissolve instantly when placed on the tongue, releasing the drug, which dissolves or disperses in saliva. As saliva passes down into the stomach, the drugs may be absorbed from the mouth, pharynx, or oesophagus. Fast dissolving tablets have the following benefits: ease of swallowing without water, rapid onset of action, enhanced dissolution rate, increased gastric absorption, improved oral

bioavailability, reduced first pass metabolism, and improved patient compliance.²

Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID) that is used to treat rheumatoid arthritis, osteoarthritis, and other chronic and acute pain and inflammation conditions. Because ibuprofen's serum concentrations and analgesic effect are linked, rapid absorption could be a requirement for its rapid onset of action. The drug's major drawbacks include its low solubility in biological fluids, gastric irritation, and a 2-hours biological half-life. It is practically water insoluble, resulting in poor solubility and, as a result, poor GI absorption and bioavailability.^{3,4} Fast dissolving tablets of Ibuprofen were made using super-disintegrants and direct compression to improve dissolution rate and thus absorption.

MATERIALS AND METHODS

Materials

Ibuprofen pure drug obtained from yarrow chemicals Mumbai. Mannitol, Sodium starch glycolate, Croscarmellose sodium was obtained from Yarrow chem. products, Mumbai.

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Microcrystalline cellulose was bought from Qualigens fine chemicals, Mumbai. Talc and magnesium stearate was obtained from Molychem, Mumbai.

Isolation of *Ocimum gratissimum* mucilage (a novel disintegrate)⁵

The seeds of *O. gratissimum* were soaked in distilled water for 12 hours before being blended to separate the mucilage from the seeds. The volume was passed through eight folds of muslin cloth after 15 minutes of blending. The mucilage was precipitated from the filtrate by adding three parts acetone (75%) to the mucilage. After 6 hours of drying at 45°C, the powder was weighed to determine the yield.

Characterization of *O. gratissimum* mucilage (a novel disintegrate)

The *O. gratissimum* mucilage prepared was evaluated for the following.^{6,7}

Solubility: *O. gratissimum* mucilage solubility was tested in various solvents like distilled water, aqueous buffers of pH 1,2,3,4,6 mentioned in IP 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: mucilage powder (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 hours. The volumes of the sediment in the tubes were recorded. The swelling index (%) of the material was calculated as follows.

$$\text{SI}\% = \left[\frac{\text{volume of sediment in water} - \text{volume of sediment in light liquid paraffine}}{\text{volume of sediment in light liquid paraffine}} \right] \times 100$$

Test for Gelling Property mucilage prepared were evaluated for their gelling property by heating a 7% w/v dispersion of each in water at 100°C for 30 minutes.

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, 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

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

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

Percentage Compressibility Index Percentage: compressibility of the powder mixed was determined by Carr's Compressibility Index calculated by the following formula.⁹

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

LBD=loose bulk density

TBD= Tapped 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.^{8,9}

Fourier Transform Infrared (FTIR) Spectroscopy: FTIR spectra of mucilage were recorded on samples prepared in potassium bromide (KBr) disks using a FTIR (Tokyo, Japan). The scanning range was 500 to 4000 cm⁻¹. Samples were mixed with (KBr) to form disks by means of a hydrostatic press at 6–8 tons pressure.

Differential Scanning Calorimetry (DSC): DSC thermogram *O. gratissimum* rams of Ibuprofen and their mixtures (1:1) with *O. gratissimum* were recorded on Perkin Elmer thermal analyzer samples (2–5 mg) were sealed into aluminum pans and scanned at a heating rate of 10°C min⁻¹ over a temperature range 30–350°C.

Preparation of Ibuprofen Fast Dissolving Tablets^{10,11}

The tablets were prepared by direct compression method employing 2³factorial design in which 3 independent variables {super-disintegrants i.e., *O. gratissimum* (A), sodium starch glycolate(B), Croscarmellose Sodium (C)} and 2 dependent variable (water absorption and percent of drug dissolved in 5 min) were selected. The composition of formulation given

Table1: Formulae of Ibuprofen fast dissolving tablets employing *O. gratissimum* mucilage.

Ingredients (mg/tablet)	F1	F2	F3	F4	F5	F6	F7	F8
Ibuprofen	200	200	200	200	200	200	200	200
<i>O. Gratissimum</i>	----	25	---	25	---	25	---	25
Sodium starch Glycolate	----	---	25	25	---	---	25	25
Croscarmellose Sodium	----	---	---	---	25	25	25	25
Mannitol	30	55	55	30	55	30	30	5
MCC	250	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

in Table 1. For *O. gratissimum* (A), the lower level i.e., 0% concentration and upper level i.e. 5% 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. *O. gratissimum*, 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.

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 kg/cm².^{12,13}

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.

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.¹⁴

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

Drug Content Uniformity

For content uniformity, ten tablets was 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 spectrophotometrically at 276 nm after appropriate dilution with pH 7.2 phosphate buffer. The drug content was calculated as an average of three determinations.¹²

Wetting Time

The wetting time of tablets was measured by placing five circular tissue papers in a petri dish of 0.10 m in diameter. 10 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.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 wet, completely. The wetted tablet was then weighed. Water absorption ration R was determined using the following equation.

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

Where,

W_d = Tablet weight after water absorption.

W_e = Tablet weight before water absorption.

In-vitro Disintegration Time¹³

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 ± 0.2°C. The time in second taken for complete disintegration of the tablet with no palatable mass remaining in the apparatus was measured.

In-vitro Dissolution Studies¹⁴

The *in vitro* dissolution rate study of Ibuprofen fast dissolving tablets was performed using 8 stage dissolution test apparatus (Lab India) 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 a 0.45 μ membrane filter, diluted and assayed at 276 nm using an analytical technol *O. gratissimum* Eli co SL 218 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 seclusion of *O. gratissimum* adhesive was viewed as fine, free-streaming great gulping powder. It was insoluble in fluid solvents and insoluble in natural solvents tried (methanol, petrol ether, dichloromethane, and chloroform). The pH of 0.1% fluid scattering was viewed as 7.62 ± 0.001. *O. gratissimum* adhesive displayed great expanding in water. The expanding file was viewed as 100 ± 0.003% demonstrating that it is reasonable for super-disintegrant. All micrometric properties showed great stream properties required assembling of tablets. The thickness of *O. gratissimum* adhesive was viewed as 0.3012 ± 0.0004 g/cc. The point of rest and compressibility record showed great stream properties of *O. gratissimum* adhesive.

The FTIR range of *O. gratissimum* adhesive is displayed in Figures 1 to 3. The presence of pinnacle retention at 1434.10 cm⁻¹

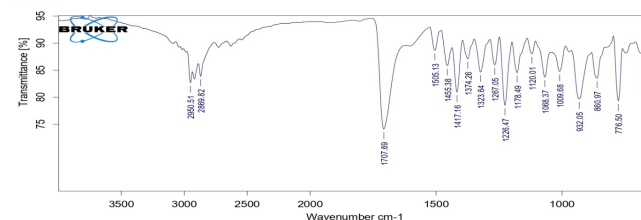


Figure 1: Fourier transform infrared pure Ibuprofen.

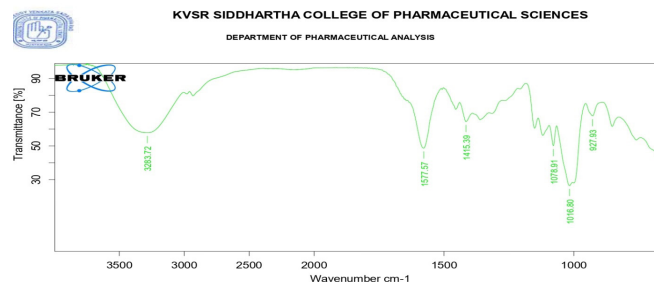


Figure 2: Fourier transform infrared *O. gratissimum* mucilage

trademark pinnacle of ester, so from FTIR studies; it was presumed that *O. gratissimum* adhesive (ester) was framed when the adhesive was permitted to respond with formic corrosive. As the *O. gratissimum* adhesive was somewhat fine powder and it had gotten every one of the attributes of super-disintegrants it was reasoned that *O. gratissimum* adhesive can be utilized as novel super-disintegrant in the detailing of quick dissolving tablets.

Evaluation of Tablets

Hardness

The hardness of tablets from all bunches was viewed as in the scope of 3.7 ± 0.046 kg/cm² to 4.0 ± 0.002 kg/cm². All tablets were found hard enough so they could undoubtedly endure the taking care of and capacity conditions without becoming 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 $0.12 \pm 0.032\%$ to $0.15 \pm 0.059\%$ 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 198.92 ± 0.78 to 200.21 ± 0.11 . 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, i.e., 85 to 115 % of average content Table 2.

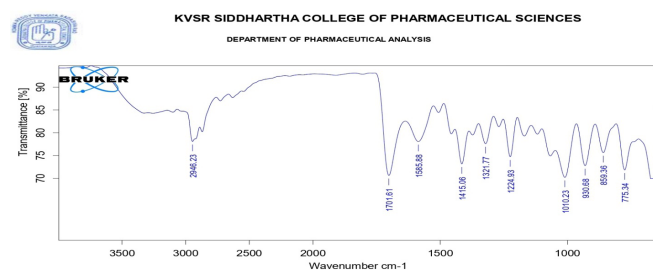


Figure 3: Fourier transform infrared Ibuprofen and mucilage

Disintegration Studies

In-vitro disintegration time was done by the USP disintegration apparatus. The disintegration rate has a correlation with water absorption capacity of disintegrate and The *in-vitro* disintegration time was found between 240 ± 02 to 20 ± 01 s. The outcomes were tabulated and data demonstrated in Table 2. All the formulation showed disintegration time of less than 240s. It was found that the formulation F2 will show least disintegration time 20s as compared to other formulation. The order for a disintegration time in the fast-dissolving tablet was found to be $F2 < F8 < F7 < F6 < F5 < F4 < F3 < F1$. 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 48.5 ± 0.01 to 195 ± 0.04 s. This increased behavior due to the water taking the ability of super disintegrants. The wetting time found was tabulated and data demonstrated in Table 2 and Figure 3. It was found that the formulation F2 containing 5% mucilage and 5% croscarmellose sodium showed more water absorption ratio i.e., 195 ± 0.04 s compared to other formulations.

In-vitro Dissolution Studies

Dissolution rate depends on the water absorption of the disintegrant, among all the formulations F2 has more water absorption 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 Figures 4 and 5. In all formulations F2 formulation

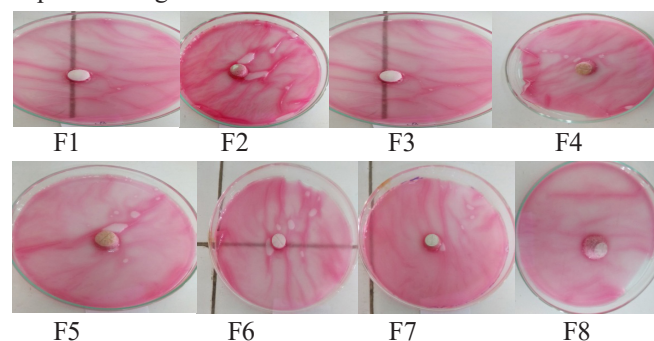


Figure 3: Water absorption ratio of Ibuprofen fast dissolving tablets employing novel superdisintegrant

Table 2: Physical properties: hardness, friability drug content of Ibuprofen fast dissolving tablets prepared by direct compression method involving mannitol as a diluents

Formulation	Hardness Kg/cm ²	Friability (%) \pm S.D	Drug content (mg/tab) \pm S.D	Disintegration Time(s) \pm S.D	Wetting time (sec) \pm S.D	Water Absorption (%) \pm S.D
F1	3.9 ± 0.003	0.12 ± 0.032	200.21 ± 0.11	240 ± 02	250 ± 0.11	48.5 ± 0.01
F2	4.0 ± 0.002	0.13 ± 0.053	199.32 ± 0.57	20 ± 01	15 ± 1.34	195 ± 0.04
F3	3.8 ± 0.006	0.14 ± 0.057	199.81 ± 0.17	80 ± 01	67 ± 1.8	55 ± 0.05
F4	3.9 ± 0.023	0.11 ± 0.078	200.52 ± 0.54	63 ± 02	62 ± 0.56	115 ± 0.09
F5	3.9 ± 0.037	0.12 ± 0.024	201.51 ± 0.55	71 ± 02	51 ± 0.15	131 ± 0.31
F6	3.8 ± 0.034	0.15 ± 0.059	199.42 ± 0.64	61 ± 01	85 ± 0.37	147 ± 0.52
F7	3.7 ± 0.046	0.12 ± 0.078	198.92 ± 0.78	45 ± 02	89 ± 1.23	123 ± 0.44
F8	3.9 ± 0.043	0.14 ± 0.095	200.21 ± 0.11	43 ± 01	77 ± 0.45	160 ± 0.21

was selected as the promising formulation containing 5% *O. gratusimum* and 5% with 99.94% release in 10 minutes.

The dissolution parameters of the formulation from (F1–F8) which were made by direct compression method were shown in the table1. In all these cases the PD5 (percent dissolved in 5 min) was more in F8 which consists at 5% *O. gratusimum*, 5% sodium starch glycolate and Croscarmellose Sodium. The same was in the case of water absorption and percent of drug dissolved in 5 minutes). The water absorption and percent of drug dissolved in 5 min reveals that *O. gratusimum* mucilage was effective at 5% along with 5% sodium starch glycolate and croscarmellose sodium when the formulations were made by direct compression using these super-disintegrants. From the results, it was concluded that *O. gratusimum* (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 2³-factorial design.

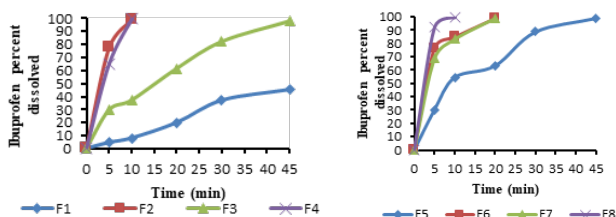


Figure 4: dissolution profiles of Ibuprofen fast dissolving tablets employing natural superdisintegrant (F1-F8)

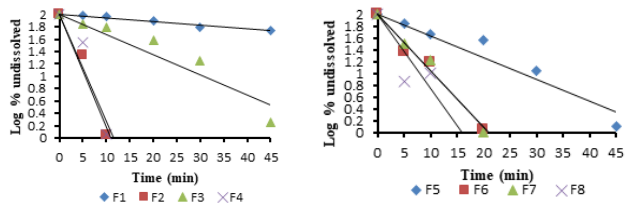


Figure 5: Log time Vs log percent undissolved of Ibuprofen fast dissolving tablets employing natural superdisintegrant (F1-F8).

The fast dissolving tablets and release parameters (percent drug released in 5 min) of the fast dissolving formulated were analyzed as per ANOVA of 2³-factorial design, values are indicated Table 3, indicated that the individual effects of *O. gratusimum* (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 water absorption and percent of drug dissolved 5 minutes of Ibuprofen fast dissolving tablets.

Independent variables and response variables can be co-related by using a polynomial regression algorithm. It is a second order model equation, for the 2n experimental design polynomial equation was written as Equation.

$$Y = \beta_0 + \beta_1A + \beta_2B + \beta_3C + \beta_1\beta_2 AB + \beta_1 \beta_3 AC + \beta_2\beta_3 BC + \beta_1\beta_2 \beta_3 ABC$$

Where,

Y is the measured response

β_0 is the arithmetic mean response

$\beta_1, \beta_2, \beta_3, \beta_1\beta_2, \beta_1 \beta_3, \beta_2\beta_3, \beta_1\beta_2 \beta_3$ are the coefficients for the corresponding factors A, B, C, AB, AC, BC, and ABC are the percentages of *O. gratusimum*, sodium starch glycolate and croscarmellose sodium and interaction terms respectively. Following formula was used to calculate the coefficient and it was given as Equation.

$$\beta = \sum XY/2n$$

Where β : Coefficient

X : Corresponding variable (A,B,C)

Y : Response value (Percent dissolved in 5 minutes or Dissolution efficiency in 5 minutes)

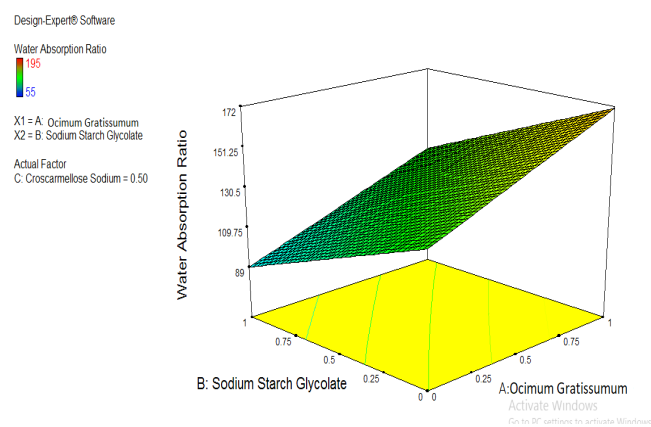
n : Level

Contour plots and response surface plots were drawn by using Star Ease, Inc. (Minneapolis, MN) Design Expert 11 Version software.

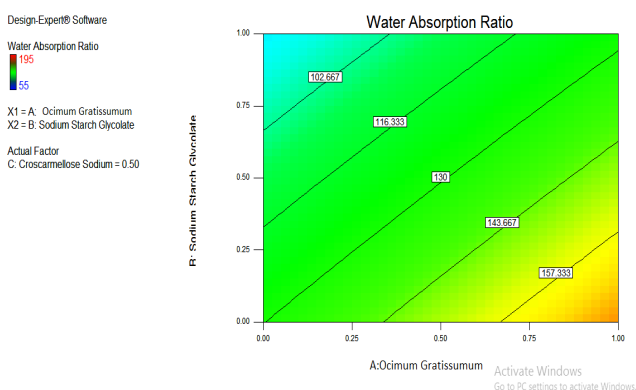
From the response surface plot and contour plots (Figure 6a and b), it was known that the concentration of *O. gratusimum* mucilage was directly proportional to the percent dissolved

Table 3: ANOVA studies For Percent Dissolved at 5 Minutes

Source of variance	Degree of freedom	Sum square	Mean sum square(sum square/d.f)	Variation ratio(f) (mss/mss error)	f ratio	Significant/non significant
Replicates	2	0.1925	0.09625	1.274231678	2.77	p > 0.05
Treatments	7	19426.7	2775.242857	36740.80378	4.66	p < 0.05
No superdisintegrant	1	74448.6	74448.62	985608.208	4.66	p < 0.05
<i>O. Gratusimum</i> (A)	1	12010.9	12010.9	159009.5508	4.66	p < 0.05
SSG (B)	1	1705.22	1705.22	22575.01655	4.66	p < 0.05
<i>O. Gratusimum</i> x SSG (AB)	1	1318.68	1318.684	17457.75508	4.66	p < 0.05
CCS	1	3066.82	3066.82	40600.92671	4.66	p < 0.05
<i>O. Gratusimum</i> x CCS (AC)	1	561.634	561.6338	7435.341087	4.66	p < 0.05
SSG x CCS(BC)	1	670.984	670.9837	8882.999338	4.66	p < 0.05
<i>O. Gratusimum</i> x SSGx CCS(ABC)	1	92.4338	92.43375	1223.70922	4.66	p < 0.05
ERROR	14	1.0575	0.075535714			
Total	23	19427.9				



(a) Response Surface Plot



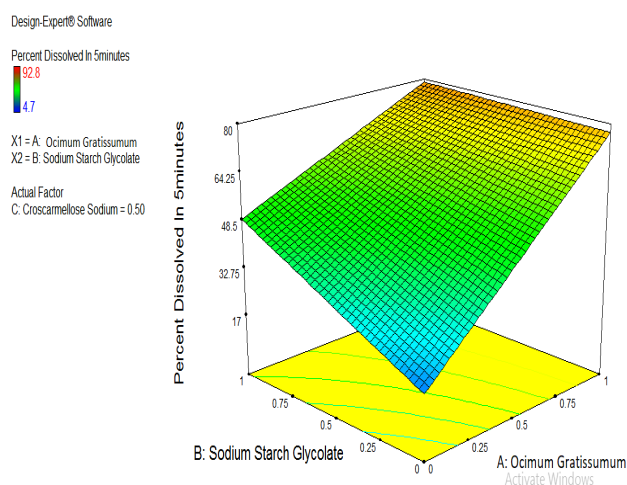
(b) Contour Plot

Figure 6: (a) Response Surface Plot (b) Contour Plot of Ibuprofen Fast Dissolving Tablets. (Effect of ocimum gratissimum mucilage and Sodium starch glycolate on water absorption)

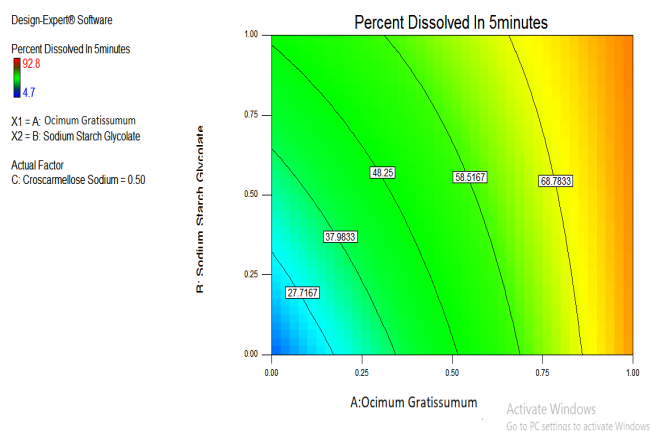
in 5 minutes, which indicate as the concentration of *O. gratissimum* mucilage increases the percent dissolved in 5 minutes also increases. The concentration of the other two super-disintegrants i.e., sodium starch glycolate (B) and croscarmellose sodium (C) also have a positive effect on the water absorption ratios. Contour plots obtained for A and B was linear, it indicates that a linear relationship has been established between the concentrations of A & B and percent dissolved in 5 minutes. Percent dissolved in 5 minutes of Ibuprofen fast dissolving tablets is more with a *O. gratissimum* (A) concentration at a range of 4–5% and sodium starch glycolate (B) concentration at a range of 4–5%.

Surface response plots and contour plots of *O. gratissimum* (A) and sodium starch glycolate (B) were shown in Figure 7.a & b. Contour plots obtained for A and B was linear, it indicates a linear relationship of A & B on dissolution efficiency in 5 minutes. Dissolution in 5 minutes of Ibuprofen fast dissolving tablets is more with a *O. gratissimum* (A) concentration at a range of 4–5% and sodium starch glycolate (B) concentration at a range of 4–5%.

The concentration level of independent variable i.e., super-disintegrants at which optimum response was obtained was studied from the independent variables and their interaction



(a) Response Surface Plot



(b) Contour Plot

Figure 7: Effect of *Ocimum gratissimum* (A) and Sodium starch glycolate (B) on Dissolution in 5 minutes of Ibuprofen Fast Dissolving Tablets:

effects on the responses. From the polynomial equations it was clearly evident that super-disintegrants (*O. gratissimum*, sodium starch glycolate and croscarmellose sodium) A, B, C and interactions between A, B & C showed positive effect on the percent dissolved in 5 minutes and water absorption of Ibuprofen fast dissolving tablets, whereas interactions between the AB, AC and AC showed negative effect on the percent dissolved in 5 minutes and water absorption of ibuprofen fast dissolving tablets. Contour plots, indicate that low levels of *O. gratissimum* (A) and high levels of sodium starch glycolate (B) and croscarmellose sodium (C) favours the percent dissolved in 5 minutes and water absorption of Ibuprofen fast dissolving tablets. To obtain more percent dissolved in 5 minutes and more water absorption high levels of super-disintegrants i.e., *O. gratissimum* (A), sodium starch glycolate(B), croscarmellose sodium (C) are needed in formulation of Ibuprofen fast dissolving tablets.

The results of physical properties of Ibuprofen fast dissolving tablets, *in-vitro* disintegration time and *in-vitro* dissolution studies, it was known that the formulation F8 employing 5% concentration of *O. gratissimum*, 5% concentration of sodium

starch glycolate and 5% croscarmellose sodium exhibited more percent dissolved in 5 minutes and water absorption. Hence, F8 is considered as an ideal formulation of Ibuprofen, whereas formulation F2 with novel super-disintegrant i.e., *O. gratisimum* in the concentration range of 5% is also comparable to the formulation F8. Therefore, when compared to F8, F2 was found to be more economical with single novel super-disintegrant.

CONCLUSION

O. gratisimum is an efficient super-disintegrant for fast dissolving tablets. The disintegration and water absorption of the fast-dissolving tablets of Ibuprofen was good and depended on the concentration of super-disintegrant employed i.e., *O. gratisimum* (5%), and sodium starch glycolate (5%). The formulated fast dissolving tablets of Ibuprofen employing *O. gratisimum* and croscarmellose sodium exhibited good dissolution drug dissolved in 5 min which can be used for the fast therapeutic action of Ibuprofen.

Overall, *O. gratisimum* was found to be a super-disintegrant when combined with sodium starch glycolate, the dissolution dissolved in 5 minutes 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 minutes.

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