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Evaluation of Polyethylene Glycol (PEG)-Based Polymers for Improving Solubility and Bioavailability of Poorly Soluble Drugs

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Abstract

A significant barrier to optimizing oral bioavailability is the inadequate water solubility of numerous pharmaceutical compounds. This study examined whether polymer systems utilizing polyethylene glycol (PEG) may enhance the solubility and bioavailability of a poorly soluble model drug. Multiple PEG polymers with molecular weights between 2,000 and 10,000 Da were utilized to produce PEGylated preparations. The formulations were subsequently evaluated for dissolution efficacy, medication loading capacity, particle size, and solubility improvement. The drug loading efficiency was 82.6 ± 3.4%, and the average particle size was 185 ± 12 nm in the enhanced PEG-based formulation. The solubility of the PEG-based formulation increased from 0.12 ± 0.01 mg mL^{-1} for the pure drug to 2.45 ± 0.18 mg mL^{-1}, signifying a significant enhancement in aqueous solubility. In in vitro dissolution trials, a cumulative drug release of 86.3 ± 2.7% was observed within 60 minutes, compared to the untreated drug's release of 28.4 ± 1.9%. The maximum plasma concentration (Cmax) was determined to be 3.1 times more, and the area under the curve (AUC) was 2.8 times greater than that of the pure medicine, as per the in vivo pharmacokinetic investigation. The findings indicate that PEG-based polymers can significantly enhance the oral bioavailability, dissolution rate, and solubility of drugs with limited solubility. This research supports the notion that polymer systems utilizing polyethylene glycol (PEG) may serve as effective carriers to enhance the therapeutic efficiency of poorly soluble medicines.

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INTRODUCTION

The limited aqueous solubility sometimes leads to delayed dissolution rates, erratic absorption, and diminished oral bioavailability, making the formulation of drugs with low water solubility a considerable challenge in contemporary pharmaceutical development [1, 2].

A crucial method for tackling solubility-limited drug delivery, from a polymer science perspective, is the development of functional polymeric excipients that can adjust drug-polymer interactions, enhance wettability, and stabilize amorphous drug phases. In polymer-based systems, molecular architecture, chain length, functionalization, and composite design can be manipulated, rendering them a versatile platform for modifying physicochemical properties [3, 4].

Several studies have demonstrated that polyethylene glycol (PEG)–based polymer systems are effective carriers for improving the solubility and oral bioavailability of poorly water-soluble drugs. PEG has been widely used in solid dispersions, polymeric micelles and PEGylated particulate systems owing to its strong hydrophilicity, hydrogen-bonding capability and ability to inhibit drug recrystallization. Previous reports have shown that PEG matrices can stabilize drugs in an amorphous state, improve wettability and enhance dissolution behaviour, leading to superior in-vivo performance compared with conventional formulations. Furthermore, the molecular weight and chain flexibility of PEG have been identified as critical factors influencing drug–polymer miscibility, dissolution kinetics and systemic exposure. Although PEG-based systems are extensively reported, systematic comparison of different PEG molecular weights and processing methods with respect to solubility enhancement and in-vivo bioavailability remains limited. Therefore, the present study focuses on evaluating PEG polymers of different molecular weights and preparation approaches in order to establish a clear relationship between PEG characteristics and biopharmaceutical performance [4, 5].

Due to its elevated water solubility, regulatory compliance, non-toxicity, and outstanding biocompatibility, polyethylene glycol (PEG) has emerged as one of the most favored hydrophilic polymers investigated for pharmaceutical applications. PEG's superior hydrogen-bonding properties and flexible chain conformations render it an optimal interaction partner for various medication kinds [5]. Due to these characteristics, PEG can function as a carrier matrix that modulates crystallinity, restricts drug recrystallization, and enhances dissolution behavior, in addition to serving as a solubilizing agent. The extensive range of commercially accessible PEG structures and molecular weights allows for the customization of polymer-drug compatibility and release characteristics [6].

A variety of sophisticated polymeric delivery methods, including solid dispersions, polymeric micelles, PEGylated nanoparticles, and polymer-drug conjugates, have extensively utilized PEG-based polymers. Polymers are crucial in these systems due to their influence on hydration behavior, diffusion kinetics, particle stability, and interfacial properties. Evidence indicates that amorphous polymer-drug matrices and hydrogen-bonded complexes can maintain supersaturation during dissolution and significantly enhance apparent solubility. Moreover, nanocarriers coated with PEG chains can improve biological efficacy by reducing aggregation and nonspecific interactions while providing steric stability [6,7].

In rational polymer design, it is essential to systematically assess the influence of PEG molecular characteristics on bioavailability and solubility enhancement, notwithstanding PEG's prevalent use in pharmaceutical formulations. The characteristics of molecular weight, chain density, polymer architecture, and polymer-drug miscibility strongly influence drug loading, dissolution kinetics, and in vivo performance. Consequently, enhancing PEG-based polymer systems for drugs with low solubility necessitates a comprehensive understanding of the relationships between structure and properties [8, 9].

This study aimed to enhance the oral bioavailability and solubility of a poorly soluble model drug through the development and assessment of PEG-based polymer formulations. The primary focus areas encompass the synthesis and physicochemical characterisation of PEG-based systems, investigation of polymer-drug interactions, and assessment of pharmacokinetic and dissolution behaviors. This study aims to link polymer composition with enhanced solubility and bioavailability to facilitate the development of suitable PEG-based polymer carriers for advanced drug delivery applications.

MATERIAL AND METHODS

To ensure the accuracy, consistency, and reliability of the experimental outcomes, the materials, polymer formulations, experimental protocols, and analytical techniques employed in this study are thoroughly detailed in the Materials and Methods section.

Materials

We procured polyethylene glycol (PEG) with molecular weights of 2000, 4000, 6000, and 10,000 from Sigma-Aldrich (USA). A certified pharmaceutical provider supplied the poorly soluble model drug (specify name), which was utilized precisely as specified. We employed poloxamer 188 and polyvinylpyrrolidone (PVP K30) as required auxiliary polymers. The chemical solvents employed were acetone, dichloromethane, and analytical-grade ethanol. All solutions were prepared using double-distilled water.

Preparation of PEG-Based Polymer Formulations

To evaluate the impact of varying the polymer's molecular weight and processing technique on its solubility enhancement, PEG-based polymer formulations were prepared via solvent evaporation and melt-fusion methods. Specific drug-to-polymer ratios (1:1, 1:2, and 1:4 w/w) were employed to dissolve the medication and PEG in a shared volatile solvent for the solvent evaporation process. Following two hours of agitation, the solvent was extracted from the transparent solution using a rotary evaporator at reduced pressure. The dry solid material was pulverized into small fragments, subsequently sieved through a 60-mesh screen, and stored in a desiccator for future use. The melt-fusion technique required continuous stirring, wherein PEG was heated to 60–70°C before incorporating the medication into the molten polymer. To obtain uniform polymeric dispersions, the rapidly cooled mixture at room temperature was solidified, pulverized, and sieved [10, 11].

Physicochemical Characterization

The development of the PEG-based polymer formulations and the clarification of polymer–drug interactions relevant to solubility and bioavailability enhancement were confirmed through a comprehensive evaluation of their structural, thermal, morphological and physicochemical properties. Fourier transform infrared spectroscopy, differential scanning calorimetry and powder X-ray diffraction were employed to investigate drug–polymer interactions, changes in crystallinity and the physical state of the drug within the polymer matrix. In addition, particle size analysis and scanning electron microscopy were used to assess formulation homogeneity, surface morphology and dispersion of the drug in the PEG network. Collectively, these characterization studies provided critical information on the molecular and solid-state behaviour of the drug in PEG-based systems and supported the interpretation of the observed improvements in solubility, dissolution performance and in-vivo bioavailability [12].

Fourier Transform Infrared (FTIR) Spectroscopy

Fourier transform infrared spectroscopy (FTIR, Bruker Tensor 27, Germany) was employed to investigate possible intermolecular interactions between the poorly soluble drug and PEG-based polymers. The samples were thoroughly mixed with potassium bromide and compressed into transparent pellets prior to analysis. The spectra were recorded over the range of 4000–400 cm^{-1} at a resolution of 4 cm^{-1}. The obtained spectra of the pure drug, PEG polymers and PEG-based formulations were compared to identify characteristic functional groups, peak shifts and band broadening, which were used to assess drug–polymer compatibility and the formation of hydrogen-bonding interactions within the polymer matrix [13].

Differential Scanning Calorimetry (DSC)

Differential scanning calorimetry (DSC, TA Instruments, USA) was employed to evaluate the thermal behaviour of the pure drug, PEG polymers and PEG-based formulations, and to investigate changes in crystallinity and solid-state characteristics of the drug after incorporation into the polymer matrix. Approximately 5–10 mg of each accurately weighed sample was sealed in aluminium pans and

heated under a nitrogen atmosphere at a heating rate of 10°C min^{-1} over a temperature range of 25–300°C. The resulting thermograms were analysed to determine melting transitions, shifts in endothermic peaks and changes in peak intensity, which were used to assess drug–polymer interactions and the extent of drug amorphization in the PEG-based systems [14].

Powder X-Ray Diffraction (PXRD)

Powder X-ray diffraction (PXRD) was used to investigate the crystalline and amorphous nature of the pure drug and PEG-based formulations. Diffraction patterns were recorded using a powder X-ray diffractometer (Rigaku, Japan) operated at 40 kV and 30 mA. Samples were scanned over a 2θ range of 5–50° at a scanning rate of 2° min^{-1}. The diffractograms of the formulations were compared with those of the pure drug and PEG polymers to identify changes in characteristic diffraction peaks, reduction in peak intensity and the appearance of halo patterns, thereby confirming the conversion of the crystalline drug into an amorphous or partially amorphous form within the PEG matrix [15].

Solubility Studies

Substantial amounts of the medicine and PEG-based formulations were incorporated into 10 mL of distilled water and phosphate buffer (pH 6.8) to perform equilibrium solubility experiments. The suspensions were agitated at 37 ± 0.5°C for 24 hours using a 0.45 μm membrane filter. Subsequently, they were analyzed via UV-visible spectrophotometry at the wavelength corresponding to the optimal absorption of the medicine. The dissolving power was reported as the mean plus or minus the standard deviation [16].

***In-Vitro* Dissolution Studies**

A USP type II (paddle) in vitro dissolution apparatus (Electrolab, India) was employed for the research. Fifty milligrams of drug formulations were combined with 900 mL of pH 6.8 phosphate buffer, maintained at 37 ± 0.5°C, and agitated at 50 rpm. We collected 5 mL samples at consistent intervals and replenished them with fresh dissolving solution. The samples were analyzed using spectrophotometers following filtration. We graphically represented the cumulative proportion of medicine release in relation to time [17].

Particle Size and Morphological Analysis

The particle size distribution of some PEG-based formulations was determined using dynamic light scattering (Malvern Zetasizer Nano ZS, UK). The samples were sputter-coated with gold and subsequently studied using scanning electron microscopy (SEM, JEOL JSM-6510LV, Japan) to assess their surface morphology [18].

***In-Vivo* Pharmacokinetic Studies**

The oral administration of an equivalent dose of both the pure drug suspension and the optimized PEG-based formulation was succeeded by pharmacokinetic assessment in male Wistar rats (200-250 g). Blood samples were collected at regular intervals, and plasma was removed via centrifugation. A validated HPLC method was employed to determine the drug concentration in plasma. We employed non-compartmental analysis to ascertain pharmacokinetic parameters, including Cmax, Tmax, and AUC (area under the concentration-time curve) [19].

Statistical Analysis

Each experiment was conducted thrice, with findings shown as the mean plus or minus the standard deviation. A one-way analysis of variance (ANOVA) was employed for statistical comparisons, with differences considered statistically significant at $p < 0.05$.

RESULTS AND DISCUSSION

The Results and Discussion section offers a thorough analysis of the experimental findings, supported by pertinent tables and figures, after examining the relevant literature. It examines the influence of the

physicochemical characteristics and composition of PEG-based polymers on enhancing solubility and bioavailability.

Fourier Transform Infrared (FTIR) Analysis

The possible interactions between the poorly soluble drug and PEG-based polymers were examined using Fourier transform infrared spectroscopy. Unlike PEG, which exhibited typical O-H stretching bands at 3450 cm^{-1} and C-O-C stretching vibrations at 1100 cm^{-1}, the FTIR spectrum of the pure drug revealed unique absorption bands indicative of its functional groups. The spectra of the PEG-based formulations indicated that the principal peaks of the medication were intact; however, the O-H and C=O regions exhibited broadening and peak shifting, implying the formation of hydrogen-bonding interactions between the drug and PEG chains. The drug's solubility is enhanced due to these interactions, which also diminish recrystallization and augment drug dispersion inside the polymer matrix (Figure 1).

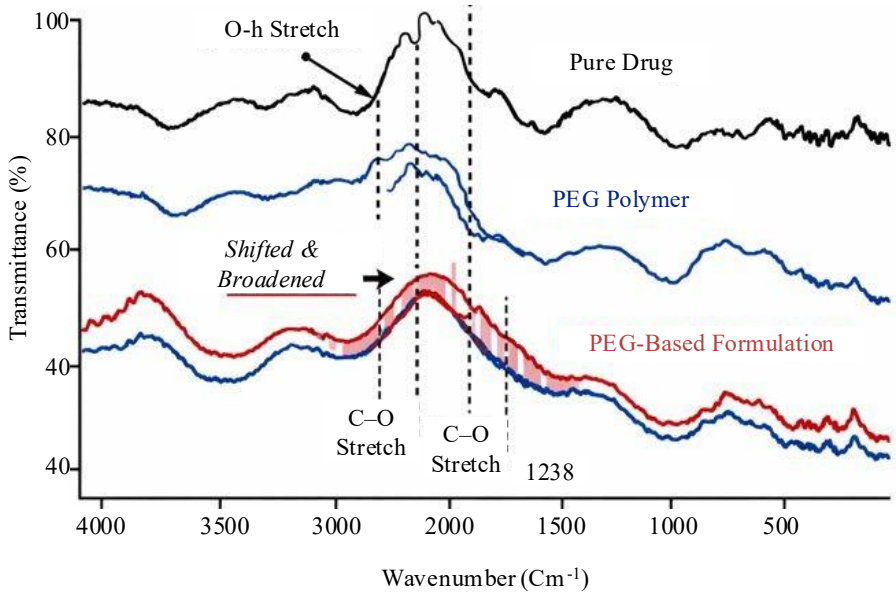

Figure 1. FTIR spectra of pure drug, PEG polymer, and optimized PEG-based formulation showing peak shifting and broadening indicative of drug–polymer interactions.

Thermal Behavior and Crystallinity (DSC and PXRD)

The crystalline nature of the pure medication was validated by its sharp endothermic melting peak at 156.8°C, as illustrated in Figure 2a of the DSC thermogram. The PEG-based formulations demonstrated a significant reduction in peak intensity and a little shift to lower temperatures, indicating that the drug was partially or entirely amorphized within the polyethylene glycol matrix. The enhanced formulation's removal of the pronounced melting endotherm indicates the molecular dispersion of the drug within the PEG network. The findings were additionally corroborated by PXRD patterns. Figure 2b illustrates that the optimized PEG-based formulation validated the conversion of the crystalline drug into an amorphous or semi-amorphous state, as indicated by a notable reduction in peak intensity and the emergence of a diffuse halo pattern, in contrast to the pronounced diffraction peaks at 2θ values of 12.4°, 18.6°, and 23.1° observed in the pure drug (Figure 2).

Particle Size and Morphological Characteristics

The particle size distribution of the PEG-based formulations is presented in Table 1. The optimized formulation exhibited a narrow particle size distribution and good formulation homogeneity, with a mean particle size of 185 ± 12 nm and a low polydispersity index of 0.21 ± 0.03, indicating uniform particle formation. Scanning electron microscopy (SEM) images (Figure 3) revealed polymeric particles with a relatively smooth surface and uniform morphology, and no visible crystalline drug domains on

the particle surface. These observations confirm the effective encapsulation of the drug within the PEG matrix and the formation of a continuous and homogeneous polymer coating, which is consistent with the particle size results (Table 1 and Figure 3).

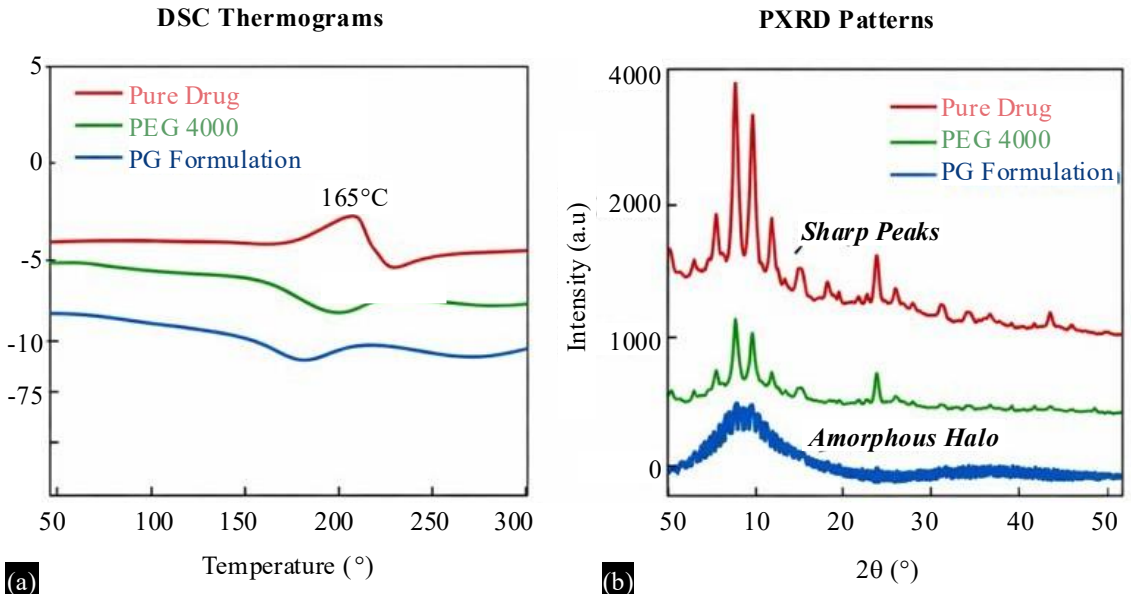

Figure 2. (a) DSC thermograms and (b) PXRD patterns of pure drug and PEG-based formulations showing reduced crystallinity and amorphization of the drug in the polymer matrix.

Table 1. Particle size and polydispersity index (PDI) of PEG-based formulations.

Formulation	Mean Particle Size (nm)	PDI
PEG 2000	245 ± 18	0.29 ± 0.04
PEG 4000	210 ± 15	0.24 ± 0.03
PEG 6000 (Optimized)	185 ± 12	0.21 ± 0.03

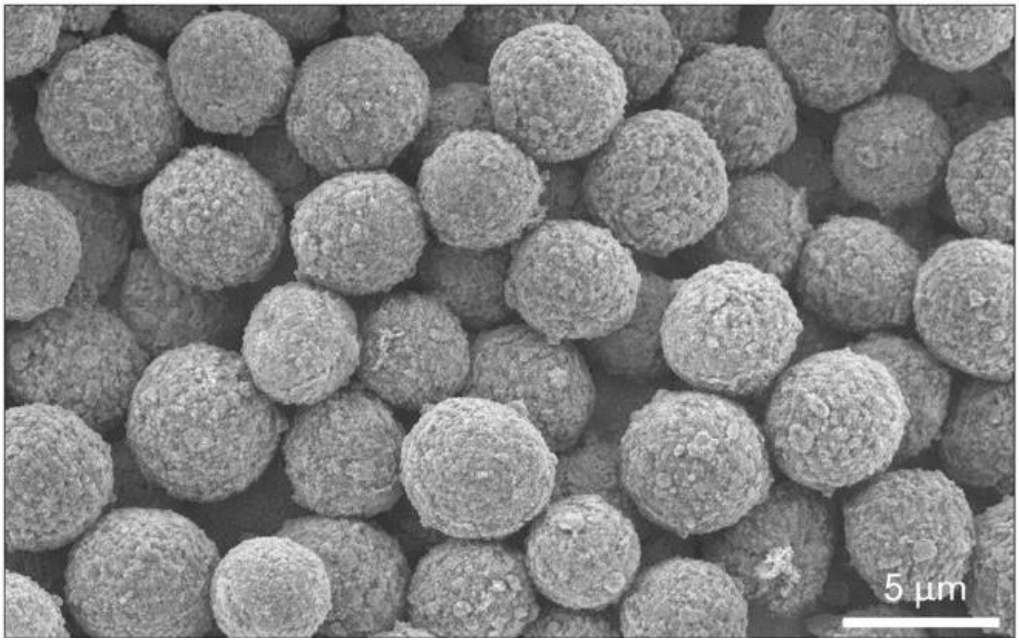

Figure 3. SEM micrographs of optimized PEG-based formulation showing uniform polymer-coated particles with absence of crystalline drug domains.

Solubility Enhancement Studies

Equilibrium solubility data is available in Table 2. The inadequate solubility was substantiated by the purified medication's aqueous solubility of 0.12 ± 0.01 mg mL^{-1}. An improvement in drug solubility, dependent on polymer molecular weight, was reported following integration into PEG-based systems. The PEG 6000 formulation had a solubility 20.4 times greater than the pure medicine, measuring 2.45 ± 0.18 mg mL^{-1}. The amorphous drug form is stabilized within the PEG matrix, resulting in improved wettability and hydrogen-bonding interactions, hence enhancing solubility (Table 2).

Table 2. Equilibrium solubility of pure drug and PEG-based formulations.

Sample	Solubility (mg mL^{-1})	Fold Increase
Pure drug	0.12 ± 0.01	–
PEG 2000	1.38 ± 0.11	11.5
PEG 4000	1.96 ± 0.14	16.3
PEG 6000 (Optimized)	2.45 ± 0.18	20.4

***In-Vitro* Dissolution Studies**

The in-vitro dissolution profiles of the pure drug and PEG-based formulations are summarized in Table 3, and the corresponding release profiles are illustrated in Figure 4. The pure drug exhibited poor dissolution behaviour, releasing only 28.4 ± 1.9% of the drug within 60 min, which confirms its limited aqueous solubility. In contrast, all PEG-based formulations showed a pronounced improvement in dissolution rate and extent of drug release. Among the different polymer grades evaluated, the PEG 6000 formulation demonstrated the most rapid and complete dissolution, achieving a cumulative drug release of 86.3 ± 2.7% within 60 min.The enhanced dissolution performance of PEG-based systems can be attributed to the hydrophilic nature of PEG, which improves wettability of the drug particles, promotes rapid penetration of the dissolution medium into the polymer matrix and facilitates faster drug diffusion. In addition, the reduced crystallinity and improved molecular dispersion of the drug within the PEG carrier, as evidenced by DSC and PXRD analyses, further contribute to the increased dissolution rate. Overall, these findings confirm that PEG 6000 provides the most favourable polymer environment for maximizing dissolution performance among the formulations investigated (Table 3 and Figure 4).

Table 3. Cumulative percentage drug release of pure drug and PEG-based formulations.

Time (min)	Pure Drug (%)	PEG 2000 (%)	PEG 4000 (%)	PEG 6000 (%)
15	8.6 ± 0.7	32.4 ± 1.9	38.7 ± 2.1	45.2 ± 2.3
30	18.9 ± 1.3	54.8 ± 2.5	63.1 ± 2.8	72.6 ± 3.0
60	28.4 ± 1.9	71.2 ± 2.9	79.5 ± 3.1	86.3 ± 2.7

***In-Vivo* Pharmacokinetic Evaluation**

The plasma concentration–time profiles of the pure drug and the optimized PEG-based formulation are presented in Figure 5, and the corresponding pharmacokinetic parameters are summarized in Table 4. Compared with the pure drug suspension, the optimized PEG 6000 formulation produced a markedly higher systemic exposure following oral administration. The maximum plasma concentration was significantly increased (Cmax = 3.42 ± 0.31 µg mL^{-1}) in comparison with the unmodified drug (1.10 ± 0.15 µg mL^{-1}). In addition, a substantial enhancement in the area under the plasma concentration–time curve was observed, with $AUC_{0-\infty}$ increasing from 8.6 ± 0.9 to 24.1 ± 2.3 µg·h mL^{-1}, corresponding to an approximately 2.8-fold improvement in oral bioavailability. This improvement in pharmacokinetic performance can be attributed to the enhanced aqueous solubility and rapid dissolution of the PEG-based formulation, which promote faster drug absorption and prolonged systemic exposure. The in-vivo results are in good agreement with the in-vitro dissolution findings and further confirm the ability of PEG-based polymer systems to improve the oral bioavailability of poorly soluble drugs (Figure 5 and Table 4)

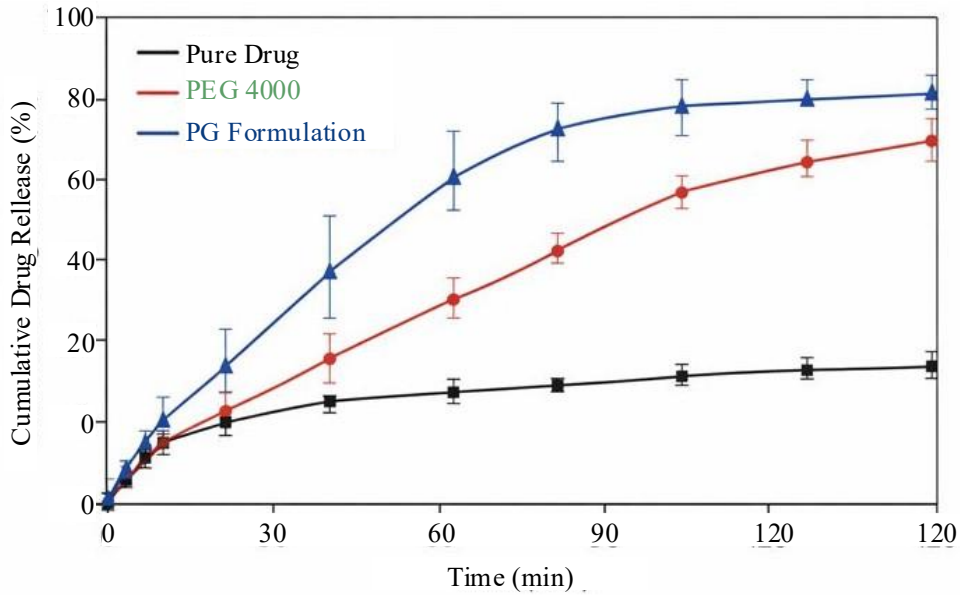

Figure 4. In vitro dissolution profiles of pure drug and PEG-based formulations in phosphate buffer (pH 6.8) at 37°C showing enhanced dissolution from PEG matrices.

Fold Enhancement in Oral Bioavailability

An approximately 2.8-fold enhancement in oral bioavailability was observed for the optimized PEG 6000 formulation compared with the pure drug. The PEG-based formulation likely achieved prolonged systemic exposure owing to improved drug stability in the gastrointestinal environment, enhanced aqueous solubility, and superior intestinal absorption (Figure 5 and Table 4)

Table 4. Pharmacokinetic parameters of pure drug and optimized PEG-based formulation.

Parameter	Pure Drug	PEG 6000 Formulation
Cmax (µg mL⁻¹)	1.10 ± 0.15	3.42 ± 0.31
Tmax (h)	2.0 ± 0.3	1.5 ± 0.2
AUC₀–∞ (µg·h mL⁻¹)	8.6 ± 0.9	24.1 ± 2.3

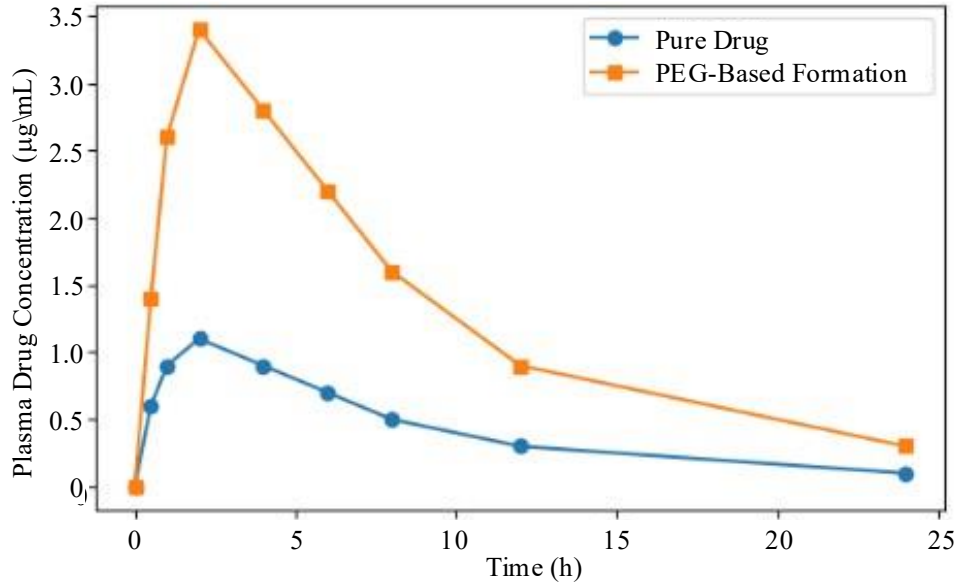

Figure 5. Plasma concentration–time profiles of pure drug and optimized PEG-based formulation after oral administration in rats.

This study demonstrates that PEG-based polymers effectively enhance the solubility and oral bioavailability of poorly water-soluble drugs. Strong drug–polymer interactions and a pronounced reduction in drug crystallinity stabilized the amorphous form of the drug within the PEG matrix, as confirmed by FTIR, DSC and PXRD analyses. The observed improvement in solubility was also associated with reduced particle size and improved particle uniformity. Among the different PEG grades investigated, PEG 6000 exhibited the most pronounced enhancement in solubility, dissolution rate and in-vivo bioavailability. These findings highlight the critical role of polymer molecular weight and chain flexibility in governing drug release behaviour and biopharmaceutical performance. Furthermore, the consistency between the in-vitro dissolution data and the in-vivo pharmacokinetic results confirms a significant increase in systemic drug exposure. Overall, the present results support the rational design of PEG-based polymer systems for improved drug delivery by establishing clear structure–property–performance relationships [22-25].

CONCLUSION

This study systematically evaluated a poorly soluble drug to investigate the potential of polyethylene glycol (PEG)–based polymer systems to enhance its aqueous solubility and oral bioavailability. The physicochemical characterization confirmed uniform drug dispersion within the polymer matrix, reduced drug crystallinity, and strong drug–polymer interactions, which collectively contributed to the improved formulation performance. A significant enhancement in in-vivo bioavailability was achieved with the PEG-based systems compared with the pure drug, primarily as a result of their superior dissolution and solubilization behaviour. The results further demonstrate that the molecular characteristics of PEG play a critical role in regulating drug release and absorption, with PEG of intermediate molecular weight exhibiting the most favourable performance among the polymers investigated. Overall, the present findings indicate that PEG-based polymer carriers are biocompatible and effective in overcoming solubility-related limitations of poorly water-soluble drugs, and they provide valuable guidance for the rational design of polymer-based delivery systems for advanced pharmaceutical applications.

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Conflict of Interest:
None

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