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Original Article

Leveraging Factorial Design for Enhancing Formulation of Ketorolac Tromethamine Fast-Disintegrating Tablets

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ABSTRACT

Aim: Fast disintegrating tablets of Ketorolac tromethamine were prepared by formulating it with various super disintegrants with view to reduce disintegration time of tablets and to increase dissolution properties. **Materials and Methods:** The study employed One Factor at a Time (OFAT) tests to identify crucial variables and optimal response ranges. The primary factors affecting the disintegration time and drug release were found to be Croscarmellose sodium, Crospovidone, and Magnesium stearate concentrations and these were considered as independent factors, with disintegration time and drug release after 10 min as dependent variables. The experimental design and data analysis were performed using Stat-Ease Design Expert® V12.0.1.0. **Results:** The study utilized FTIR to analyze pure Ketorolac and its combination with super disintegrants. Pre-compression testing was conducted to assess the flow properties of the powder blend, and all formulations exhibited desirable flow characteristics. All formulations were found to have Average densities between 0.45 g/cm^3 and 0.56 g/cm^3, a repose angle between 25.5 and 29.6º, compressibility index between 8.69 and 30.35, Hausner's ratio from 1.09 to 1.43. Tablet formulations had suitable hardness, thickness, disintegration time, and friability. Response polynomial equations were generated to quantify the impact of excipient concentrations on Ketorolac release parameters. Croscarmellose sodium concentration had a direct influence on disintegration time, while Crospovidone and Magnesium Stearate did not affect disintegration time. **Conclusion:** The study demonstrates that fast-dissolving tablets of Ketorolac tromethamine can be effectively produced using a direct compression method and a range of super disintegrants in various concentrations. The formulation with the highest concentration of Croscarmellose sodium as the super disintegrant yielded the best results in terms of disintegration time and solubility.

Keywords: Ketorolac tromethamine, Croscarmellose sodium, Crospovidone and magnesium stearate, One Factor at a Time approach (OFAT).

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INTRODUCTION

In order to improve the drug's safety and effectiveness, modern breakthroughs in the field of Novel Drug Delivery System have focused on creating new dosage forms that can be administered in a variety of ways. Patients of various ages and conditions, including the young and old, the bedridden and crippled, and those with mental illness, might have trouble swallowing. When put on the tongue, fast dissolving tablets dissolve quickly, generally within a few seconds, and do not need to be diluted with water before eating.[1-3] "A solid dosage form containing a medicinal substance or active ingredient which disintegrate rapidly when placed upon the tongue," as defined by the United States Food and Drug Administration (USFDA).[4,5]

Some medications' bioavailability is improved by these innovative drug delivery methods because they are absorbed in the oral cavity and by saliva before they reach the stomach. Drugs are less likely to be metabolised inefficiently in this administration method.[6,7]

The application of factorial design principles can provide a systematic approach to exploring the interplay between formulation variables and their impact on the disintegration, dissolution, and taste-masking properties of ketorolac tromethamine fast-disintegrating tablets, ultimately leading to an optimized and clinically relevant dosage form.

Ketorolac tromethamine is a potent Nonsteroidal Anti-Inflammatory Drug (NSAID) that is commonly used for the management of moderate to severe pain. Fast-Disintegrating Tablets (FDTs) are a convenient dosage form that offers rapid

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drug release and absorption, making them ideal for patients who have difficulty swallowing traditional tablets. In order to optimize the formulation of ketorolac tromethamine FDTs, factorial design can be leveraged to systematically study the effect of multiple variables on the tablet properties.

MATERIALS AND METHODS

The various materials used in this study are of analytical grade and are as follows: Drug- Ketorolac, Diluent-Micro crystalline cellulose (AvicelPH102), Lactose monohydrate, Super disintegrent-Crascarmellose Sodium, Crospovidine, Lubricant: Magnesium stearate. All the formulations and evaluations have been performed using Tablet Press (9 Station, Single Rotary), Friabilator, Dissolution Apparatus (USP Type II), Monsanto Hardness Tester, U.V Visible Spectrophotometer, Digital Vernier Calipers, Disintegration Apparatus and FTIR apparatus.

Design for optimization of Ketorolac FDT Tablets

One-Factor-at-a-Time (OFAT) tests were 1st carried out to determine the most crucial variables and the optimal response ranges. Concentrations of Croscarmellose sodium, Crospovidone, and Magnesium stearate were shown to be the most significant variables for Ketorolac. In this study, a 2^3 full factorial design was employed to evaluate the effect of 3 factors-concentration of croscarmellose sodium (A), concentration of crospovidone (B), and concentration of magnesium stearate (C) on 2 response variables-disintegration time and percent drug release at 10 min. The experimental design consisted of eight runs, with each run representing a different combination of levels of the 3 factors. The levels of the factors selected for each factor were mentioned in Table 1. Following the protocols laid forth for the experimental design, the tests were carried out, and the results for the dependent variables were recorded in spreadsheets. Within the experimental setting, response surfaces were analysed using the Stat-Ease Design Expert® software version 12.0.1.0.

Formulation of disintegrating tablets of Ketorolac Tromethamine

In a clean, dry porcelain mortar, we ground all the components to a powder and combined them in the appropriate geometric proportions. All of the components for FDT tablets were mixed with various super disintegrants to make many test batches. After 20 min of dry blending, a combination of KRT powder, crospovidone, cross carmellose sodium, and lactose monohydrate, MCC was added. The powder blend resulting from the mixes and the magnesium stearate was then immediately punched using a rotary tablet machine fitted with 9 mm flat round punches to provide the FDT tablets containing 10 mg of KRT.

PreCompression Parameters

Organoleptic properties

Against a black and white backdrop, the color of the drug sample may be determined by looking at it with the naked eye or by using a compound microscope. After that, they'll see how their numbers stack up against the gold standard.

Bulk Density (BD)

The density of a powder is defined as the ratio of its entire mass to its bulk volume. The volume occupied by 25 g of KRT mix with excipients was determined by weighing and transferring the blend into 50 mL measuring cylinders without tapping. The following formula was used to get the bulk density:

$$\text{Bulk density} = \frac{\text{Mass of the blend}}{\text{Untapped Volume}}$$

Tapped Density (TD)

It is the ratio of the powder's total mass to its tapped volume. In order to accurately measure the KRT mix, 25 g were weighed and transferred to graduated cylinders. The initial space taken up by the medication mixtures was recorded. Then, 500 taps were performed on the cylinder using a tapped density tester (Electro Lab USPII) in accordance with USP guidelines. The tapped density was determined by plugging the volume and mass of the powdered medicines into a formula.

$$\text{Tapped density} = \frac{\text{Mass of the blend}}{\text{Tapped Volume}}$$

Flow properties (Angle of Repose)

Powder's angle of repose was calculated using the funnel technique. In a funnel, we carefully extracted 25 g of the medication mix plus the excipients. The funnel was raised to the perfect height, with its tip resting on the very top of the powder mound. Powder was allowed to freely pour out of the funnel. The angle of repose was determined by measuring the powder cone's diameter and plugging the results into the following equation.

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

Where h and r are pile height and radius.

Compressibility Index (Carr's index-CI)

It indirectly affects flow rate, cohesion, and particle size. Predicting powder flow characteristics is easy, rapid, and popular. Based on apparent bulk density and tapped density, the bulk drug's % compressibility was calculated:

$$\text{Carr's Index (CI)} = \frac{(\text{Tapped density} - \text{Bulk density})}{(\text{Tapped density})} \times 100$$

Determination of Hausner Ratio (HR)

Hausner's ratio of powder was measured by the formula:

$$\text{Hausner's ratio} = (\text{Tapped density})/(\text{Bulk density})$$

Post Compression Parameters

Physical Appearance

Tablet form, smoothness, chipping, cracks, surface texture, color, embossing, and debossing are measured to determine compressed tablet appearance.[8-14]

Hardness

Tablets should withstand mechanical stress during handling and delivery. Monsanto hardness testers measured MDT hardness (kg/cm^2).

Friability (F)

FDT formulations (20) were weighed and put in the Roche Friabillator at 25 rpm for 4 min, falling six inches every revolution. Dedusting and reweighing the tablets was done. The following formula computed friability percentage:

$$\% F = \frac{(\text{Initial weight} - \text{Final weight})}{(\text{Initial weight})} \times 100$$

Weight variation test

Each FDT formulation (20) was weighed, the average weight computed, and the tablet weights compared. The tablets passed the USP testing with just 2 tablets outside the % limit and no tablets over 2 times the restriction. The weight fluctuation percentage should not exceed ±7.5%.

Thickness

Select tablets from each batch have been assessed using a vernier calipers to determine their average thickness.

Disintegration time

The Electrolab ED-2L disintegration test device, India was used to determine the disintegration time. Using distilled water kept at 37±2°C as the immersion fluid, one tablet was put in each of the basket's six tubes, and the device was run for the allotted amount of time. When tablets totally dissolve, the time in seconds is recorded.

In vitro Dissolution Studies of FDTs

Drug release experiments were performed utilizing USP-II equipment at 50 RPM was performed on the developed FDT formulations of ketorolac. 600 mL of water at 37±0.5°C was employed as the dissolution medium, which was shown to be optimal for sink conditions. At various time points, 5 mL samples were taken and swapped for an equal volume of new media. After being filtered with Whatman filter paper, the dissolution samples were examined by a validated UV spectroscopic technique operating at 321 nm.

RESULTS AND DISCUSSION

Fourier Transmission Infra-Red (FT-IR) study

As shown in Figure 1 an ATR-FT-IR spectrophotometer was used to compare the spectra of pure ketorolac and its physical mixing with super disintegrants as part of a preformulation investigation. Their spectra were identical. It was found that even in the presence of super disintegrants, the drug did not show any symptoms of incompatibility.

Calibration of Ketorolac

Using a UV/visible spectrophotometer, the maximum wavelength at which KTM absorbs light was determined to be 321 nm. Linear regression was performed on a previously constructed calibration curve. Good linear correlation between concentrations 2-12 µg/mL was observed, as shown by the correlation coefficient for standard curves being extremely close to one. Therefore, in the aforementioned range, drug behaves according to Beer Lambert.

Pre-compression evaluations

The powder blend's flow characteristics were checked prior to compression. Tablets of the necessary grade may be easily produced thanks to the powder blend's superior flow qualities during the tableting process. The Organoleptic features are colorless. All of the different forms have densities between 0.36 and 0.45 g/cm^3. All the different forms have average densities between 0.45 g/cm^3 and 0.56 g/cm^3. All formulations were found to have a repose angle between 25.5 and 29.6°. All the different formulations have a compressibility index between 8.69 and 30.35. Powder mixes of all nine formulae fall within a Hausner's ratio of 1.09 to 1.43. All 9 powder mix compositions were found to have satisfactory flow characteristics. Table 2 displays the different pre-compression parameters.[15-20]

Post-compression evaluations

All the tablets came in with a hardness of less than 3 kg/cm^2, regardless of the formulation. All batches of tablets were found to have a friability rate of less than 1%, meaning they passed the test for friability. Each formulation's tablets were subjected to a weight variation test to verify they were consistent in weight, which would show that the powder mixes used in each formulation were distributed evenly. All tablet formulations were determined to have a weight variation of less than 7.5%. All tablets of each formulation tested had the uniform weight, as shown by the

Table 1: List of factors and their levels.

Factors	Level (-1)	Level (+1)
A: Croscarmellose sodium (mg)	5	10
B: Crospovidone (mg)	1	3
C: Magnesium stearate (mg)	0.5	1.5

Table 2: Pre-compression characterization of KRT blend.

Code	Parameters				
	Angle of Repose (θ)	BD (g/cm³)	TD (g/cm³)	CI (%)	HR
F1	28.2	0.36	0.49	26.53	1.36
F2	25.5	0.39	0.56	30.35	1.43
F3	28.1	0.39	0.48	18.75	1.23
F4	29.6	0.42	0.46	8.69	1.09
F5	25.7	0.40	0.46	13.04	1.15
F6	27.2	0.38	0.45	15.55	1.18
F7	27.1	0.41	0.53	22.64	1.29
F8	27.8	0.39	0.46	15.21	1.17
F9	27.4	0.45	0.54	16.66	1.20

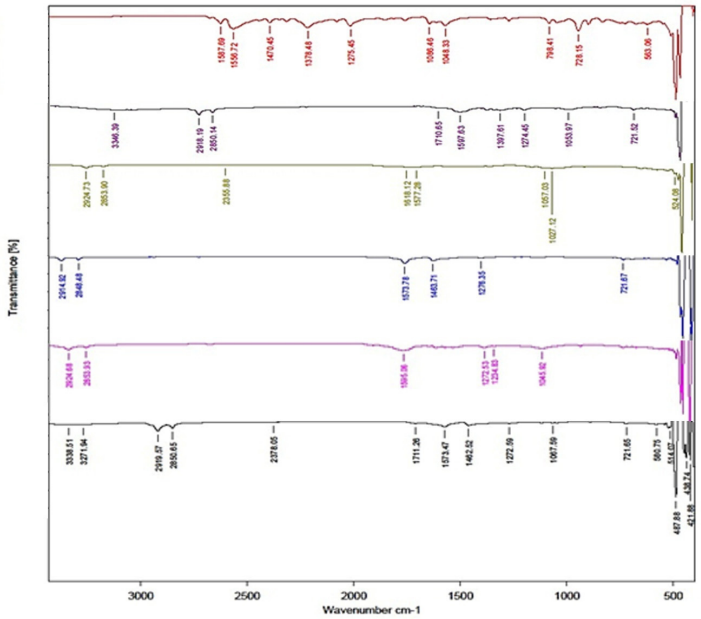

Figure 1: ATR-FTIR Spectra of pure drug and other excipients.

findings as mentioned in Table 3. It was determined that the thickness of tablets across all nine formulations ranged from 2.2 mm to 2.5 mm. All tablets vary in drug concentration from 95.46% to 98.84%. *In vitro* drug release of Ketorolac fast disintegrating tablet formulation has been exhibited in Figure 2. Dissolution study of Ketorolac fast disintegrating tablet formulations and design summary for Ketorolac fast disintegrating tablets were presented in Tables 4 and 5.

Data Analysis of Ketorolac Fast Disintegrating Tablets

The polynomial equations were generated for the responses. The generated equations illustrated the quantitative effect of Croscarmellose sodium, Crospovidone and magnesium stearate on Ketorolac release parameters like % drug released at 10 min and disintegration time. The magnitude and signs of the coefficients of the excipients (Croscarmellose sodium, Crospovidone and magnesium stearate) viz A, B and C in polynomial equations were correlated with the responses R1 and R2. Proper statistical tests were performed, and an appropriate model was chosen as a result. As assessed by Analysis of Variance (ANOVA), the polynomial equations have a statistically significant value ($p \leq 0.05$). The graphical optimization was performed to generate the design space as shown in Figure 3.

Effect of excipients concentration on Disintegration Time (DT)

DT=216.5-30.75*A+11.75*B+1*C+15.25*AC

As Croscarmellose increases in concentration gradually decreases disintegration time whereas Crospovidone and Magnesium Stearate concentrations increased, the disintegration time

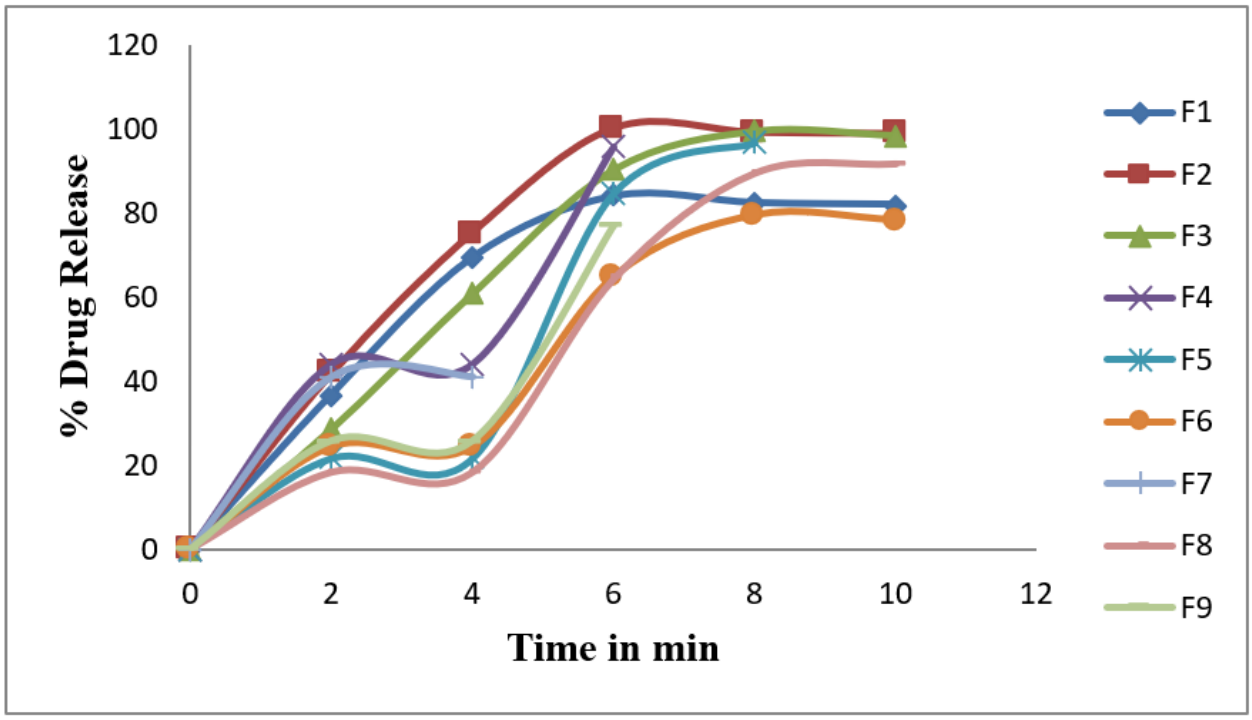

Figure 2: *In vitro* drug release of Ketorolac fast disintegrating tablet formulations.

Table 3: **Post-compressional parameters of FDTs of Ketorolac.**

Formulation code	Appearance	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm²)	Friability (%)	Disintegration Time (sec)
F1	Pale white colour, concave tablet	97.8	2.5	2.8	0.68	189
F2		97.8	2.4	2.7	0.66	186
F3		99.2	2.4	2.8	0.62	248
F4		97.4	2.5	3.1	0.67	150
F5		98.5	2.3	2.9	0.66	258
F6		98.2	2.2	2.9	0.62	218
F7		100.8	2.5	3.0	0.68	218
F8		98.6	2.5	2.8	0.65	265
F9		97.5	2.4	2.7	0.63	181

Table 4: **Dissolution study of Ketorolac fast disintegrating tablet formulations.**

Time in min	%Drug Dissolution								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
2	36.8	41.71	28.52	43.91	21.54	24.38	40.93	18.30	25.80
4	69.38	75.22	60.72	43.91	21.54	24.38	40.93	18.30	25.80
6	83.87	100.03	90.20	95.50	84.64	64.86	-	64.34	77.01
8	82.31	99.00	99.38	-	96.67	79.47	-	89.55	-
10	81.93	98.74	98.35	-	-	78.30	-	91.76	-

also increases. When concentration of croscarmellose sodium increased in formulations, it enhanced its ability to absorb water and swell rapidly leading to faster disintegration. This increased swelling and disintegration improved drug release in formulations. Increase in the concentration of crospovidone beyond a certain level formed a gel like network that hindered the penetration of water and dissolution of the tablet. This led to a slower disintegration time. At higher concentration magnesium stearate formed a hydrophobic layer on the tablets surface which inhibited water penetration and slow down disintegration. Magnesium stearate is hydrophobic and it coated the croscarmellose sodium particles and hindered the ability of it to absorb water and swell which resulted in increased disintegration time.

The amount of time it took for the tablet to disintegrate into tiny pieces when placed in water was measured and depends on the formulation's super disintegrant type and concentration. Disintegration time was the most important factor for mouth dissolving tablets, and the guidelines require that it be shorter than 30 sec to 3 min. Disintegration times for all tablet formulations were found to be acceptable as mentioned in Table 5 and Figure 4.

In vitro dissolution studies

FDTs were kept in water to test drug release *in vitro*. By increasing the rate at which the active medication is released from the dosage form, super disintegrants improved the bioavailability and absorption of the medicine when added to solid dose formulations. All the different formulations had the same peak drug release time of 10 min. Except for Formulations (F4, F5, F6, F7, and F9), all formulations showed drug release of above 80% in 10 min.[21-23]

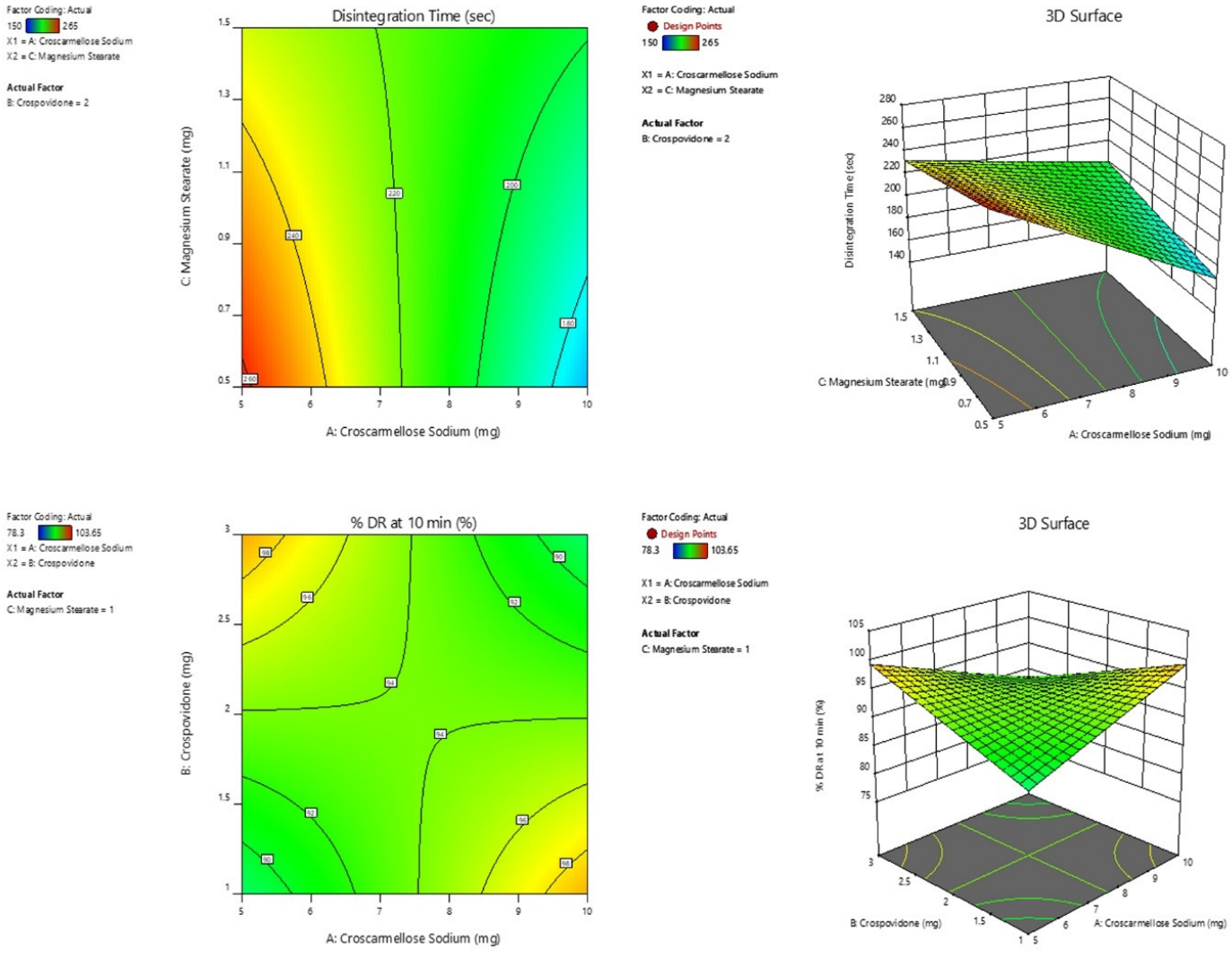

Figure 3: Overlay plot showing the design space for optimum factor conditions.

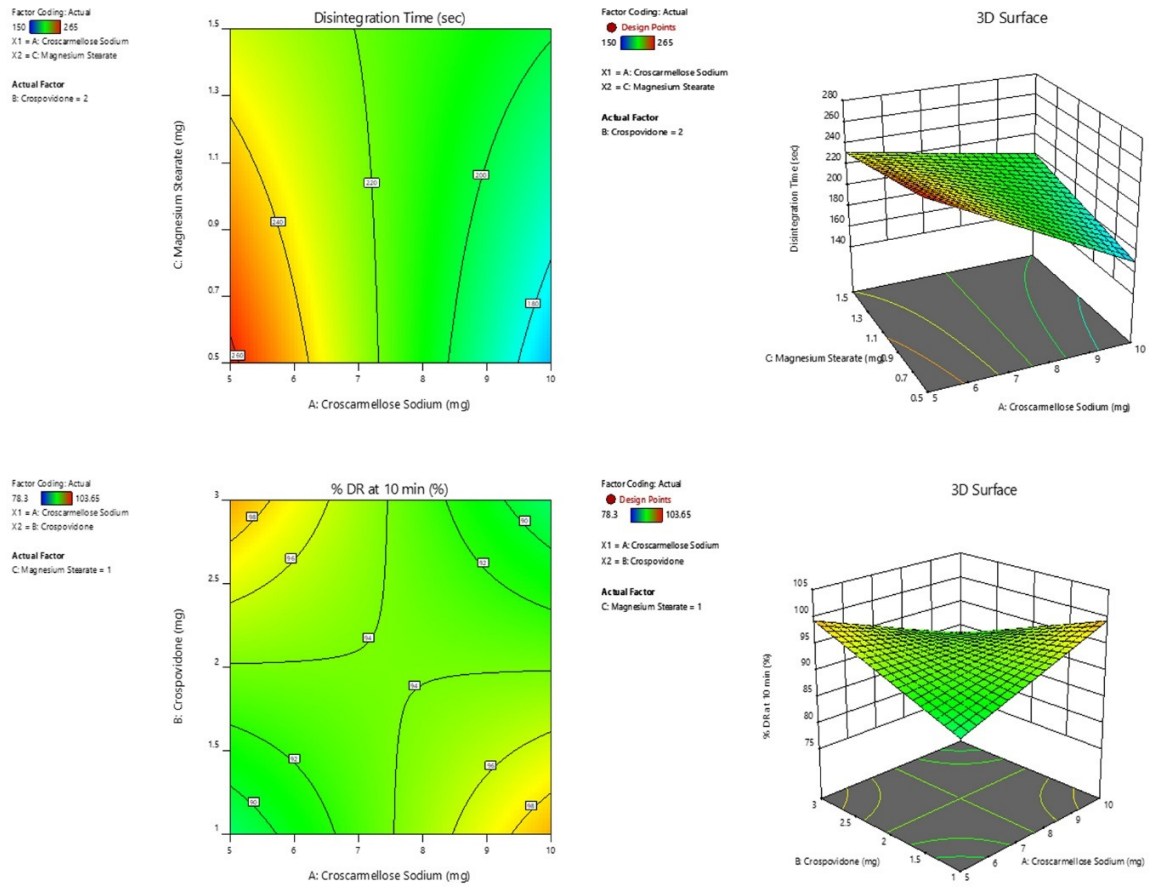

Figure 4: Effect of Croscarmellose sodium, Crospovidone and Magnesium stearate on Disintegration time and % drug release at 10 min.

Table 5: Design Summary for Ketorolac fast disintegrating tablets.

Run	Factor1	Factor2	Factor3	Response 1	Response 2
	A: Croscarmellosesodium (mg)	B: Crospovidone (mg)	C: Magnesium stearate (mg)	Disintegration time (sec)	%DRat 10min (%)
1	5	1	1.5	218	78.3
2	10	1	1.5	186	98.74
3	5	3	1.5	248	98.35
4	10	3	0.5	189	81.93
5	10	1	0.5	150	103.65
6	10	3	1.5	218	101.7
7	5	3	0.5	258	96.67
8	7.5	2	1	181	113.61
9	5	1	0.5	265	91.76

CONCLUSION

In conclusion, factorial design offers a powerful approach for systematically optimizing the formulation of ketorolac tromethamine FDTs. By studying the impact of multiple factors on tablet properties, researchers can identify formulation variables that significantly influence drug release and tablet characteristics. In this study, disintegrant concentrations and lubricant concentration were identified as critical factors affecting the disintegration time and percent drug release of ketorolac tromethamine FDTs. In comparison to other formulations tested,

the one with a higher concentration of croscarmellose sodium as the super disintegrant performed very well.

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ABBREVIATIONS

FDT: Fast Disintegrating Tablet; **KRT:** Ketorolac Tromethamine; **NSAID:** Nonsteroidal Anti-Inflammatory Drug; **USFDA:** United States Food and Drug Administration; **OFAT:** One-Factor-at-a-Time; **BD:** Bulk Density; **TD:** Tapped Density; **CI:** Carr's Index; **HR:** Hausner's Ratio; **FT-IR:** Fourier Transform Infrared; **USP:** United States Pharmacopeia; **UV:** Ultraviolet; **MCC:** Microcrystalline Cellulose; **RPM:** Rotations Per Minute; **KRT:** Ketorolac Tromethamine; **µg/mL:** Micrograms per Milliliter; **nm:** Nanometer; **g/cm³:** Grams per Cubic Centimeter; **°:** Degrees.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

SUMMARY

Ketorolac's high solubility bolsters the possibility of its effectiveness in producing the intended therapeutic effect quickly after ingestion. An essential property of the medication is its high solubility in water, which speeds up its absorption and dissolution. This characteristic is especially crucial for the creation of Fast-Dissolving Tablets (FDTs), as the medication must dissolve rapidly in the oral cavity's aqueous environment. The chemical compatibility of ketorolac with the super disintegrants in the formulation was evaluated using FT-IR spectroscopy. There were no discernible changes in the FT-IR spectra of pure ketorolac and its physical mixing with super disintegrants, suggesting that no chemical interactions took place. This implies that the chemical stability of ketorolac was maintained in the presence of super disintegrants, ensuring the integrity of the drug during formulation. Ketorolac was calibrated at 321 nm using UV/visible spectrophotometry, which offered a dependable and repeatable way to measure the medication in different formulations. The precision and correctness of the procedure are validated by the calibration curve's linearity and near-one correlation coefficient. This analytical method's dependability for determining drug concentration in future dissolution tests is further supported by its conformity to Beer-Lambert Law in the concentration range of 2-12 µg/mL. Pre-compression analyses are essential for guaranteeing the powder blend's flow characteristics, which have an immediate effect on the tablet production process. It was discovered that the flow characteristics, as shown by metrics like Hausner's ratio of 1.09 to 1.43, bulk density, tapped density of 0.45 g/cm³ and 0.56 g/cm³, angle of repose between 25.5 and 29.6° and compressibility index between 8.69 and 30.35, were within allowable bounds. The powder blends exhibited good flow properties, which is essential for producing tablets with uniform weight, content, and physical characteristics. The physical properties of the tablets, including their thickness ranged from 2.2 mm to 2.5 mm, hardness, friability, weight variation, and disintegration time, were the main focus of the post-compression tests. The tablets' continuous hardness of less than 3 kg/cm² ensured that they were not overly hard, which could have prolonged the breakdown period. With values less than 1%, the friability results showed that the tablets were strong enough to resist mechanical stress during handling and shipping. Consistent content consistency in the finished dosage forms is suggested by the uniformity in tablet weight variation, which fell within an acceptable range. The tablets' disintegration time, which is critical for FDTs, was within the necessary range of less than 30 sec to 3 min, guaranteeing a quick start to action. The addition of super disintegrants effectively increased the disintegration time and drug release from the tablets, as evidenced by the *in vitro* dissolution assays. Most of the formulations showed more than 80% drug release in less than 10 min, demonstrating how effective the FDTs are at quickly delivering ketorolac. Notwithstanding, a few formulations (F4, F5, F6, F7, and F9) exhibited marginally reduced drug release; hence, additional excipient concentration optimization may be necessary to attain the intended release profile. The polynomial equations produced for the responses, which included drug release % and disintegration time, shed light on the quantitative impacts of excipient concentrations on the performance of the formulation. The results of the investigation showed that the amount of Croscarmellose sodium had a substantial influence on disintegration time, where longer disintegration times are associated with higher concentrations. On the other hand, magnesium stearate and crospovidone had less of an impact on the disintegration time. The interaction between excipients, especially when croscarmellose was combined with other excipients, prolonged the dissolving period and thus altered the drug release at 10 min. ANOVA validates the statistical significance of these results, which emphasize how crucial it is to carefully optimize excipient amounts in order to obtain the appropriate tablet properties.

All things considered, the preformulation investigations and assessments offered a thorough comprehension of the medication's characteristics and the influence of excipients on the composition. The results are encouraging and suggest that the formulated FDTs may be an effective way to administer ketorolac, with quick drug release and disintegration.

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