RESEARCH PAPER

Improved Dissolution Performance of Fenoprofen Calcium Using PEG 6000 Solid Dispersions: Preparation by Fusion Method and Physicochemical Characterization

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ABSTRACT

Objective: This study aimed to enhance the dissolution performance of poorly water-soluble Fenoprofen calcium by developing solid dispersions using polyethylene glycol 6000 (PEG 6000) via the fusion method.

Methods: Solid dispersions were prepared in drug-to-polymer ratios of 1:1, 1:2, and 1:3. The formulations were evaluated for percentage yield, drug content, solubility, and in vitro dissolution. Fourier Transform Infrared Spectroscopy (FTIR) was employed to assess drug-polymer compatibility.

Results: The prepared solid dispersions exhibited significantly improved solubility compared to the pure drug. Drug content ranged from 75.0% to 87.5%. Notably, formulation F2 (1:2 ratio) demonstrated the highest dissolution performance, achieving a maximum cumulative drug release of 98.82% within 100 minutes, which was markedly higher than the pure drug. FTIR analysis confirmed the absence of significant drug-polymer interactions, indicating good compatibility and stability of the formulation.

Conclusion: Solid dispersion of Fenoprofen calcium using PEG 6000 via the fusion method significantly enhances dissolution behavior. The optimized formulation (F2) shows promising potential for improving oral bioavailability of poorly water-soluble drugs.

Keywords: Fenoprofen calcium, solid dispersion, PEG 6000, dissolution enhancement, FTIR

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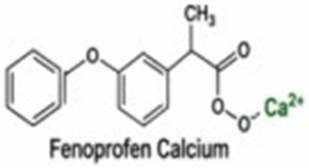
GRAPHICAL ABSTRACT

Improved Dissolution Performance of Fenoprofen Calcium Using PEG 6000 Solid Dispersions: Preparation by Fusion Method and Physicochemical Characterization



Fenoprofen Calcium

OBJECTIVE

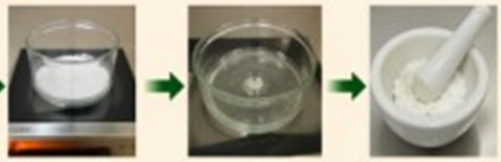
To enhance the solubility and dissolution of poorly water-soluble **Fenoprofen calcium** by preparing solid dispersions using **PEG 6000** via the fusion (melting) method.

METHODOLOGY

1 RAW MATERIALS


Fenoprofen Calcium (API) — PEG 6000 (Hydrophilic Carrier)

2 FUSION METHOD

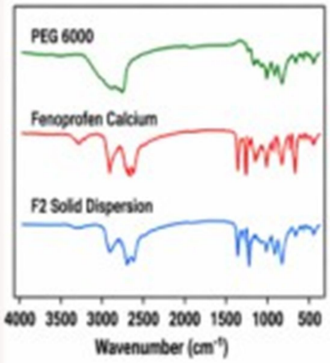

Accurately Weighed Drug + PEG 6000 Melted → Molten Mixture Allowed to Cool → Solidified Mass Scraped, Crushed and Sieved

3 FORMULATIONS PREPARED

Formulation	Drug : PEG 6000 (Ratio)
F1	1 : 1
F2	1 : 2
F3	1 : 3

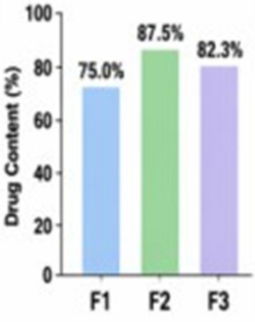
CHARACTERIZATION & RESULTS

FTIR STUDY



No Significant Drug-Polymer Interaction Confirms Compatibility

DRUG CONTENT

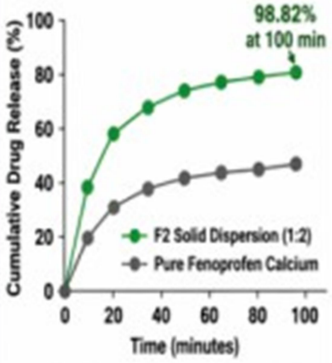


Acceptable Drug Content Ensures Uniformity

SOLUBILITY

Solid Dispersions Show Enhanced Solubility

***IN VITRO* DISSOLUTION**



Significantly Enhanced Dissolution Performance

CONCLUSION & KEY OUTCOME

Fusion Method Solid Dispersion with **PEG 6000** Significantly Improves Dissolution of Fenoprofen Calcium.

Optimized Formulation **F2** (1:2 Ratio) Achieved **98.82%** Drug Release within **100 Minutes**.

A Promising Strategy to Enhance Solubility, Dissolution and Potential Bioavailability of Poorly Water-Soluble Drugs.

1. INTRODUCTION

Solubility significantly affects drug absorption and therapeutic efficacy. Poor aqueous solubility and slow dissolution reduce bioavailability and complicate formulation [1,2]. Hydrophilic carriers are now widely studied for improving solubility [3].

Many new drugs are poorly water-soluble, making solubility enhancement a key challenge in drug development [4]. Since oral drugs must dissolve in gastrointestinal fluids for absorption, BCS Class II and IV compounds can improve bioavailability through the use of suitable polymer matrices [5].

Several techniques for improving solubility have been developed to overcome this issue.

Solubility enhancement methods are broadly classified into physical and chemical modifications of the drug. Among these, solid dispersion is a highly effective approach for improving the solubility of poorly water-soluble drugs. According to Chiou and Riegelman, solid dispersions are systems in which one or more active ingredients are dispersed in an inert carrier or matrix in the solid-state using melting, solvent, or melting-solvent methods [6]. Typically, the drug is hydrophobic, while the carrier is hydrophilic. Solid dispersions are categorized as simple eutectic mixtures, glass solutions or suspensions, complexes, amorphous precipitates in crystalline carriers, and solid solutions [7].

Calcium 2-(3-phenoxyphenyl) propanoate dihydrate is the IUPAC designation for Fenoprofen calcium. It has the chemical formula $C_{15}H_{14}O_3 \cdot 0.5Ca$ with a molecular weight of 261.31 g/mol. Fenoprofen calcium is a non-steroidal anti-inflammatory drug (NSAID). In many areas of chemistry, the charge-transfer (CT) process between molecules that donate and accept electrons is crucial [8]. These CT complexes form quickly, which makes them useful for developing a wide range of spectrophotometric techniques for analyzing various chemical and pharmaceutical substances [9].

1.1 Materials and methods

Di-sodium hydrogen-o-phosphate (CAS number: 7558-79-4), Potassium dihydrogen-o-phosphate (CAS number: 7778-77-0), Ethanol (CAS number: 64-17-5) , Methanol (CAS Number : 67-56-1) , Poly ethylene glycol 6000 (CAS Number -25322-68-3), Fenoprofen drug (CAS Number: 53746-45-5), Acetone (CAS number :67-64-1), Ethyl acetate (CAS number:141-78-6), Dimethyl sulfoxide (CAS number: 67-68-5) were used in the formulation and assessment of solid dispersion.

2. FABRICATION OF SOLID DISPERSION BY THE FUSION METHOD

In this method, Formulation contents are mentioned in Table 1. Polyethylene glycol, a hydrophilic carrier, and Fenoprofen calcium, which had been precisely weighed, were placed in a china dish and heated until they melted. After melting, the mixture was allowed to cool. Simultaneously, in the ratio of 1:2 and 1:3 is also melted and cooled. The final solid masses were scraped, crushed, weighed, and the percentage yield of solid dispersion was calculated [10-11].

Table 1: Formula for the fusion process of creating solid dispersions.

Sl. No.	Ingredients	SD1	SD2	SD3
1	Fenoprofen calcium (mg)	1000	1000	1000
2	Polyethylene glycol 6000 (mg)	1000	2000	3000

3. EVALUATION

3.1 Determination of melting point of Fenoprofen Calcium

The capillary tube was taken and sealed at one side. A small amount of Fenoprofen drug was taken in the capillary tube. The capillary tube was tied with the thermometer in such a way that the drug was exactly beside the mercury of the thermometer [12]. The liquid paraffin was taken in the Thiele's tube. The capillary that had been knotted was placed inside the thiele's tube. After that, the thermometer's temperature increased as the Thiele's tube arm was heated. A note was made of the temperature at which the medication liquefied [13].

3.2 Authentication of Fenoprofen Calcium using ATR-FTIR

Fenoprofen was analyzed using Fourier transform infrared spectroscopy to authenticate its functional groups of the pure drug. Fenoprofen's infrared spectrum was captured using a Bruker Alpha equipment maintained at 25±0.5°C. No specific sample preparation was required, and the analytical process was straightforward. The Fenoprofen API was placed on a zinc solenoid crystal plate, and the anvil was gently screwed over the sample. The spectra were then collected by scanning the drug sample in the 4000-400 cm−1 region, and the various functional groups of the Fenoprofen were evaluated [14-15].

3.3 Determination of Absorption maxima of Fenoprofen Calcium

3.3.1 Preparation of Sorenson's buffer (6.8pH)

Solution A was produced by dissolving 3.75g of di-sodium hydrogen orthophosphate in a 100mL volumetric flask and adding distilled water to make up the remaining volume. Solution B was produced by dissolving 0.908g of potassium di-hydrogen phosphate in a 100mL volumetric flask and adding distilled water to make up the remaining volume. A 500 mL volumetric flask was filled with 35.75 mL of solution A and 14.25 mL of solution B. The solutions were dissolved, and the volume was adjusted using distilled water [16-17].

3.3.2 Preparation of FPC standard stock solution

100 mg of the drug was dissolved in 10 milliliters of ethanol to create the Fenoprofen calcium solution, which was then topped off with 100 milliliters of distilled water. As a result, a solution with 1 mg/mL of the drug was produced. An absorption maximum (λ max) was found at 270 nm when the UV absorption spectrum of Fenoprofen calcium was studied in the

200-400 nm range of a 10 µg/mL solution in Sorenson's buffer (pH 6.8) [18].

3.4 Standard calibration of Fenoprofen Calcium

3.4.1 Preparation of FPC Aliquots

In a 100 mL volumetric flask, 100 mg of fenoprofen calcium was dissolved in 10 mL of ethanol. The Sorenson's buffer was used to create the final volume. To create a stock solution of 100µg/mL, 10 mL of this solution was diluted with Sorenson's buffer (pH 6.8) in a 100 mL volumetric flask. Stock solutions of 0, 20, 40, 60, 80, and 100µg/mL were obtained by aliquoting 0, 2, 4, 6, 8, and 10 mL of the stock solution into 10 mL volumetric flasks and then adding buffer (pH 6.8) to bring the volume up to 10 mL. At 270 nm, it was measured using a Shimadzu 1900i UV spectrophotometer [19].

3.5 Solubility study of Solid dispersion

Solid dispersions made by the melting process were tested for solubility using organic solvents such as Methanol, Acetone, Distilled water, Ethyl acetate, and Dimethyl sulfoxide, in which the drug Fenoprofen calcium is soluble, in accordance with the drug's solubility profile, Solid dispersion (SD) technology addresses this by incorporating poorly soluble drugs into hydrophilic polymer matrices, enhancing solubility through improved wettability, reduced particle size, and amorphization [20]. In a test tube, 100 mg of a solid Fenoprofen calcium (1:1,1:2,1:3) dispersion was combined with two to three milliliters of water and other solvents such as Ethanol, Methanol, Ethyl acetate, Acetone, and DMSO, in that order. Then test tubes were placed in a Sonicator for 10 minutes and observed the solubility of solid dispersion of FPC [21].

3.6 Drug release research in vitro

Using 900mL of Sorenson's buffer pH 6.8 at 37 ± 0.5 and a stirring rate of 100 rpm, in vitro drug release experiments were carried out in a USP Type II Dissolution equipment. Physical mixture and solid dispersion in the powdered form is taken in the filter bags and labelled with different ratios 1:1, 1:2, 1:3 respectively which is introduced into dissolution flasks.1mL samples are withdrawn at every 20 minutes interval of time. Simultaneously, the dissolution media were replenished with a fresh 1 mL of buffer to maintain artificial sink condition. The withdrawn sample was diluted in the buffer 1 mL is taken in 10 mL of volumetric flask. The volume was made up with Sorenson's buffer pH 6.8 up to the mark. Amount of drug was estimated using a UV spectrophotometer at λmax 270 nm [22].

3.7. Drug content analysis

A 100 mL volumetric flask was filled with preparations equal to 2000 mg of solid dispersion samples, which were precisely weighed and then dissolved in Sorenson's buffer (pH 6.8). The volume was adjusted to the proper level [2 mg/mL-FPC] using Sorenson's buffer pH 6.8. The flask was then filtered after five minutes in a Sonicator [23]. One milliliter (mL) of the filtrate mentioned above was transferred into a volumetric flask and diluted with Sorenson's buffer (pH 6.8). 0.02 mg/mL of FPC was added to 100 mL of Sorenson's buffer, which has a pH of 6.8. The absorbance of the above solution was measured against a suitable blank solution following the aforementioned dilution. Fenoprofen calcium's drug content was determined using a curve [24].

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4. RESULTS

4.1 Preparation of Solid dispersion of Fenoprofen Calcium

Table 2: Percentage yield of F1-F3

Sl. No.	Sample	Percentage Yield (%)
1	F1	97.5
2	F2	85.3
3	F3	86.5

4.2 Determination of Melting point of Fenoprofen Calcium

Figure 1: Melting point of FPC

Table 3: Melting of FPC

Sample	Fenoprofen Calcium
Melting point (°C)	169
Literature value (°C)	168-170

4.3 FTIR analysis

To confirm that FCP and the polymers employed in the preparation were compatible, FTIR estimation was done. Figure 2 displays the spectrum for a pure sample of FCP and the fusion process, respectively

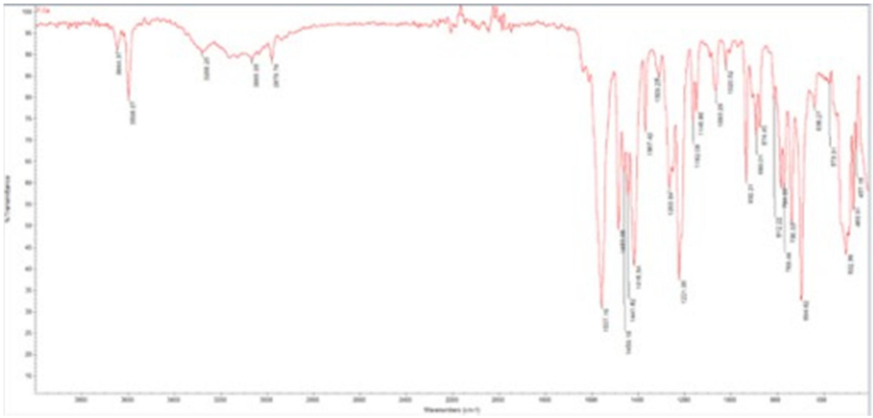

Figure 2: FTIR of FPC

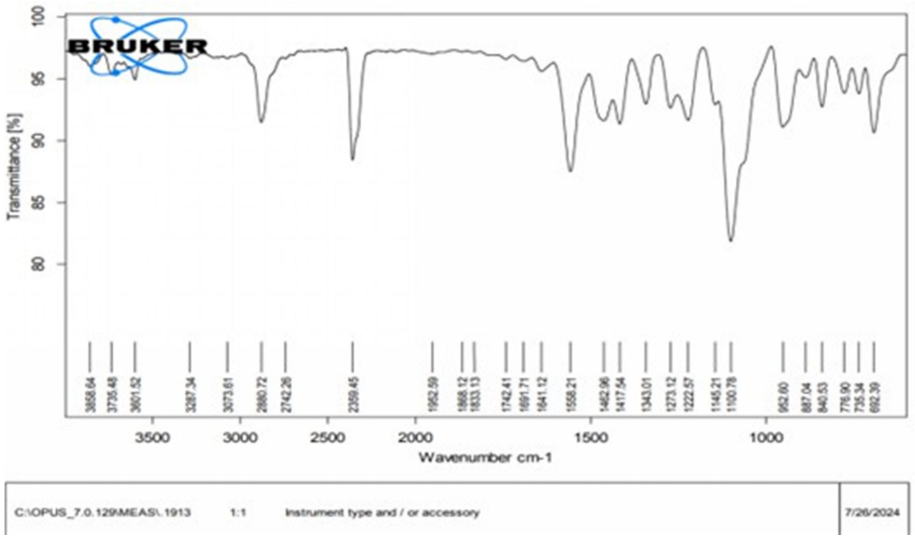

Figure 3: FTIR of PEG 6000

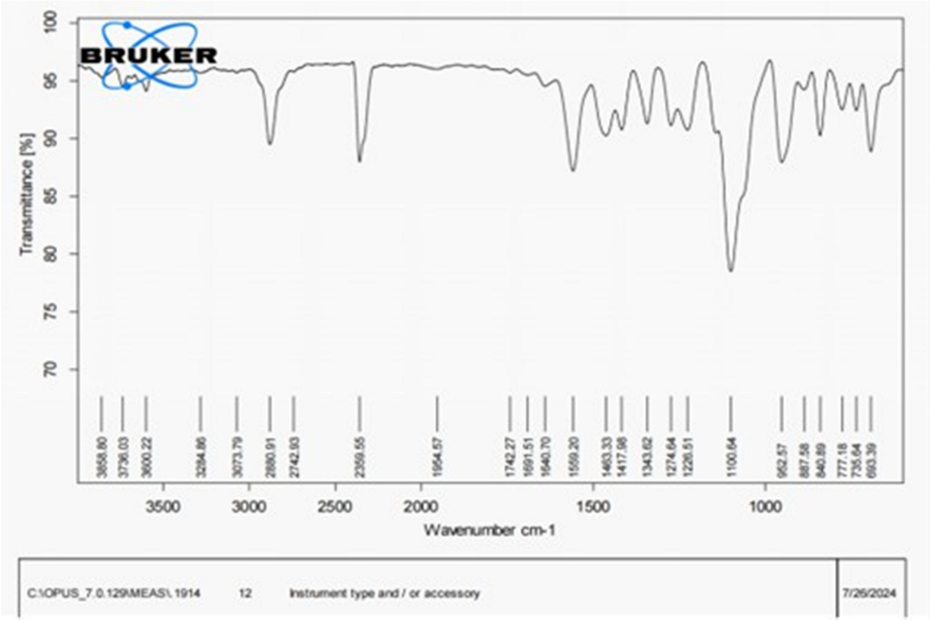

Figure 4: FTIR of Solid dispersion of F1

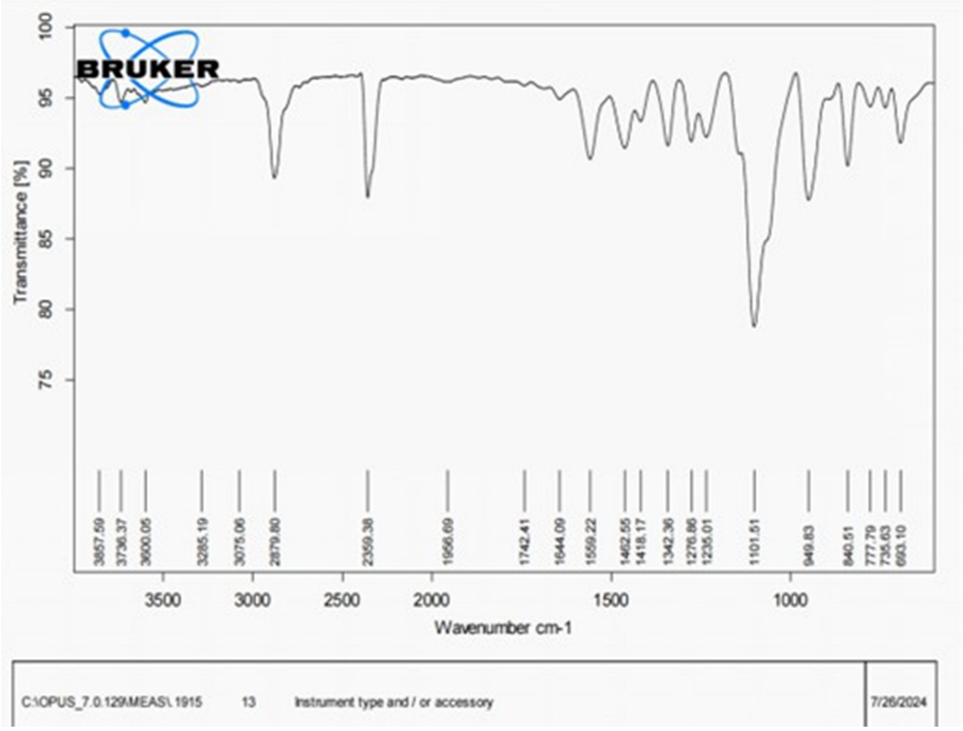

Figure 5: FTIR of Solid dispersion of F2

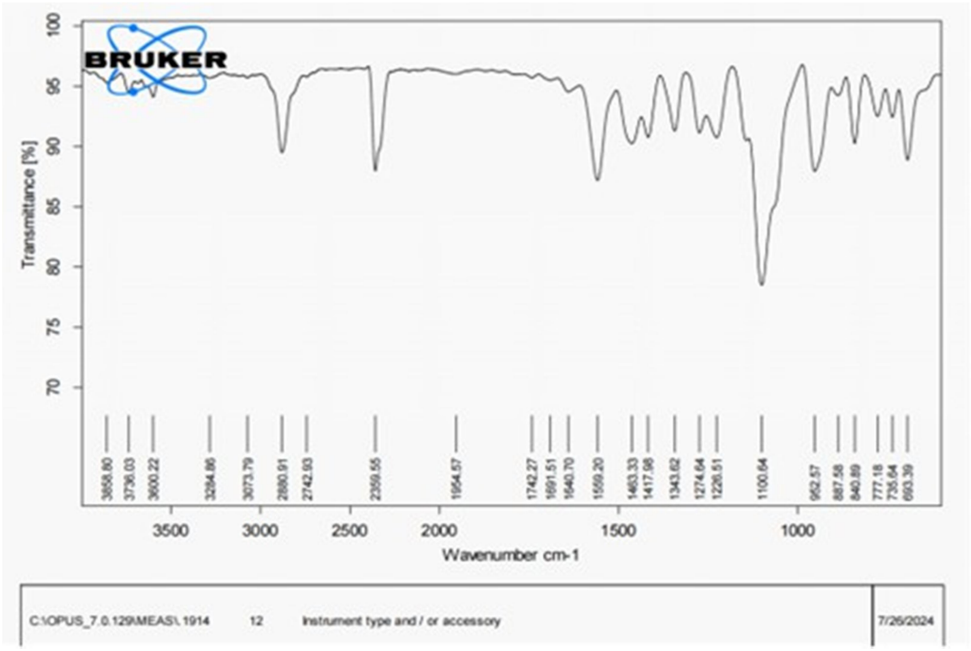

Figure 6: FTIR of Solid dispersion of F3

Determination absorption maxima of Fenoprofen Calcium

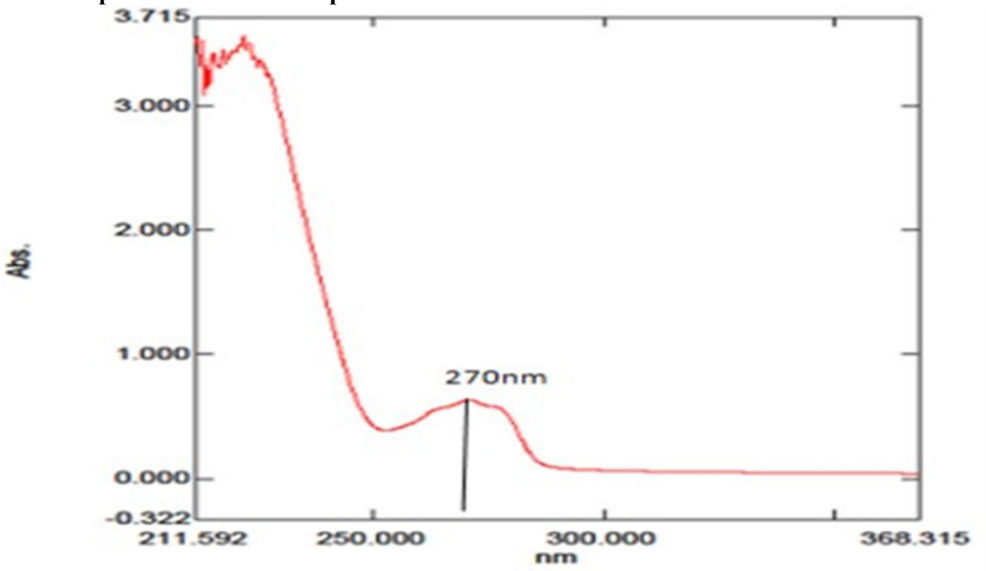

Figure 7: Absorption maxima of FPC

Table 4: Absorption maxima of FPC

Sample	Fenoprofen Calcium
Obtained Absorption Maxima (nm)	270 nm
Literature Value (nm)	270 nm

4.4 Standard calibration of Fenoprofen Calcium

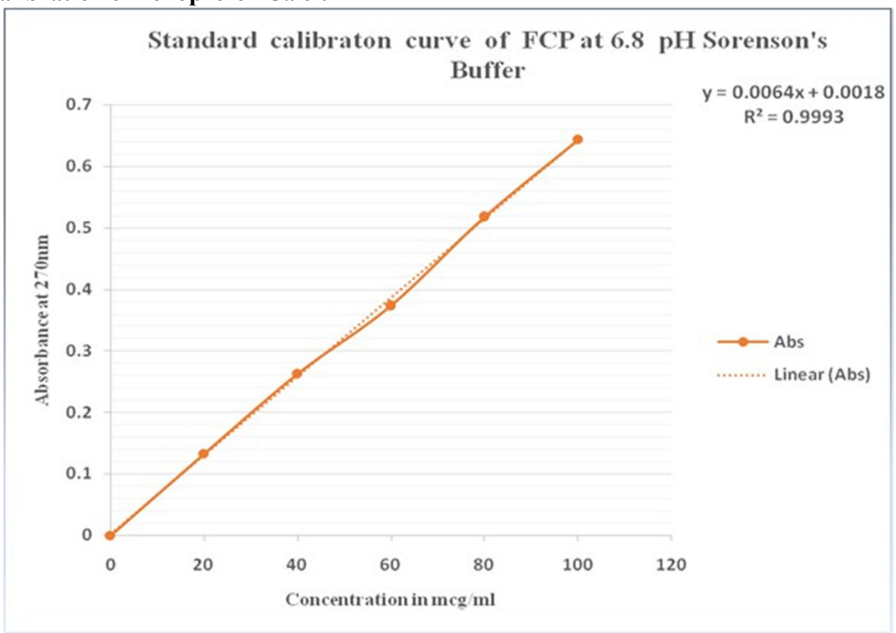

Figure 8: Standard calibration curve of FCP

Table 5: UV readings of FPC aliquots at 270 nm

Sl. No.	Concentration (µg/mL)	Trial 1	Trial 2	Trial 3	Mean ± SD
1	0	0.000	0.000	0.000	**0.000 ± 0.000**
2	20	0.170	0.316	0.094	**0.193 ± 0.113**
3	40	0.263	0.262	0.264	**0.263 ± 0.001**
4	60	0.392	0.377	0.354	**0.374 ± 0.019**
5	80	0.530	0.517	0.508	**0.518 ± 0.011**
6	100	0.642	0.645	0.641	**0.643 0 ± 0.002**

Determination of solubility of solid dispersion of Fenoprofen calcium

Table 6: Solubility studies of Solid dispersion

Solvent Name	Solubility of Solid Dispersion (Fusion Method)
Distilled water	Completely soluble
Methanol	Completely soluble
Acetone	Completely soluble
Ethyl acetate	Freely soluble
Dimethyl sulfoxide	Completely soluble
Ethanol	Insoluble

4.5 %Drug content analysis

The percentage drug content of the solid dispersions prepared by the fusion method was found to range between 75% and 87.5%. Specifically, the drug content values for SD1, SD2, and SD3 were observed within this range, as illustrated graphically in Figure 10.

Table 7: Drug content of formulations F1, F2, F3

Sl. No.	Sample	Drug Content (% ± SD)
1	F1	87.5 ± 0.013
2	F2	84.8 ± 0.024
3	F3	75.0 ± 0.041

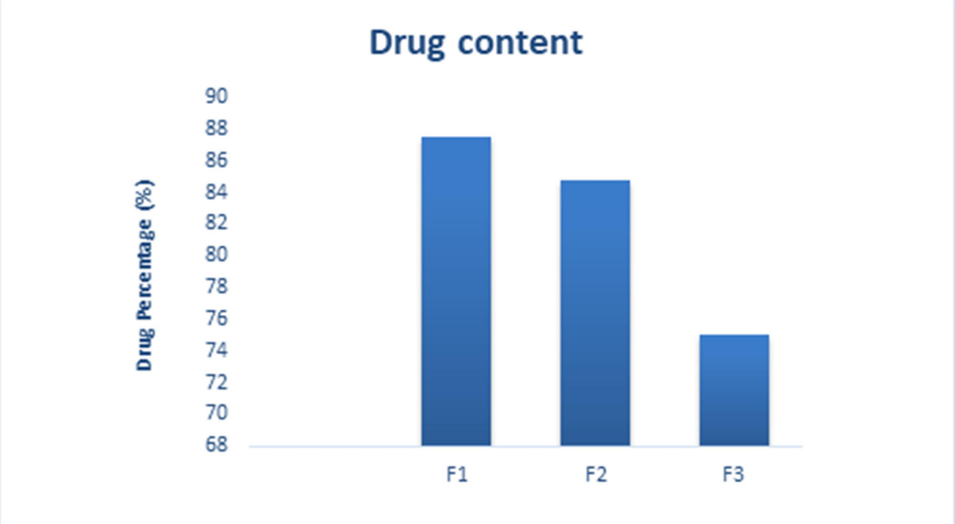

Figure 10: Drug content graph of Solid Dispersion of F1, F2, and F3

4.6 Dissolution studies

Table 8: In Vitro release profile of Solid dispersion- F1 to F3

Sl. No.	Time (min)	F1 (%CDR ± SD)	F2 (%CDR ± SD)	F3 (%CDR ± SD)
1	20	35.55 ± 0.42	41.20 ± 0.38	26.17 ± 0.51
2	40	43.62 ± 0.36	53.46 ± 0.47	52.46 ± 0.44
3	60	54.92 ± 0.52	60.55 ± 0.33	59.14 ± 0.49
4	80	77.47 ± 0.61	87.34 ± 0.58	84.95 ± 0.57
5	100	96.41 ± 0.72	98.82 ± 0.69	97.26 ± 0.63

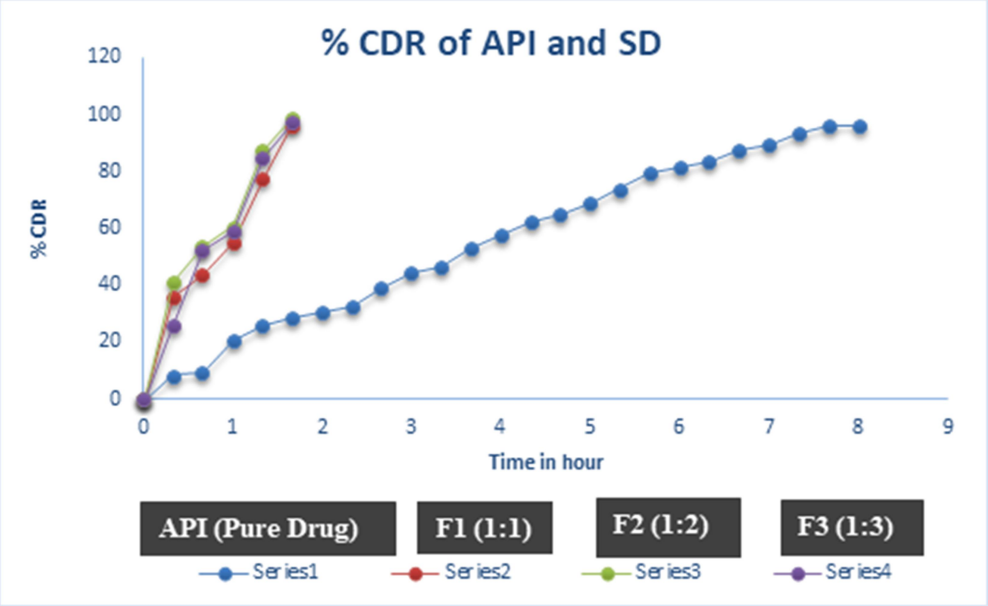

Figure 11: % CDR v/s Time profile of API, F1, F2, and F3

5. DISCUSSION

The present study focused on the preparation and evaluation of Fenoprofen calcium solid dispersions to enhance its solubility and dissolution performance. Various physicochemical and analytical techniques were employed to assess the quality, compatibility, and performance of the developed formulations.

The melting point of Fenoprofen calcium was determined to be **169 °C**, which falls within the reported range (168-170 °C), confirming the purity and integrity of the drug. This parameter is critical for quality control, as any deviation may indicate the presence of impurities or degradation.

Fourier Transform Infrared Spectroscopy (FTIR) analysis confirmed the identity of Fenoprofen calcium by exhibiting characteristic functional group peaks consistent with reported spectra. No significant shifts or disappearance of peaks were observed in the solid dispersions, indicating the absence of chemical interaction between the drug and polymer, and confirming compatibility.

The absorption maximum (λmax) of Fenoprofen calcium was found to be **270 nm**, in agreement with literature values. This validates the suitability of UV-visible spectrophotometry for quantitative estimation of the drug. The calibration curve constructed in Sorenson's buffer (pH 6.8) demonstrated excellent linearity with a regression coefficient ($\mathbf{R^2 = 0.9993}$), confirming the reliability and accuracy of the analytical method.

Solid dispersions were successfully prepared using the fusion method in different drug-to-polymer ratios (F1: 1:1, F2: 1:2, and F3: 1:3). Among these, formulation F1 showed the highest percentage yield (97.5%), followed by F3 (86.5%) and F2 (85.3%). These variations indicate that polymer concentration influences the efficiency of the preparation process, which is important for scalability.

Solubility studies revealed that the prepared solid dispersions exhibited improved solubility in comparison to the pure drug, particularly in aqueous media. This enhancement can be attributed to improved wettability, reduced crystallinity, and better dispersion of the drug within the hydrophilic carrier matrix.

Drug content analysis showed values ranging from **75.0% to 87.5%**, with F1 exhibiting the highest drug content. These results confirm acceptable uniformity, although slight variations may be due to differences in drug distribution within the polymer matrix.

In vitro dissolution studies demonstrated a significant enhancement in drug release from solid dispersions compared to the pure drug. Among the formulations, F2 exhibited the best performance, achieving a **maximum cumulative drug release of 98.82% within 100 minutes**, followed by F3 and F1. The improved dissolution can be attributed to increased surface area, reduced particle size, and the amorphous or molecular dispersion of the drug in the PEG 6000 matrix.

Overall, the experimental design and analytical methods employed in this study ensured reliable and reproducible results. The findings clearly indicate that solid dispersion using PEG 6000 via the fusion method is an effective strategy to enhance the solubility and dissolution rate of Fenoprofen calcium.

However, further studies are recommended to evaluate **in vivo bioavailability, long-term stability, and release kinetics**, which would provide deeper insights into the practical applicability of the developed formulations. These investigations would support the potential of solid dispersion systems in improving the therapeutic performance of poorly water-soluble drugs.

CONCLUSION

The present study successfully demonstrated that solid dispersion of Fenoprofen calcium using polyethylene glycol 6000 (PEG 6000) via the fusion method significantly enhances its solubility and dissolution

performance. The prepared formulations exhibited acceptable drug content and improved solubility characteristics compared to the pure drug.

Among the formulations, F2 (1:2 drug-to-polymer ratio) showed the most promising results, achieving a **maximum cumulative drug release of 98.82% within 100 minutes**, indicating superior dissolution behavior. FTIR analysis confirmed the absence of significant drug-polymer interaction, demonstrating compatibility and stability of the formulation.

Overall, the findings suggest that the fusion method using PEG 6000 is an effective and practical approach for improving the bioavailability of poorly water-soluble drugs such as Fenoprofen calcium. However, further studies on in vivo performance, stability, and release kinetics are recommended to establish its full pharmaceutical potential.

Authors' Contributions

Pratiksha C. Chandragirivar conceptualized and supervised the study, designed the methodology, and contributed to drafting and final revision of the manuscript. Afreen Banu, Kusuma R, Srinidhi G, Yashwanth H. B, and Ameer Suheel performed the experimental work, including preparation of solid dispersions, data collection, and preliminary analysis.

Amar M. Raval contributed significantly to the research design, provided scientific guidance during formulation development and optimization, and was actively involved in data analysis, interpretation of physicochemical characterization results, and validation of findings. He also critically reviewed and revised the manuscript for important intellectual content.

All authors have read and approved the final manuscript and agree to be accountable for all aspects of the work.

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Conflict of Interest

The authors declare no conflict of interest.

Funding Source

This research received no external funding.

List of Symbols and Abbreviations

Mg	Milligram
mL	Milliliter
µg	Microgram
kg	Kilogram
Min	Minutes
UV	Ultraviolet
%	Percentage
ppm	Parts per million
rpm	Rotation per minute
w/v	Weight/volume
Conc.	Concentration
nm	Nanometer
M^3	Cubic meter
FTIR	Fourier Transform Infrared Spectroscopy
Mol	Mole
Kg/m3	Kilogram/ cubic meter
PEG	polyethylene glycol
FPC	Fenoprofen calcium
SD	Solid dispersion
F1, F2, F3	Formulation 1,2,3

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