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Formulation and Evaluation of Fast Dissolving Tablets of Ketoprofen Using Natural and Synthetic Superdisintegrants

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Abstract:

The present study was aimed at the formulation and evaluation of fast dissolving tablets (FDTs) of ketoprofen to improve its dissolution rate, bioavailability, and patient compliance. Ketoprofen, a non-steroidal anti-inflammatory drug (NSAID), exhibits poor aqueous solubility which limits its oral absorption. In the present work, fast dissolving tablets were prepared by direct compression method using synthetic superdisintegrants such as crospovidone and sodium starch glycolate along with *Ocimum basilicum* mucilage as a natural excipient. The prepared powder blends were evaluated for preformulation parameters including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio to assess their flow properties. The formulated tablets were evaluated for various physicochemical parameters such as hardness, friability, weight variation, wetting time, water absorption ratio, drug content, in-vitro dispersion time, and in-vitro dissolution studies. FTIR studies confirmed the compatibility of ketoprofen with selected excipients. The prepared formulations exhibited satisfactory mechanical strength and rapid disintegration characteristics. Among all formulations, batch F11 showed the best performance with rapid dispersion time and maximum cumulative drug release of 98.31% within 20 min.The results demonstrated that the developed fast dissolving tablets of ketoprofen significantly improved the dissolution profile of the drug and may enhance its bioavailability and therapeutic efficacy. The study concluded that direct compression technique using suitable superdisintegrants and natural excipients is an effective approach for the development of ketoprofen fast dissolving tablets.

Keywords: Ketoprofen; Fast dissolving tablets; Direct compression; Superdisintegrants; Crospovidone; Sodium starch glycolate; *Ocimum basilicum*; In-vitro dissolution; Drug release; FTIR studies.

Introduction

Oral drug delivery remains the most preferred route of administration due to its convenience, cost-effectiveness, ease of manufacturing, and improved patient compliance. However, many orally administered drugs exhibit poor aqueous solubility, which significantly limits their dissolution rate and oral bioavailability. According to the Biopharmaceutical Classification System (BCS), poorly water-soluble drugs often demonstrate incomplete absorption and variable therapeutic response. Ketoprofen, a non-steroidal anti-inflammatory drug (NSAID), is widely used in the management of pain, inflammation, rheumatoid arthritis, osteoarthritis, and musculoskeletal disorders. Despite its therapeutic effectiveness, ketoprofen exhibits poor aqueous solubility, which restricts its dissolution in gastrointestinal fluids and subsequently reduces its bioavailability.[1-3]

Enhancing the solubility and dissolution behavior of poorly soluble drugs has become a major challenge in pharmaceutical formulation development. Various techniques such as micronization, complexation, nanotechnology, and solid dispersion have been investigated to improve the dissolution profile of hydrophobic drugs. Among these approaches, solid dispersion technology has emerged as one of the most effective and widely accepted methods for enhancing drug solubility and dissolution rate. In solid dispersion systems, the drug is dispersed within a hydrophilic carrier matrix, resulting in reduced particle size, improved wettability, enhanced porosity, and conversion of the drug from crystalline to amorphous form. These factors collectively contribute to improved dissolution characteristics and enhanced oral absorption. [4-5] Fast dissolving tablets (FDTs) have gained considerable attention in recent years as an advanced oral drug delivery system designed to disintegrate or dissolve rapidly in the saliva without the need for water. FDTs offer several advantages including rapid onset of action, improved patient compliance, ease of administration, and enhanced convenience, particularly for pediatric, geriatric, and dysphagic patients who experience difficulty swallowing conventional tablets. The rapid disintegration of FDTs increases the surface area available for dissolution, thereby facilitating faster drug release and absorption.[6-8]

The incorporation of ketoprofen solid dispersion into fast dissolving tablets presents a promising strategy for improving both the dissolution rate and therapeutic performance of ketoprofen. By combining the advantages of solid dispersion technology with the rapid disintegration properties of FDTs, it is possible to achieve enhanced drug release, improved bioavailability, and faster onset of analgesic action. Selection of suitable superdisintegrants, diluents, binders, and manufacturing techniques plays a crucial role in the successful development of FDT formulations with acceptable mechanical strength and rapid disintegration characteristics.[9-11] The present study focuses on the formulation and evaluation of fast dissolving tablets containing ketoprofen solid dispersion. The study aims to improve the solubility and dissolution behavior of ketoprofen using suitable hydrophilic carriers and subsequently incorporate the optimized solid dispersion into FDT formulations. The prepared formulations are evaluated for various pre-compression and post-compression parameters including powder flow properties, hardness, friability, wetting time, disintegration time, drug content uniformity, and in vitro drug release profile. Furthermore, stability studies are carried out according to ICH guidelines to ensure the physical and chemical stability of the optimized formulation during storage. The successful development of ketoprofen FDTs with enhanced dissolution properties may provide improved therapeutic efficacy and better patient compliance compared to conventional dosage forms.

Materials and Methods

Materials

Ketoprofen was obtained from Sun Pharmaceutical Industries and used as the active pharmaceutical ingredient.

Crospovidone, sodium starch glycolate, camphor, magnesium stearate, purified talc, and saccharin sodium were used as excipients. *Ocimum basilicum* seeds were used for extraction of natural mucilage. All chemicals and reagents used in the study were of analytical grade.

Instruments: The study was carried out using analytical balance (Shimadzu), UV–Visible spectrophotometer (Shimadzu UV-1800), FTIR spectrophotometer (Shimadzu IRAffinity-1S), digital pH meter, hot air oven, HPLC system, Monsanto hardness tester, Roche friabilator, Vernier calipers, USP disintegration apparatus, and USP dissolution apparatus Type-II.

Drug Evaluation

Ketoprofen was evaluated for organoleptic properties, melting point, solubility, and identification by FTIR and UV spectroscopy.

Preformulation Studies

Pre-compression parameters including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio were evaluated to determine the flow properties of powder blends.

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

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

Extraction of *Ocimum basilicum* Mucilage

Ocimum basilicum seeds were soaked in distilled water for 12–14 h.

The mucilage obtained was filtered through muslin cloth, precipitated using ethanol, dried at 50–55°C, powdered, sieved, and stored in a desiccator.[12-14]

Preparation of Fast Dissolving Tablets

Fast dissolving tablets of ketoprofen were prepared by direct compression method using different concentrations of crospovidone, sodium starch glycolate, camphor, and *Ocimum basilicum* mucilage. All ingredients were mixed uniformly, passed through sieve no. 40, and compressed using an 8 mm rotary tablet compression machine. [15]

Table 1: Formulation of Batches

Sr. No.	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
1.	Ketoprofen (mg)	10	10	10	10	10	10	10	10	10	10	10	10
2.	Crospovidone (mg)	40	30	20	40	50	25	–	–	–	–	–	–
3.	Saccharin Sodium (mg)	25	25	25	25	25	25	25	25	25	25	25	25
4.	Sodium Starch Glycolate (mg)	10	20	20	10	–	25	–	–	–	–	–	–
5.	Camphor (mg)	30	40	20	30	40	20	30	30	30	40	40	20
6.	Ocimum basilicum (mg)	–	–	–	–	–	–	30	40	20	20	10	40
7.	Magnesium Stearate (mg)	2	2	2	2	2	2	2	2	2	2	2	2
8.	Purified Talc (mg)	2	2	2	2	2	2	2	2	2	2	2	2
	Calculated Total Weight (mg)	119	129	99	119	129	109	99	109	89	99	89	99

Evaluation of Fast Dissolving Tablets [16]

Prepared tablets were evaluated for weight variation, hardness, thickness, friability, drug content, disintegration time, and in-vitro dissolution study.

$$\% \text{ Friability} = \frac{W_1 - W_2}{W_1} \times 100$$

The dissolution study was performed using USP Type-II dissolution apparatus containing 900 mL phosphate buffer pH 6.8 maintained at 37 ± 0.5°C at 50 rpm. Samples were withdrawn at predetermined intervals and analyzed spectrophotometrically at 246 nm.

Drug Release Kinetics

The dissolution data were fitted to zero-order, first-order, Higuchi, and Korsmeyer–Peppas kinetic models to determine the mechanism of drug release. Dissolution profiles were also compared using similarity factor (f_2) and difference factor (f_1).

Results and Discussion

Analytical Evaluation

Descriptive Characteristics

Ketoprofen was observed as a white, odorless, amorphous powder. The white appearance indicated the purity of the drug, while the absence of odor suggested freedom from volatile impurities or degradation products. The amorphous nature of ketoprofen may contribute to improved solubility and dissolution characteristics compared to crystalline forms.

FTIR Spectroscopy

The FTIR spectrum of ketoprofen exhibited characteristic peaks corresponding to its functional groups, confirming the identity of the drug.

The broad peak observed at 2500–3300 cm^{-1} indicated O–H stretching of the carboxylic acid group, while the sharp peak around 1650–1750 cm^{-1} confirmed C=O stretching of ketone and carboxylic groups. Peaks observed between 1450–1600 cm^{-1} represented aromatic C=C stretching vibrations. These characteristic peaks were consistent with the reported spectrum of ketoprofen, confirming the purity and identity of the drug.

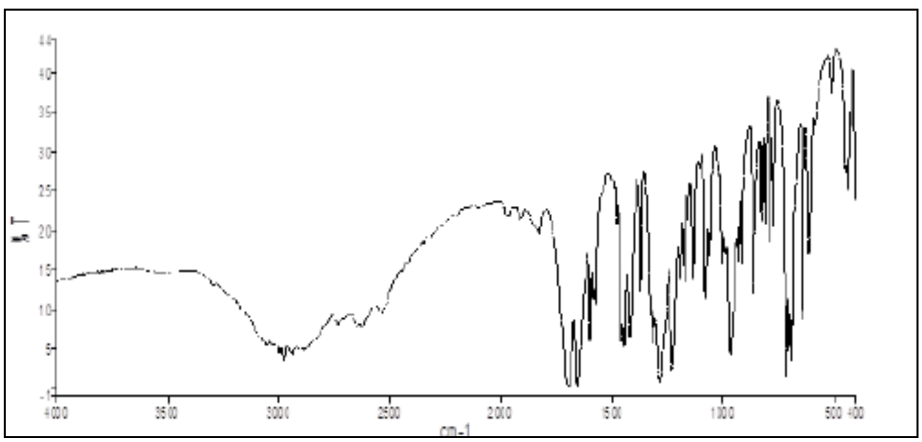

Figure 1: FTIR Spectrum of Ketoprofen

UV Spectroscopy

The UV spectrum of ketoprofen showed a distinct absorption maximum (λmax) at 258 nm, which was attributed to the benzophenone chromophore present in the structure of ketoprofen. The observed λmax was found to be in agreement with standard literature values, confirming the authenticity of the drug sample.

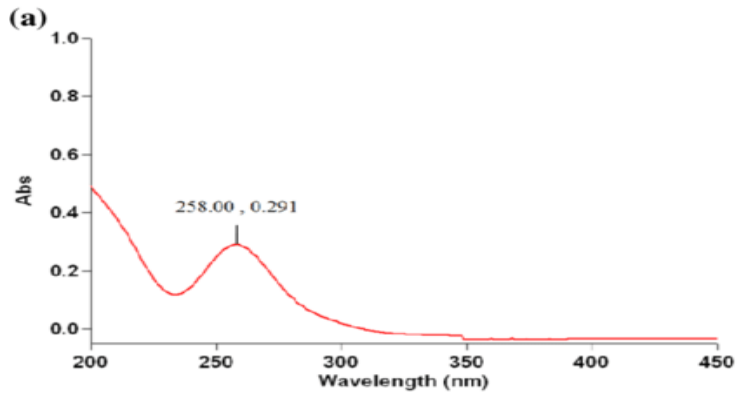

Figure 2: UV Spectra of Ketoprofen

Melting Point

The melting point of ketoprofen was found to be 94.2°C, which was in close agreement with the reported value.

The observed melting point confirmed the purity and identity of the drug.

Solubility Study: Ketoprofen was found to be slightly soluble in water and freely soluble in alcohol, phosphate buffer pH 1.2, and phosphate buffer pH 6.8.

The higher solubility in buffer solutions indicated favorable dissolution behavior in gastrointestinal pH conditions, which is advantageous for oral drug delivery systems.

Preformulation Studies

The powder blends prepared for compression were evaluated for flow and compressibility characteristics. The angle of repose values ranged from 24.43° to 27.72°, indicating good flow properties. Carr's index values ranged between 15.124–15.953%, while Hausner's ratio values ranged from 1.213–1.275, indicating acceptable compressibility and flowability of powder blends.

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

The results suggested that all powder blends possessed satisfactory flow properties suitable for direct compression method.

Table 2: Preformulation parameters for powder blend

Batch	Bulk Density (gm/mL)	Tap Density (gm/mL)	Carr's Index	Hausner's Ratio	Angle of Repose
F1	0.39±0.077	0.531±0.015	15.346±0.25	1.235±0.08	25.27±0.24
F2	0.42±0.058	0.572±0.039	15.234±0.73	1.246±0.07	26.37±0.35
F3	0.43±0.032	0.562±0.022	15.524±0.71	1.234±0.07	25.82±0.75
F4	0.40±0.054	0.622±0.015	15.785±0.64	1.275±0.07	27.72±0.56
F5	0.39±0.089	0.586±0.015	15.235±0.58	1.235±0.03	24.43±0.34
F6	0.38±0.044	0.652±0.022	15.532±0.34	1.244±0.06	25.43±0.56
F7	0.44±0.031	0.587±0.043	15.467±0.37	1.223±0.05	26.34±0.12
F8	0.43±0.082	0.545±0.066	15.358±0.75	1.213±0.07	26.31±0.24
F9	0.47±0.065	0.576±0.084	15.953±0.36	1.254±0.08	25.62±086
F10	0.45±0.025	0.587±0.056	15.124±0.32	1.275±0.06	26.74±0.74
F11	0.42±0.078	0.569±0.015	15.643±0.58	1.245±0.06	26.24±0.45
F12	0.41±0.023	0.545±0.015	15.865±0.35	1.221±0.08	25.83±0.23

Physicochemical Evaluation of Fast Dissolving Tablets

The prepared fast dissolving tablets showed satisfactory physicochemical characteristics.

Hardness of tablets ranged from 3.2–3.7 kg/cm², indicating adequate mechanical strength.

Friability values were below 1% for all formulations, demonstrating good resistance to abrasion during handling.

$$\% \text{ Friability} = \frac{W_1 - W_2}{W_1} \times 100$$

The weight variation test indicated uniform distribution of tablet mass within acceptable pharmacopoeial limits. Wetting time ranged from 12.22–15.42 s, suggesting rapid penetration of saliva into the tablet matrix. Water absorption ratio values indicated efficient swelling behavior of superdisintegrants and natural mucilage.

Table 3: Physio-chemical evaluation of Tablet

Batch	Hardness (Kg/cm^2)	Friability (%)	Weight Variation	Water absorption ratio*(%)	Drug Content (%)	*In vitro* Dispersion Time (sec.)
F1	3.5±0.06	0.42±0.46	120±5.35	78.45±0.18	98.50±0.73	12 ± 1.20
F2	3.2±0.02	0.42±0.04	121±3.35	83.56±0.21	98.65±1.09	12 ± 0.60
F3	3.6±0.03	0.43±0.07	120±3.62	82.25±0.24	97.20±0.56	11 ± 0.80
F4	3.3±0.07	0.44±0.01	118±7.95	87.65±0.18	97.45±1.48	13 ± 0.50
F5	3.2±0.04	0.43±0.02	119±1.35	83.43±0.31	97.38±0.45	10 ± 0.30
F6	3.2±0.02	0.45±0.08	117±1.13	75.73±0.13	98.45±0.23	10 ± 0.30
F7	3.4±0.02	0.47±0.04	120±1.42	91.53±0.63	97.30±0.97	11 ± 0.30
F8	3.2±0.06	0.48±0.06	119±1.24	84.63±0.34	99.30±0.54	12 ± 0.30
F9	3.2±0.04	0.43±0.03	122±1.64	79.73±0.97	98.30±0.75	12 ± 0.30
F10	3.7±0.05	0.47±0.05	121±1.43	81.43±0.31	99.38±0.55	09 ± 1.20
F11	3.4±0.03	0.49±0.06	120±1.13	79.73±0.13	98.45±0.34	08 ± 0.60
F12	3.2±0.01	0.45±0.04	118±1.64	90.53±0.63	98.30±0.98	11 ± 0.80

Drug content values ranged from 97.20–99.38%, confirming uniform drug distribution within the formulations. In-vitro dispersion time ranged between 8–13 s, demonstrating rapid disintegration behavior of the prepared fast dissolving tablets. Among all formulations, batch F11 showed the shortest dispersion time of 8 s and satisfactory physicochemical properties, indicating effective superdisintegrant action and rapid tablet disintegration.

In-vitro Drug Release Study

The in-vitro dissolution study demonstrated rapid drug release from all formulations. Drug release profiles revealed that formulations containing optimized concentrations of superdisintegrants and *Ocimum basilicum* mucilage showed enhanced dissolution characteristics.

Formulation F11 exhibited the highest cumulative drug release of 79.53% at 5 min, 87.52% at 10 min, and 98.31% at 20 min, indicating superior dissolution performance compared to other formulations.

The enhanced drug release may be attributed to rapid tablet disintegration, improved wettability, and swelling action of superdisintegrants.

Table 4: Percent Cumulative drug release of Batches F1 to F12

Batch	Cumulative Drug release at 5 min	Cumulative Drug release at 10 min	Cumulative Drug release at 20 min	Cumulative Drug release at 30 min
F1	56.36±1.753	73.24±0.245	89.34±1.754	95.53±0.986
F2	58.56±1.357	78.97±0.543	86.86±1.457	93.35±0.346
F3	59.34±1.754	72.07±0.753	85.75±1.724	92.55±0.864
F4	71.43±0.357	88.45±1.524	95.88±0.567	--
F5	55.75±1.724	79.24±0.932	86.94±0.843	94.45±0.735
F6	58.45±1.524	78.64±0.556	84.24±0.233	95.76±0.852
F7	56.36±1.753	73.24±0.245	89.34±1.754	95.53±0.986
F8	58.56±1.357	78.97±0.543	86.86±1.457	93.35±0.346
F9	75.27±0.924	81.24±0.735	96.01±0.357	--
F10	73.75±0.934	84.24±0.636	94.41±0.733	--
F11	79.53±0.986	87.52±0.574	98.31±1.378	--
F12	72.35±0.346	88.45±0.735	96.37±1.135	--

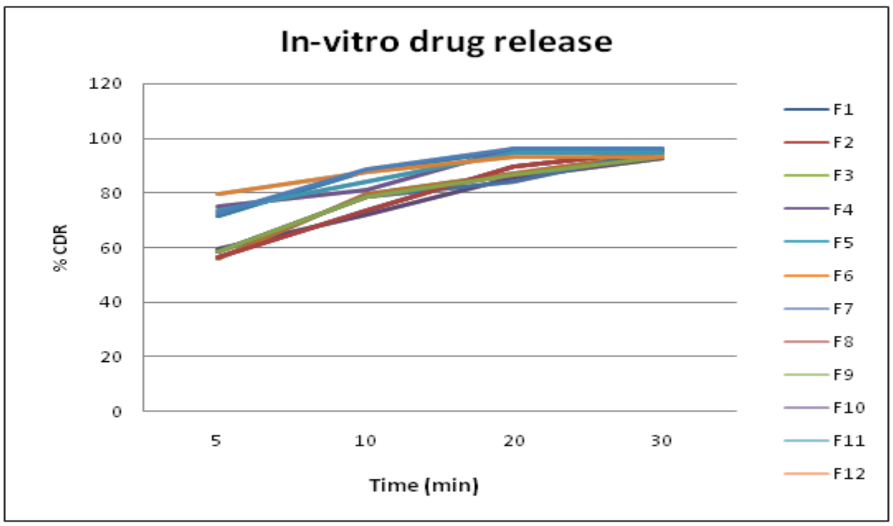

Figure 3: Percent drug release of Batches F1 to F12

Formulations F4, F9, F10, and F12 also showed rapid drug release, achieving more than 94% drug release within 20 min. In contrast, formulations containing lower concentrations of superdisintegrants showed relatively slower release profiles. The rapid dissolution behavior observed in optimized formulations confirmed the suitability of the direct compression method and the effectiveness of selected excipients in developing fast dissolving tablets of ketoprofen with enhanced dissolution properties.

Overall, the study demonstrated that fast dissolving tablets containing ketoprofen could be successfully formulated with satisfactory physicochemical properties and rapid drug release characteristics, thereby improving the dissolution profile and potential bioavailability of ketoprofen.

Conclusion

The present study successfully formulated and evaluated fast dissolving tablets (FDTs) of ketoprofen using different superdisintegrants and natural excipients by direct compression method. Preformulation studies confirmed that the powder blends possessed satisfactory flow properties and compressibility suitable for tablet compression. FTIR compatibility studies demonstrated the absence of any significant interaction between ketoprofen and the selected excipients, indicating their compatibility and stability within the formulation. The prepared fast dissolving tablets showed acceptable physicochemical characteristics including hardness, friability, weight variation, drug content uniformity, wetting time, and in-vitro dispersion time within pharmacopoeial limits. The formulations exhibited rapid disintegration and enhanced dissolution behavior, which are essential characteristics of fast dissolving tablets. Among all the formulations, batch F11 showed the best performance with rapid dispersion time and maximum cumulative drug release of 98.31% within 20 min. The improved drug release profile may be attributed to the combined effect of superdisintegrants and the porous tablet structure produced during formulation.

The results of the study indicated that fast dissolving tablets of ketoprofen can be effectively developed using direct compression technique to enhance dissolution rate and potentially improve bioavailability and therapeutic efficacy. The developed formulation may provide better patient compliance, rapid onset of action, and improved convenience compared to conventional oral dosage forms.

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