ORIGINAL ARTICLE

Amelioration of Orodispersible Ibuprofen Tablets through Direct Compression for Enhanced Drug Delivery

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Abstract

Aim: The current study aimed to develop orally dispersible tablets (ODTs) of ibuprofen using the direct compression method, incorporating modified agar (FD formulation) and an agar-effervescent mixture (FE formulation) as disintegrants. **Materials & Methods:** Formulations were prepared using the direct compression technique. Two types of disintegrants were employed: modified agar and agar-effervescent mixtures. The prepared tablets were evaluated for multiple quality control parameters including weight variation, uniformity of active pharmaceutical ingredient (API), wetting time, hardness, thickness, disintegration time, friability, hydration capacity, *in vitro* dispersion time, drug release profile, preliminary stability, and compatibility between API and excipients. FTIR spectroscopic analysis was performed to assess potential drug-excipient interactions. Drug release studies were conducted using phosphate buffer (pH 6.8), and release kinetics were analyzed using established mathematical models. **Results & Discussion:** The powder blends exhibited satisfactory flow and compressibility characteristics suitable for direct compression. All formulated tablets showed no signs of chipping, capping, or sticking during manufacturing. Tablet hardness, friability, and disintegration times were within pharmacopeial limits. Among the formulations, FD4 and FE3 demonstrated superior performance, with *in vitro* dispersion times of 44 seconds and 49 seconds, respectively, and wetting times of less than one minute. Both formulations exhibited high drug release-97.17% (FD4) and 98.29% (FE3)-within 15 minutes, following first-order release kinetics and the Higuchi diffusion model. FTIR analysis confirmed no drug–excipient incompatibility. Short-term stability studies indicated no significant changes in dispersion time or drug content, and statistical analysis supported the stability of both formulations. These results indicate that both FD4 and FE3 are promising candidates for fast-dissolving ibuprofen tablets. **Conclusion:** This study successfully formulated orally dispersible tablets of ibuprofen using a simple and cost-effective direct compression method. The developed tablets disintegrated rapidly in the oral cavity, showed good mechanical strength, and achieved enhanced drug dissolution. The promising performance of FD4 and FE3 formulations suggests that ODTs of ibuprofen containing disintegrants could be effective in managing conditions like emesis, offering rapid onset of action without the need for water.

Key words: Agar, direct compression method, drug dissolution, effervescent mixture, ibuprofen, orodispersible tablets

INTRODUCTION

Orodispersible tablets (ODTs) have emerged as a promising dosage form for such targeted drug delivery, particularly for people who cannot swallow conventional tablets (e.g. pediatric, geriatric, and dysphagic patients).[1] The direct compression method, which is known for its simplicity and cost-effectiveness, has drawn

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significant attention in the pharmaceutical industry for ODT development.[2]

Ibuprofen (IBP), as a Nonsteroidal anti-inflammatory drug (NSAID), is frequently prescribed for the treatment of pain and inflammation caused by a range of illnesses such as dental pain, menstrual pain, and arthritis.[3] IBP is classified as a BCS class-II drug because of its weak solubility, and its solubility profile shows a pH dependency. Furthermore, IBP has a short elimination half-life of approximately 1.8–2 h. Its clinical applicability is therefore limited by its short elimination half-life and low solubility, and a multiple-dosage regimen is necessary to maintain the ideal plasma drug concentration.[4,5] As a result, for medications with limited solubility to reach a therapeutically meaningful plasma concentration, a large dose of the drug must be administered. Due to their high concentration, poorly soluble drugs that are given in large quantities have decreased systemic bioavailability and increased local toxicity at sites of aggregate deposition. However, its conventional oral formulations often present challenges such as delayed onset of action and gastrointestinal side effects, limiting its therapeutic efficacy and patient compliance.[6]

The development of orodispersible IBP tablets using the direct compression method offers a promising approach to address these challenges. Rapid breakdown in the oral cavity is the goal of this dosage form, which leads to faster onset of action and improved patient compliance.[7] Superdisintegrants play a pivotal role in ODT formulations. Synthetic superdisintegrants are commonly used, whereas natural polymers, such as agar, offer eco-friendly, biocompatible, and cost-effective alternatives.[8] Moreover, the direct compression method facilitates the incorporation of excipients that enhance the solubility and bioavailability of IBP, potentially reducing the dose required to achieve therapeutic effects and minimizing adverse reactions.[9]

This study focused on the formulation development of IBP ODTs prepared by using agar as a super-disintegrating agent and the direct compression method, investigating various formulation parameters to optimize the tablet disintegration time, mechanical strength, and drug release profile. The results of this study have the potential for the development of an effective and patient-friendly dosage form of IBP, contributing to improved pain management and overall patient satisfaction.[10]

In summary, the development of IBP or dispersible tablets through direct compression represents a significant advancement in drug delivery systems, with the ability to improve therapeutic outcomes and patient adherence. This study aims to explore and optimize the formulation parameters of IBP ODTs, understanding the possible advantages and practical applications of this innovative dosage form in clinical practice.[11]

The chemical structure of ibuprofen is shown in Figure 1. The mechanism of action of superdisintegrants used in the formulation is illustrated in Figure 2.

MATERIALS AND METHODS

Material

The ingredients used in this work were commercial samples. IBP (GlaxoSmithKline Pharmaceuticals Ltd., Nashik, Maharashtra), as well as mannitol, sodium bicarbonate, tartaric acid, sodium lauryl sulfate, Purified Talc, aspartame, peppermint flavor, potassium dihydrogen orthophosphate, and disodium hydrogen phosphate, all of which are sourced from Loba Chemie Pvt. Ltd.

Method

Preparation of treated agar (TAG) as superdisintegrant

To make TAG powders, 5–10 g of powder was taken individually and mixed with distilled water of 100 mL. Continuous stirring was done for 1 day with stirrer at 37 ± 1 °C. This caused swelling and water absorption. After that, it was kept in big petri plate for drying for 3 days at 37 ± 1 °C in incubator.[12] The treated agar preparation process is represented diagrammatically in Figure 3. The particle size distribution of agar and treated agar is shown in Table 1.

Mechanism of action TAG as super disintegrating agent[13]:

- TAG, a polysaccharide composed of agaropectin and agarose, acts as an effective superdisintegrant due to its high gel strength and desirable swelling behavior.
- Agarose imparts gel strength, while agaropectin contributes to viscosity. Its porous structure, strong water absorption, and free-flowing nature enhance tablet disintegration.

Formulation of ODTs

Direct compression method[14]

Five formulations (FD1–FD5) were prepared using varying concentrations of TAG and microcrystalline cellulose. Ingredients were sieved (#60), blended geometrically, and compressed into 200 mg tablets using an 8 mm flat punch. The composition of the ibuprofen orodispersible tablets prepared by the direct compression method is presented in Table 2.

Effervescent method

For formulations FE1–FE5, all ingredients were sieved (#60) and mixed geometrically. Preheated sodium bicarbonate and tartaric acid (80°C, 2 h) were blended and incorporated.

Table 1: Particle size distribution analysis of agar and modified agar

Agar			Treated agar		
Sieve no.	Weight retained (g)	Percentage of retained	Sieve no.	Weight retained (gm)	Percentage of retained
60	1.53	76.50	60	0.07	3.5
85	0.35	17.50	85	0.41	20.5
100	0.10	5.00	100	0.84	42.0
120	0.02	1.00	120	0.68	34.0
Total	2.00	100	Total	2.00	100

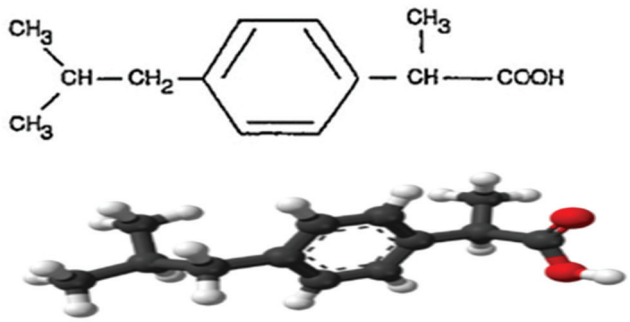

Figure 1: Structure of ibuprofen

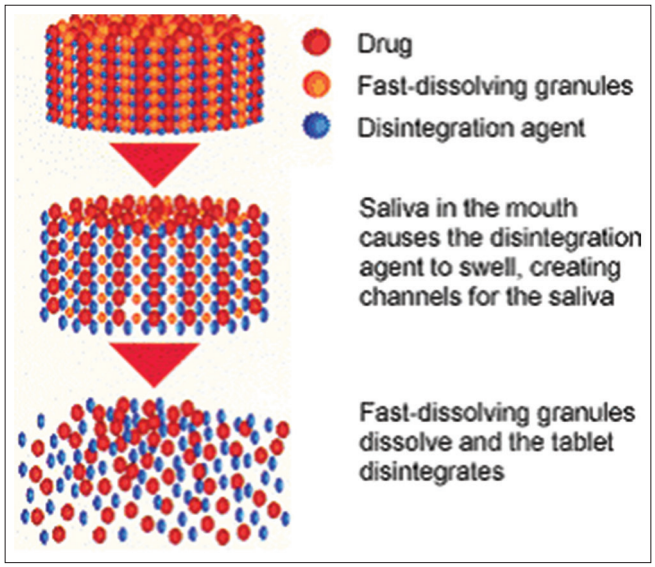

Figure 2: Mechanism of action of superdisintegrants

Finally, talc and sodium lauryl sulfate were added and mixed for 2 min before compression. The composition of formulations prepared by the effervescent method is given in Table 3.

Evaluation

Characterization of drug

The sample of IBP drug was characterized in terms of its organoleptic properties, melting point etc.

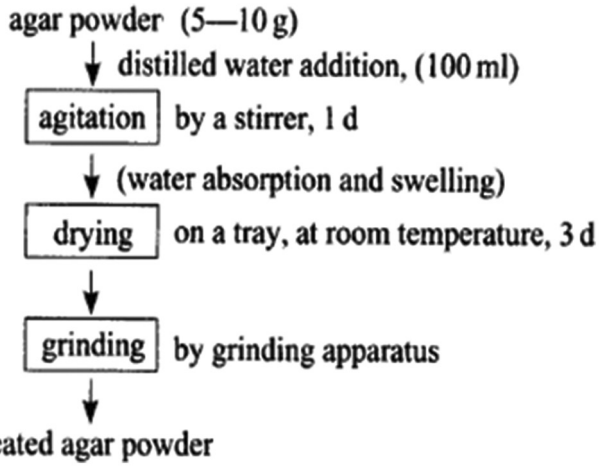

Figure 3: Diagrammatic illustration for treated agar preparation

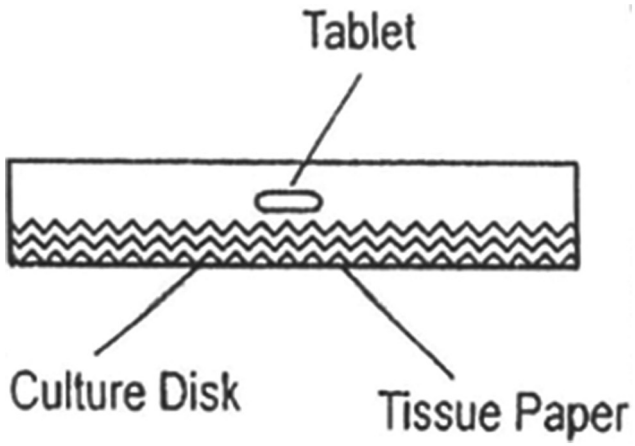

Figure 4: Diagrammatic illustration of water absorption and wetting time

Melting point[15]

Capillary tube was fused from one side and filled with drug. The sample was loaded into the melting point apparatus. Then melting point of pure substance was determined.

Drug solubility[16]

Drug solubility was assessed by dissolving a small quantity of it in various solvents, including deionized water, 0.1N HCl, 0.1N NaOH, and a buffer solution with a pH of 6.8.

Table 2: Composition of direct compression-prepared Ibuprofen tablets

Ingredients (mg)	Formulation code				
	FD1	FD2	FD3	FD4	FD5
Ibuprofen	100	100	100	100	100
Mannitol	2	2	2	2	2
SLS	1	1	1	1	1
Purified talc IP	1	1	1	1	1
TAG*	-	12	16	20	25
MCC*	96	84	80	76	71
Flavor	q.s.	q.s.	q.s.	q.s.	q.s.
Total	200	200	200	200	200

TAG*: Treated agar, MCC*: Microcrystalline cellulose

Table 3: Composition of ibuprofen orodispersible tablets (Effervescent technique)

Ingredients (mg)	Formulation code				
	FE1	FE2	FE3	FE4	FE5
Ibuprofen	100	100	100	100	100
Sodium bicarbonate	16	10	12	16	20
Tartaric acid	16	10	12	16	20
Mannitol	2	2	2	2	2
SLS	1	1	1	1	1
Purified Talc IP	1	1	1	1	1
TAG*	-	15	15	15	15
MCC*	64	61	57	49	41
Flavor	q.s.	q.s.	q.s.	q.s.	q.s.
Total	200	200	200	200	200

TAG*: Treated agar, MCC*: Microcrystalline cellulose

Table 4: Flow characteristics determination[24]

Carr's index (%)	Flow ability	Hausner's ratio range
≤10	Excellent	1–1.11
12–16	Good	1.12–1.18
18–20	Moderate	1.19–1.25
23–28	Acceptable	1.26–1.34
28–35	Poor	1.35–1.45
32–87	Very poor	1.46–1.59
>40	Extreme poor	>1.6

Determination of λ_{max} of IBP[17]

10 mg of IBP was dissolved in 100 mL of pH 6.8 buffer solution, which gives 100 µg/mL of concentration. Using this solution, the λ_{max} of IBP was determined in a ultraviolet (UV) spectrophotometer.

Construction of a calibration curve in a 6.8 pH phosphate buffer[18]

IBP (10 mg) was dissolved in 100 mL of phosphate buffer (pH 6.8) to create a 100 µg/mL solution. Using this stock solution, concentrations of 2, 4, 6, 8, 10, 12, and 14 µg/mL were prepared. The absorbance of each solution was determined at 220 nm, and the results were recorded. The correlation coefficient was calculated. Table 8 mentions the absorption result.

Table 5: Impact of repose angle on flow characteristics

Angle of repose	Flow characteristics
<20°	Excellent
20°–30°	Good
30°–34°	Passable
>40°	Very poor

Table 6: Percentage of weight variation

Average tablet weight	Percentage Weight Variation Limits (±%)
130 or less	±10
130–324	±7.5
≥324	±5

Table 7: Physical characterization of drug

S. No.	Properties	Specification
1	Color	white
2	Physical form	crystalline
3	Taste	tasteless
4	Melting point	76°C

Table 8: Construction of calibration curves of ibuprofen in phosphate buffer pH 6.8

S. No.	Concentration (µg/mL)	ABS.
1	0	0
2	2	0.122
3	4	0.218
4	6	0.3
5	8	0.39
6	10	0.478
7	12	0.577
8	14	0.661

Drug – excipients compatibility studies[19]

It is essential to ensure that the drug is compatible with the excipient being used and that it has not degraded during the various stages while developing a new formulation. Infrared spectroscopy effectively detects functional group changes in molecules. Fourier transform infrared spectroscopy (FTIR) spectra of IBP and its formulations were recorded

Table 9: Drug-excipient interaction studies (by FT-IR)

Formulation	=OH stretching (cm^{-1})	-C=O stretching (cm^{-1})	-CH stretching (cm^{-1})	-CH stretching in $-CH_3$ sym. (cm^{-1})	$-CH_2$ stretching sym. (cm^{-1})	-CH def. in $-CH_3$ stretching a sym. (cm^{-1})
Pure drug of Ibuprofen	3520.01	1720.85	866.08	2868.31	2922.08	1461.85
FD4	3525.34	1721.23	866.25	2867.70	2923.54	1459.85
FE3	3519.47	1723.65	866.25	2851.23	2921.09	1463.23

Table 10: Ibuprofen pre-compression parameters for FD1-FD5 and FE1-FE5 blends

Formulation	Bulk density (g/cm^3)	Tapped density (g/cm^3)	Angle of repose (°)	Carr's index (%)	Hausner ratio
FD1	0.49	0.57	21.62	14.04	1.16
FD2	0.48	0.55	21.57	12.72	1.14
FD3	0.46	0.53	23.66	13.20	1.15
FD4	0.43	0.49	25.31	12.24	1.14
FD5	0.41	0.47	23.24	12.76	1.14
FE1	0.39	0.44	23.69	11.36	1.12
FE2	0.55	0.64	24.51	14.06	1.16
FE3	0.53	0.61	25.43	13.11	1.15
FE4	0.50	0.58	26.24	13.79	1.16
FE5	0.49	0.56	26.19	12.50	1.14

using the KBr pellet method (Perkin Elmer FTIR RXI) to assess potential drug-carrier interactions. The FTIR analysis results of ibuprofen with excipients are provided in Table 9, confirming no significant interaction between drug and excipients.

Pre-compression evaluation

Bulk density (D_b)[20]

This calculation involves dividing the powder's bulk volume (V0) by its total mass (M). The weighed powder was first passed through a #20 mesh sieve and then transferred into a measuring cylinder. The initial volume, referred to as bulk volume, was recorded. Bulk density can be determined using the below-provided formula, and its unit is g/cc. The flow characteristics such as angle of repose, Carr's index, and Hausner ratio of the powder blend are shown in Table 4. The effect of repose angle on the flow properties of the powder blend is presented in Table 5.

$$D_b = \frac{M}{V_0}$$

Tapped density (D_t)[21]

It is defined as the ratio of the total mass (M) to the tapped volume (V_t). The volume was determined through 500 taps of the powder. The tapped volume was then recorded after the tapping was completed 750 times; the difference between these two volumes should be <2%. If it exceeds 2%, 1250 taps are made, and the volume of each tap is recorded. This can be represented in g/cc:

$$D_t = \frac{M}{V_1}$$

Carr's index (CI) and Hausner's ratio (HR)[22,23]

Above two parameters are indicators of powder compressibility and flow properties, calculated using the following equations:

$$CI\ (\%) = 100 \times \frac{Dt - Db}{Dt}$$

$$HR = \frac{Dt}{Db}$$

Angle of repose (θ)[24]

The angle of repose (θ) was determined using the fixed funnel method, where the powder blend was allowed to flow freely through a funnel to form a conical pile. The height (h) and radius (r) of the pile were measured, and the angle of repose was calculated using:

$$\tan \theta = \tan^{-1} (h/r)$$

Table 11: Post-compression evaluation parameters of Ibuprofen orodispersible tablets (FD1-FD5 and FE1-FE5)

Formulation	Hardness (kg/cm²)	Friability (%)	Dispersion time (sec)	Wetting time (sec)	Water absorption (%)	Drug content (%)	Weight variation
FD1	3.03	0.62	56	34	149	95.33	0.82
FD2	3.45	0.77	58	24.69	153	97.65	0.75
FD3	2.83	0.68	52	23	162	97.58	0.81
FD4	4.41	0.66	44	22.12	173	98.66	0.69
FD5	3.69	0.96	45	19.57	174	93.11	0.82
FE1	3.73	0.72	50	40	167	94.58	0.74
FE2	3.92	0.78	52	35.50	172	97.89	0.78
FE3	4.12	0.68	49	29.74	179	98.52	0.68
FE4	3.90	0.76	50	28.15	178	95.59	0.71
FE5	4.10	0.72	50	27.68	181	95.14	0.72

Post-compression evaluation

The produced tablets were assessed for quality control tests, which are mention as follows-:

The pre-compression parameters of FD and FE formulation blends are summarized in Table 10.

Test for weight variation[25]

It involves weighing a set number of tablets (typically 20) individually, then calculating the average weight. The weight of each tablet is compared with the average. The pharmacopeial limits for percentage weight variation of tablets are summarized in Table 6. The physical properties of ibuprofen, such as color, odor, solubility, and melting point, are listed in Table 7. The data are presented in Table 11.

Hardness and friability[26]

Tablet hardness was measured using a Monsanto hardness tester, with results expressed in kg/cm². The friability was assessed using a Roche Friabilator, where tablets were subjected to 100 rotations at 25 rpm, dropping from a height of 6 inches each time. After the test, the tablets were reweighed and dusted to determine weight loss. The results are summarized in Table 11.

$$\text{Friability } (\%) = \frac{Wo - W}{Wo} \times 100$$

W_0 = tablets weight before test
W = tablets weight after test

Content uniformity test[27]

For each formulation, 20 tablets were weighed, ground into powder, and a 50 mg IBP equivalent was extracted and dissolved in 0.1 N NaOH to a final volume of 100 mL. After filtration and discarding the initial filtrate, a 11.5 mL aliquot was further diluted in 0.1 N NaOH. The absorbance of the diluted solution was measured at 220 nm using a UV spectrophotometer to determine IBP content. The content should be between 90.0% and 110.0% of the stated amount. Results are shown in Table 11.

Wetting time and water absorption ratio[28]

A sheet of tissue paper that had been folded twice was used to line a small petri dish that had an interior diameter of 5 cm and was filled with 6 mL of water. The amount of time needed for the tablet to completely wet was recorded while it was placed on the paper. The tablet that had been moistened was then weighed. The outcomes were shown in Table 11. The water absorption and wetting process are shown in Figure 4.

Water absorption ratio (R) was determined through following formula:

$$R = 100 \times \frac{W2 - W1}{W1}$$

W_2 represents the tablet's weight after water absorption, W_1 indicates its weight before absorption.

In vitro dispersion time[29]

A tablet was introduced into 10 mL buffer solution with a pH of 6.8, maintained at 37 ± 0.5°C. The duration required for the complete dissolution of the tablet was recorded. Figures 5 and 6, 15, 16 Table 11 showed the results.

Dissolution test[30]

The dissolution of IBP mouth-dissolving tablets was assessed using a USP XXIII Type-II dissolution apparatus with a paddle rotating at 50 rpm. The test was conducted in 900 ml of pH 6.8 phosphate buffer, maintained at 37 ± 0.5°C. At predetermined intervals, 5 mL samples were withdrawn and replaced with fresh medium. Absorbance was measured at 220 nm using a spectrophotometer, and the cumulative drug release percentage was plotted over time. The *in vitro* release data were analyzed using various kinetic models, including

Figure 5: Dispersion time of FD4 formulation under *in vitro* conditions

Figure 6: Dispersion time of FE3 formulation under *in vitro* conditions

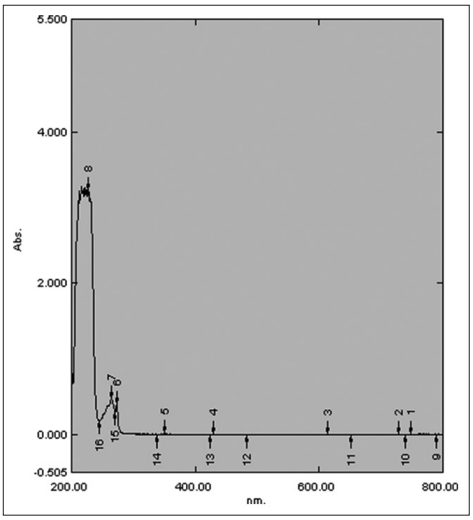

Figure 7: Scan of Ibuprofen in 6.8 pH buffer

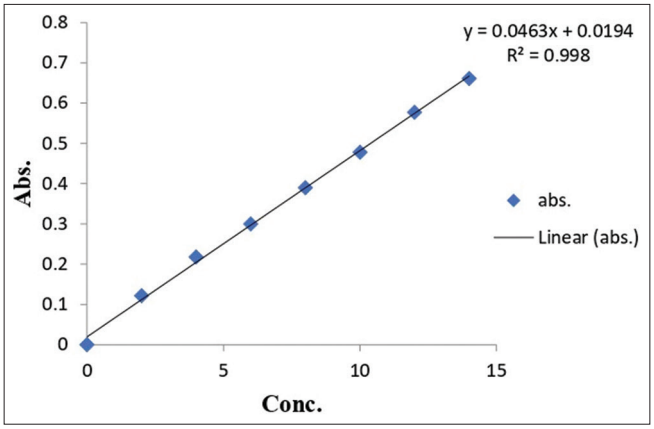

Figure 8: Calibration curve of Ibuprofen

Higuchi, Korsmeyer-Peppas, Zero Order, and First Order. Results are presented in Tables 12 and 13.

Stability testing[31]

To evaluate the stability of promising IBP formulations, FD4 and FE3, accelerated stability tests were performed. Fifteen tablets were placed in amber-colored vials with rubber stoppers and stored in a stability chamber (Osworld) at an elevated temperature of 40°C/75% RH for 90 days. The tablets were examined monthly for any physical changes, drug content, and *in vitro* dispersion time. The results are detailed in Table 14.

RESULTS AND DISCUSSION

Determination of λ_{max} of IBP

A 10 mg dose of IBP was dissolved in 100 mL of Phosphate solution adjusted to pH 6.8, which gives you 100 µg/mL of concentration. Using this solution, the λ_{max} of IBP was determined in UV spectrophotometer. The λ_{max} of IBP was found at 220 nm. The UV scan of ibuprofen in pH 6.8 buffer is shown in Figure 7. The calibration curve for ibuprofen is presented in Figure 8.

Drug-excipient compatibility study

The IR spectra of pure IBP and the formulations FD4 and FE3 exhibit characteristic absorption bands corresponding to functional groups such as =OH, -C=O, -CH, and -CH_2. The presence of comparable peaks in the formulations confirms

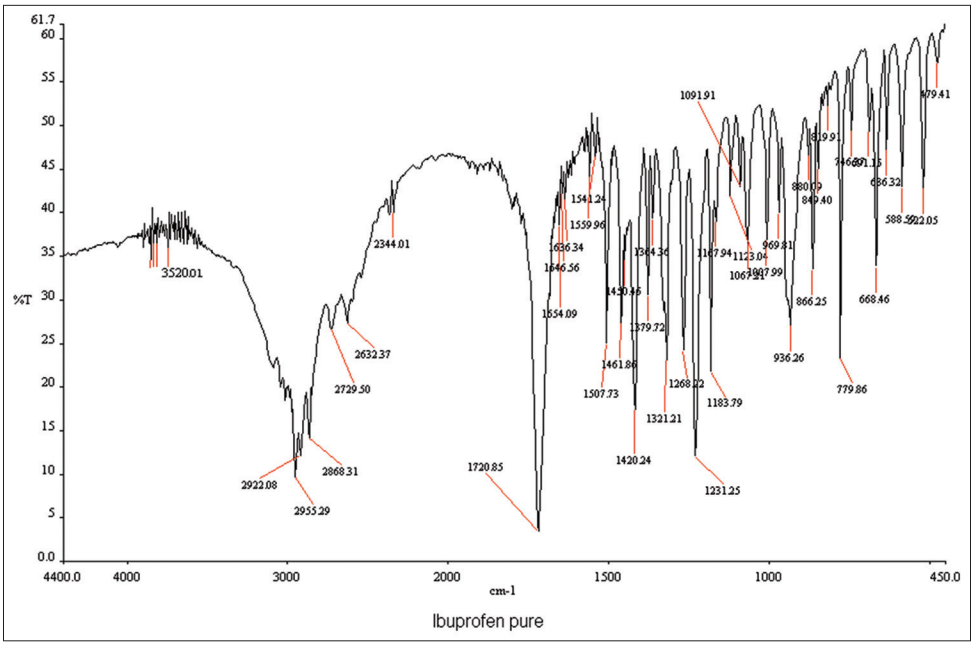

Figure 9: Infrared spectra of Ibuprofen

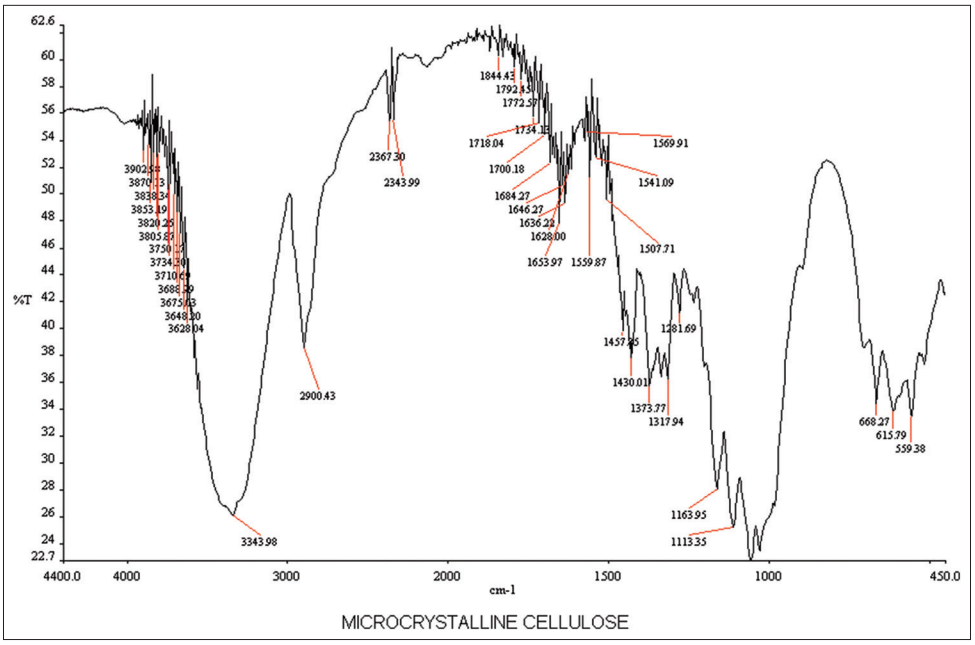

Figure 10: Infrared spectra of microcrystalline cellulose

Table 12: *In vitro* dissolution data for ibuprofen Orodispersible tablets in 6.8 pH buffer

Time (min)	FD1	FD2	FD3	FD4	FD5	FE1	FE2	FE3	FE4	FE5
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
2	22.1	30.7	33.5	43.4	33.4	29.3	32.2	43.1	39.2	37.2
4	25.4	35.3	41.7	54.5	41.4	35.6	47.6	57.5	52.7	49.2
6	35.7	44.3	54.3	66.7	59.6	44.7	52.4	68.2	61.7	57.3
8	42.5	57.8	61.5	79.5	65.6	59.5	66.4	73.7	70.3	68.5
10	59.6	66.8	74.8	86.2	79.9	62.3	75.2	87.1	77.2	74.7
15	68.7	78.8	82.2	97.2	87.2	75.2	87.8	98.3	89.4	84.7

Data are mean of *n*=3 determination±SD

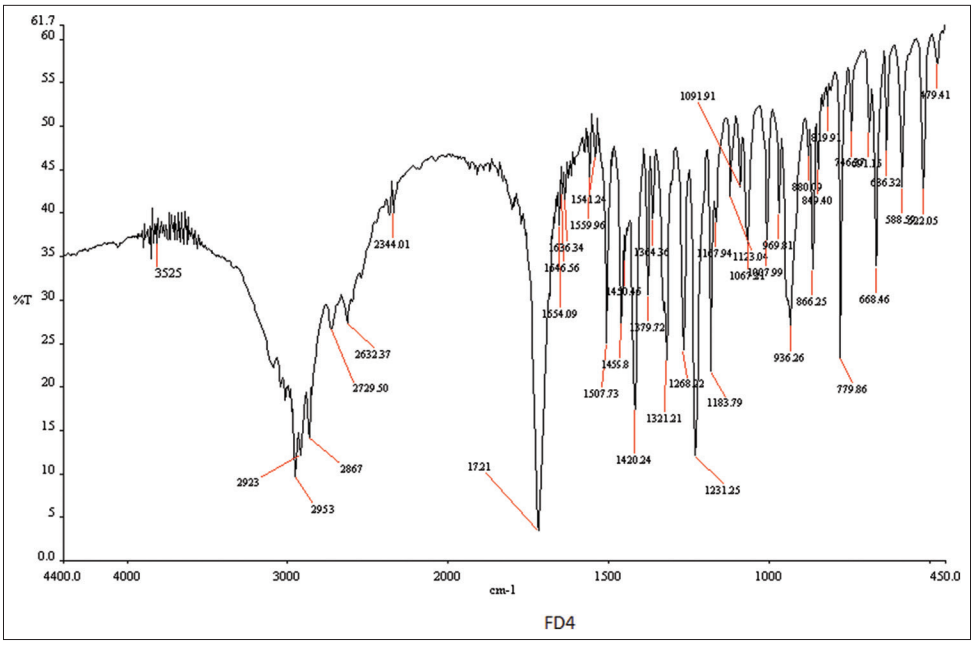

Figure 11: Infrared spectra of FD4 formulation

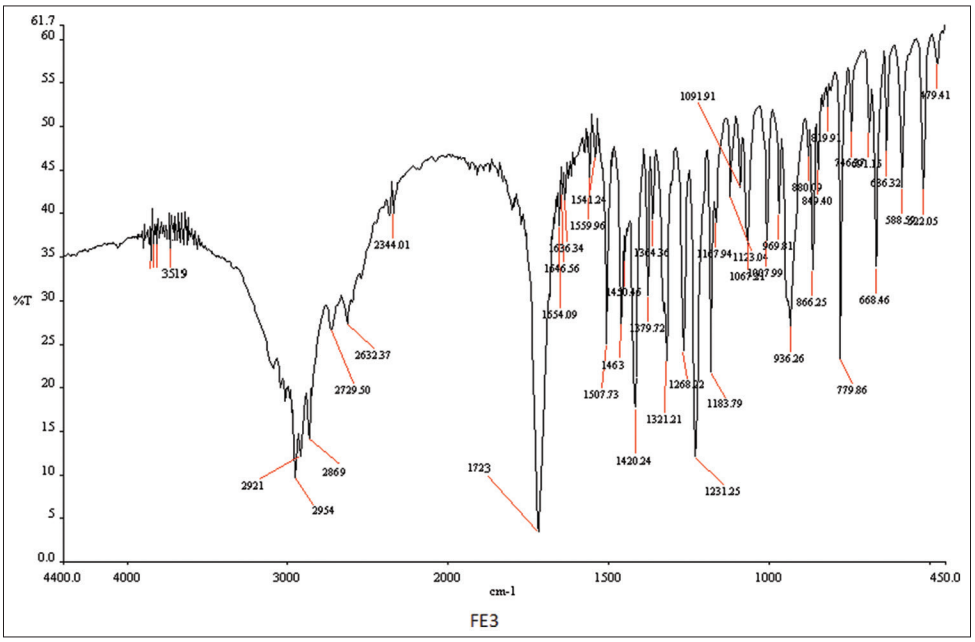

Figure 12: Infrared spectra of FE3 formulation

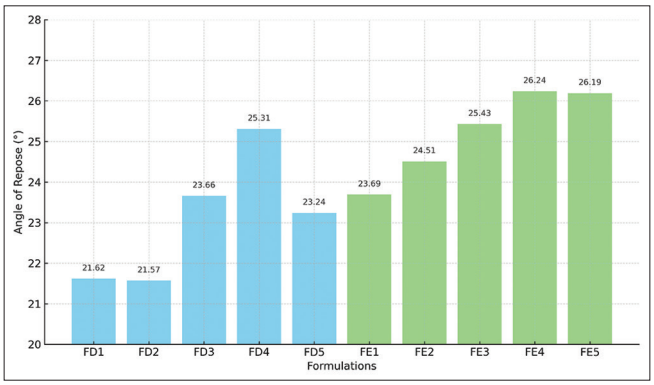

Figure 13: Angle of repose

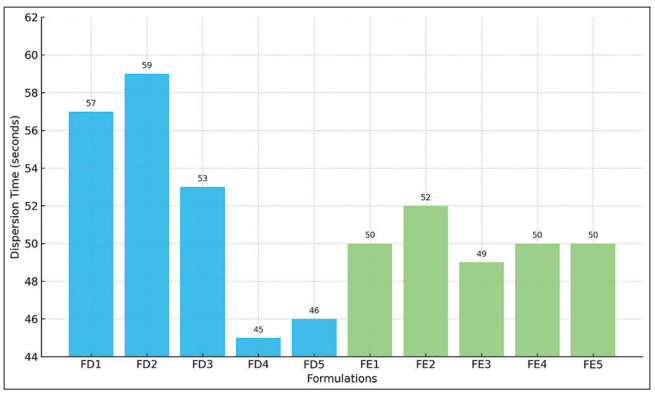

Figure 14: *In vitro* dispersion time

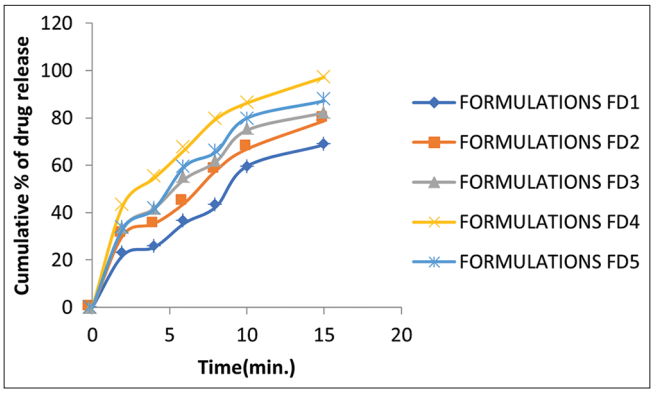

Figure 15: Zero-order release of FD formulations

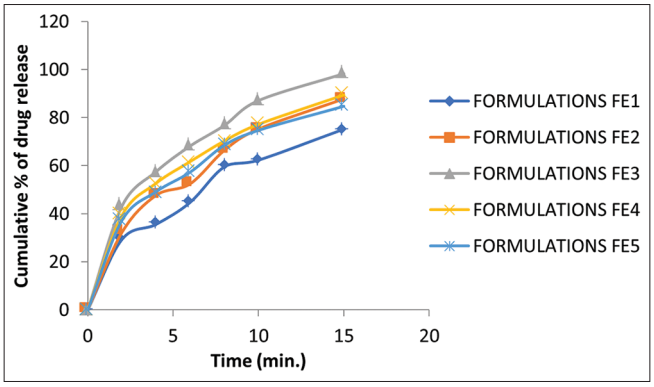

Figure 16: Zero-order release of FE formulations

that the drug remains chemically unaltered, indicating no interactions between the drug and excipients. Detailed IR spectra for IBP, MCC, FD4, FE3, and TAG are shown in Figures 9-12. The FTIR spectra of MCC confirming compatibility are displayed in Figure 10.

The pre-compression evaluation of all formulations (FD1–FD5 and FE1–FE5) showed bulk density ranging from 0.39 to 0.55 g/cm^3 and tapped density from 0.44 to 0.64 g/cm^3. Confidence interval values were observed between 11.36% and 14.06%, and HR ranged from 1.12 to 1.16, indicating acceptable compressibility. The angle of repose varied from 21.57° to 26.24°, suggesting good flow properties suitable for direct compression. The angle of repose for various formulations is illustrated in Figure 13. The in-vitro dispersion time of the optimized formulation is shown in Figure 14.

All formulations exhibited acceptable hardness ranging from 2.83 to 4.41 kg/cm^2 and friability values well below the 1% limit, indicating good mechanical strength. The dispersion time ranged from 44 to 58 s, with FD4 and FD5 showing the fastest disintegration. Wetting time varied from 19.57 to 40 s, and water absorption ratios were highest for FE5 (181%) and FD5 (174%), reflecting efficient fluid uptake. Drug content was within acceptable limits (93.11–98.66%), confirming uniformity among all batches. Weight variation among the tablets ranged from 0.68 g to 0.82 g, indicating

Table 13: Release kinetic data of ODT formulations

Formulations	Zero order (R^2)	First order (R^2)	Higuchi plot (R^2)	Plot of korsmeyer peppas	
				(R^2)	*n*
FD1	0.944	0.969	0.953	0.931	0.61
FD2	0.913	0.985	0.984	0.948	0.50
FD3	0.875	0.977	0.984	0.967	0.51
FD4	0.879	0.981	0.989	0.988	0.42
FD5	0.836	0.978	0.985	0.967	0.51
FE1	0.895	0.979	0.988	0.966	0.49
FE2	0.891	0.945	0.990	0.987	0.50
FE3	0.836	0.995	0.997	0.990	0.41
FE4	0.834	0.99	0.991	0.994	0.42
FE5	0.837	0.983	0.990	0.990	0.41

Table 14: Stability data of optimized ibuprofen formulations (FD4 and FE3) Stored at 40 ± 2°C/75 ± 5% RH for 3 Months

Time (Days)	Formulation	Drug content (%)	*In vitro* dispersion time (s)	Physical changes
1	FD4	98.66	50	—
30	FD4	98.06	50	No changes
60	FD4	97.96	49	No changes
90	FD4	97.92	49	No changes
1	FE3	98.52	49	—
30	FE3	98.26	48.12	No changes
60	FE3	98.22	49	No changes
90	FE3	97.89	48	No changes

uniformity across all formulations. These results confirm that all batches met pharmacopeial standards for ODTs, among them, FD4 and FE3 emerged as the most promising formulations.

The *in vitro* drug release from all formulations increased progressively over 15 min, with final release ranging from 68.7% (FD1) to 98.3% (FE3). Among direct compression batches, FD4 showed maximum release (97.2%), while FE3 exhibited the highest release among effervescent formulations, confirming both as optimized batches.

Drug release followed first-order and Higuchi models, indicating diffusion-controlled mechanisms. Korsmeyer-Peppas *n* values (0.41–0.61) suggest non-Fickian release. FD4 and FE3 showed the best kinetic fit, confirming them as optimized formulations.

The calculated t-values for FD4 and FE3 were 1.12 and 2.15, respectively, which are below the critical value of 4.3 ($P < 0.05$), indicating no significant changes in drug content over the 3-month periods. The zero-order release kinetics of

FD and FE formulations are presented in Figures 15 and 16, respectively.

CONCLUSION

This research aimed to develop and evaluate IBP ODTs using direct compression techniques. Various properties were assessed, including weight consistency, drug content uniformity, tablet hardness and thickness, disintegration time, friability, water absorption ratio, wetting time, *in vitro* dispersion time, dissolution rate, and potential interactions between the drug and excipients. In addition, a short-term stability study was conducted. The results indicated that the formulation exhibited satisfactory flow characteristics, and the directly compressed tablets showed no signs of chipping, capping, or sticking. The tablets' disintegration time was within the desired range, and their hardness remained within acceptable limits. Friability values were also within the specified threshold. The *in vitro* dispersion time ranged from 44 to 58 s. Drug release was found to be 97.17% and 98.29% for the FD4 and FE3 formulations, respectively, within 15 min in a pH 6.8 phosphate buffer solution. The study concluded that direct compression is a simple and economical method for preparing IBP ODTs. FD4 and FE3 were identified as promising formulations with excellent mechanical and physical characteristics. They best fit first-order release kinetics and followed the Higuchi mechanism. The short-term stability study showed no significant changes in drug content or *in vitro* dispersion time. Statistical analysis confirmed that the drug content in the FD4 and FE3 formulations remained stable after the stability study. Overall, this research demonstrated the effectiveness of orodispersible IBP tablets prepared by direct compression as a promising strategy for improving drug delivery.

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