

RESEARCH PAPER

Formulation and Evaluation of a Nanoemulsion-Based Drug Delivery System to Enhance the Oral Performance of Curcumin

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ABSTRACT

Poor aqueous solubility limits the in vitro dissolution performance of many drugs, among them curcumin which is a bioactive compound with great therapeutic potential but with poor dissolution in gastrointestinal fluids. This study aimed to develop a curcumin nanoemulsion to improve in vitro dissolution performance and physicochemical stability of the curcumin solution. Nanoemulsions were made with the following three emulsifiers: Capryol® 90, Tween® 80, and polysorbate 400 (PEG 400), and were characterized by measuring droplet size, polydispersity index, and zeta potential. In vitro dissolution performance was evaluated and compared with that of pure curcumin and physical stability was studied under different storage conditions. Data visualization techniques were used to bring integration of formulation attributes. The optimized nanoemulsion had a nanoscale droplet size in a narrow distribution with sufficient electrostatic stability. For nanoemulsion, dissolution efficiency was found to be significantly increased in vitro compared to pure curcumin in all time points, and the optimized formulation tested showed greater and consistent performance. Stability evaluation showed little variation in size under normal storage conditions, with an anticipated size increase at high temperature. In conclusion, the nanoemulsion system enhanced the dissolution behaviour of curcumin to a great extent with an acceptable physicochemical stability, and may therefore support its potential as an oral delivery platform for poorly water-soluble drugs.

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INTRODUCTION

The most common way of drug administration is oral administration due to its convenient, non-invasive way of administration and because it usually complies with high patient adherence. However, it has been observed that oral delivery of most of the active pharmaceutical ingredient (APIs) is limited by a poor level of aqueous

solubility and, hence, a slow rate of dissolution in the gastrointestinal (GI) fluids resulting in low and unpredictable absorption. The problem is very widespread in the contemporary drug development; a significant proportion of approved drugs, and even a higher percentage of development candidates are poorly soluble in water, solubility improvement has been a

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consistent concern among formulation scientists [1].

A wide variety of formulation strategies have been developed for enhancing dissolution and oral bioavailability of poorly water-soluble drugs, including cosolvents, solubilization using surfactants, salt formations and cyclodextrin complexes, amorphous solid dispersions and lipid-based carriers [2]. Recent comprehensive reviews highlight the need to select between these approaches based on the physicochemical properties of the drug (e.g. lipophilicity, melting point, and crystallinity), the desired dosage form and the possibility of obtaining clinical translation. Among the modern alternatives, lipid-based systems (self-emulsifying systems and nano-enabled lipids) are being continuously mentioned as viable alternative platforms for solubilizing hydrophobic compounds and enhancing their oral absorption potential [3].

Nanoemulsions are kinetically stable, colloidal dispersions (usually oil in water for oral administration), in which the internal phase is dispersed as drops in the nanometer size range. Their pharmaceutical relevance is highly related to (i) high interfacial surface area, (ii) efficient solubilization of lipophilic payloads in the oil phase and (iii) the capacity to present the drug in a pre-solubilized form which has the potential to enhance apparent dissolution and absorption processes. Recent reviews however also highlight that the performance of nanoemulsions is critically dependent on the formulation composition (oil/surfactant/co-surfactant choice) and manufacturing method (high energy techniques (ultrasonication or high pressure homogenization) or low energy methods), as those factors govern the droplet size distribution, physical stability and drug loading capacity. To this end, physicochemical characterization, in particular, droplet size, polydispersity index (PDI) and zeta potential are still considered to be the keys to stability prediction, as well as to reproducible oral delivery conduct [4].

Curcumin (a polyphenol constituent of *Curcuma longa*) is a popularly studied bioactive component has been widely investigated for its reported anti-inflammatory, antioxidant, and anticancer. Though such pharmacological promise exists, the oral translation of curcumin is limited by its very low aqueous solubility and low stability in GI-relevant conditions and is rapidly bio transformed,

and such characteristics represent major barriers to achieving adequate systemic exposure following conventional oral dosing of curcumin [5]. A recent systematic review on advanced oral delivery systems for curcumin concluded that nano- and micro-scale carrier systems (lipid-based approaches, among others) are commonly used to improve the bioavailability of curcumin after oral administration, when compared with unformulated curcumin, but also highlighted that formulation development and evaluation is not always optimized and that formulations vary greatly [6]. To add to this, an oral curcumin methodological review of systematic reviews that paid particular attention to the bioavailability differences between products was identified in the year 2024 as a determinant of observed results - although not always well managed in evidence synthesis - with a need to have rigorously characterised and reproducible formulations to achieve publishable and interpretable results [6].

In lipid-based system, nano primal formation and glibness on dilution in GI fluids are highly dependent on bilayer selection of excipients. Studies involving self-nanoemulsifying systems (closely related to nanoemulsions formed in situ on aqueous dispersion) indicate that the use of medium-chain lipid excipients and non-ionic surfactants are often preferred because they can offer high solubilization capacity of the drug and high emulsification speed, resulting in small droplet sizes and narrow size distribution under optimized conditions [7]. Likewise, studies of curcumin focused nanoemulsion have shown that stability can be condition-dependent (for example, studies of the effects of pH on the state of interfacial charge and the integrity of droplets) to support the case of studying nanoemulsion formulations under multiple storage and GI relevant conditions as opposed to a single time point or environment [8].

Despite extensive research on nanoemulsion-based systems in order to improve the delivery of curcumin to the oral cavity, the formulation performance is strongly determined by the choice of excipients and, therefore, the resulting physicochemical profile. In this regard, the nanoemulsion systems, precisely made up of Capryol® 90 (oil phase) and Tween® 80 (surfactant) and PEG400 (co-surfactant), are under-characterized, especially with regard to the integrated evaluation of (i) dissolution

enhancement and (ii) physicochemical stability under various storage conditions. This restriction of the available conclusions to formulation-specific applications demonstrates that a systematic formulation and evaluation scheme is necessary for this combination of ingredients.

Can a curcumin nanoemulsion loaded with Capryol® 90, Tween® 80 and PEG 400 improve in vitro dissolution performance, while having acceptable physicochemical stability for oral delivery?

The current experiment is intended to design and test a nanoemulsion with curcumin. Particularly, the research is aimed at the creation of curcumin nanoemulsions with the help of high-energy emulsification, the description of their physicochemical characteristics in terms of droplet size, polydispersity index (PDI), and zeta potential, and the comparison between the in vitro outcomes of nanoemulsions in terms of the dissolution of pure curcumin. Besides, physical stability of the formulations in varying storage conditions is investigated. Lastly, formulation performance is graphically visualized using integrative graphical techniques that do not have the redundancy effect.

MATERIALS AND METHODS

Materials

As the model poorly water-soluble compound, curcumin was used. Capryol® 90 (oil phase), Tween® 80 (surfactant) and PEG 400 (co-surfactant) were chosen as the major formulation components, and all of them are of pharmaceutical grade. Capryol® 90 consists mainly of propylene glycol mono caprylate (C8) mono esters, and it is often chosen as lipid excipient in oral lipid-based delivery systems because of its suitability in solubilization of lipophilic drugs [9].

Tween® 80 (as a non-ionic surfactant), PEG 400 as the hydrophilic co-surfactant were used to aid

in the formation of fine dispersions, and in the stabilization of the interface. Similar surfactant/co-surfactant strategies (also in the form of Tween® and PEG combinations), are often reported in nanoemulsion/SNEDD's formulation frameworks [9]. particularly when aiming to achieve droplet sizes in the nanometer range and acceptable distribution uniformity [10].

Purified (deionized) water was used for nanoemulsion preparation as well as dilution steps (aqueous phase). The materials were all stored and handled in accordance with the recommendations of the manufacturers [11].

Dissolution profiles were statistically analyzed using two-way ANOVA (formulation × time) followed by Sidak/Tukey multiple comparisons test. Significance was set at $p < 0.05$.

Formulation Composition

A formulation matrix based on three curcumin nanoemulsion compositions (F1-F3) were constructed. Curcumin concentration was fixed at 1.0% w/w and the oil phase (Capryol® 90) and surfactant concentration were varied within a practical formulation window, where PEG 400 is the co-surfactant. All percents have been expressed as %w/w and total to 100%.

Physicochemical Characterization

The optimized curcumin nanoemulsion was characterised for determination of droplet size, polydispersity index (PDI) and zeta potential as the important quality characteristics affecting dispersion uniformity and physical stability [12]. Droplet sizes and PDI were measured by dynamic light scattering (DLS) after suitable dilution of the nanoemulsion with filtered aqueous medium in order to avoid multiple scattering effects and to ensure the success of autocorrelation analysis [13]. Measurements were obtained at a controlled temperature of 25 °C and reported as mean, mean

Table 1. Composition of Curcumin Nanoemulsion Formulations.

Formulation	Curcumin (% w/w)	Capryol® 90	Tween® 80	PEG 400
F1	1	10	45	44
F2	1	12	43	44
F3 (Optimized)	1	15	40	44

+ SD on the basis of the number of replicates and PDI values were used to confirm the narrowness of the size distribution and formulation homogeneity [14].

As an indication of interfacial charge and electrostatic repulsion between droplets, zeta potential was determined by the technique of ELS (electrophoretic light scattering) [15]. The magnitude of zeta potential gives supportive evidence for the stability of the colloids; in many nanoemulsion systems it is generally observed that values with a high-enough absolute magnitude are usually associated with a low risk of aggregation and coalescence of the droplets. However, zeta potential must be understood within the context of the conditions in which the measurement was conducted (e.g., ionic strength, pH, dilution protocol and the electrokinetic model used), in that these factors may vary significantly, leading to seriously skewed calculated values and inferences

regarding its stability. Therefore, zeta potential interpretation was complimented by droplet size/ PDI tracking and storage stability monitoring [16].

In Vitro Dissolution Performance

In vitro dissolution test was performed for comparison of the release behavior of curcumin from the optimized nanoemulsion in comparison to unformulated (pure) curcumin under standardized conditions for compounds with poor water solubility [17]. Dissolution profiling is an important surrogate performance test for lipid-based and nano enabled oral delivery systems because it measures the extent and rate of transfer of the drug into the dissolution medium, which is directly relevant to the availability of the drug in dissolved form prior to intestinal absorption [18].

A compendial-style setup is where the media used (commonly USP Apparatus II or equivalent) is widely applied in curcumin enabled

Table 2. Physicochemical Characteristics of the Optimized Nanoemulsion.

Parameter	Mean $\pm$ SD	Interpretation
Droplet size (nm)	145 $\pm$ 18	Nanoscale dispersion
PDI	0.21 $\pm$ 0.04	Narrow size distribution
Zeta potential (mV)	-32.6 $\pm$ 4.1	Adequate electrostatic stability

Table 3. In Vitro Dissolution Profile (mean $\pm$ SD).

Time (min)	Nanoemulsion (%)	Pure Curcumin (%)
10	48 $\pm$ 5	9 $\pm$ 3
20	67 $\pm$ 6	14 $\pm$ 4
30	82 $\pm$ 4	19 $\pm$ 5
60	94 $\pm$ 3	28 $\pm$ 6

Table 4. Model-independent dissolution parameters of pure curcumin and nanoemulsion formulations.

Formulation	DE% (0–60 min)	MDT (min)
Pure curcumin	18.6 $\pm$ 2.1	41.8 $\pm$ 3.5
F1	61.4 $\pm$ 3.2	19.6 $\pm$ 2.1
F2	67.9 $\pm$ 2.8	16.8 $\pm$ 1.9
F3 (Optimized)	73.5 $\pm$ 2.4	13.2 $\pm$ 1.6

lipid formulations where often sequential or biorelevant media reflective of gastrointestinal environments are applied, where sink conditions can be maintained where required [19]. Alongside cumulative percent release, use of model-independent parameters such as dissolution efficiency (DE%) and mean dissolution time (MDT) can also be described to summarize an integrated, single value comparison of overall dissolution performance over a defined interval (e.g. 0-60 min) that can avoid over-reliance on data from individual time points [20].

Table 4 provides a summary of the model-independent dissolution parameters, to give a combined comparison of the release behavior of formulations.

DE%: dissolution efficiency calculated over 60 min; MDT: mean dissolution time.

Stability Assessment (Short)

The physical stability of the optimized nanoemulsion was examined under long-term and accelerated storage conditions according to general principles of pharmaceutical stability [20].

Samples were saved and tested at set time points (e.g. Day 0, 7, 14 and 30). At each time point, formulations were checked for macroscopic instability (phase separation, creaming/cracking, or precipitation), and important colloidal

properties were re-measured consisting of droplet size, PDI and zeta potential using the same procedures described in Section 3.3. This is usually done to observe the growth of the droplets and the widening of the distribution as early signs of destabilizing of a nanoemulsion [21].

RESULTS AND DISCUSSION

Data Visualization Strategy

To add value to the interpretation of the encountered formulation results in order to avoid any redundant numerical repetition of tabulated data, selected graphical representations were adopted as a way to give the integrative and comparative ability about formulation performance [22]. These visualizations were tailored to integrate multiple physicochemical and functional attributes and also impacted by bringing together analytical views; thus, to find or select the formulations and discuss the findings [23].

A multidimensional quality profile comparing the investigated curcumin nanoemulsion formulations (F1, F2 and optimized F3) has been presented in Fig. 1 using normalized performance indicators. The profile incorporates important formulation characteristics such as the droplet size, polydispersity index (PDI), the absolute zeta potential ($|\zeta|$) and dissolution efficiency at 60 min

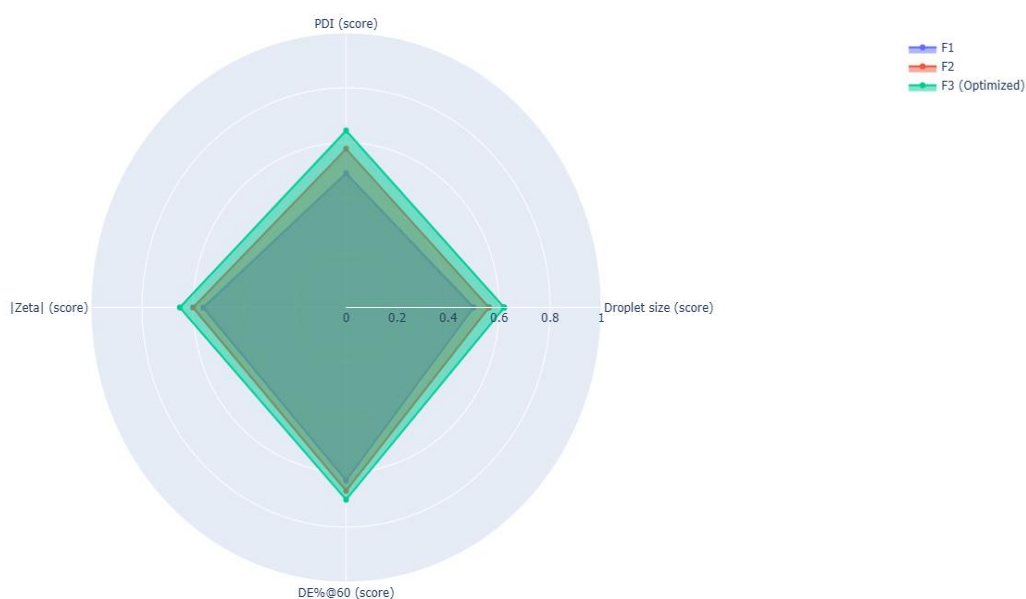


Fig. 1. Multidimensional Quality Profile.

(DE%@60) which allows holistic assessment of the nature of the formulation.

This combined display depicts the comparative strengths and trade-offs of the formulations, and it is possible to perform the simultaneous assessment of physicochemical stability and dissolution performance. The approach is helpful for formulation optimization by understanding multidimensional behavior in one analytical context instead of isolated parameters.

Fig. 2 shows the dissolution efficiency behavior for the investigated formulations as a function of time, resulting in an area-based picture of release behavior as compared to single point measurements. This visualization reveals significant formulation-dependent differences showing that the dissolution efficiency is significantly higher for all nanoemulsions formulations than for pure curcumin for every considered time window. The optimized formulation (F3) shows consistently superior dissolution efficiency over the study period, which can be attributed to the better capacity of the optimized formulation to keep curcumin in solubilized and easily available conditions. In contrast, the solubility data of pure curcumin are limited with a slow rate of drug dissolution which highlights the intrinsic solubility limitation of the unformulated drug. This type of graphical representation complements tabulation of dissolution information because it conveys both the rate and extent of dissolution enhancement in

one integrative view.

Fig. 3 is a distribution-based visualization of droplet size characteristics of the investigated nanoemulsion formulations that go beyond average particle size values. The density profiles illustrate formulation dependent results in size homogeneity and distribution width which are not defined adequately by mean size and PDI alone. The optimized formulation (F3) has a narrower and more symmetric size distribution, indicating a better uniformity of droplets together with a reduced size variability. In contrast, formulations F1 and F2 show greater spread and more dispersion (i.e. larger droplet sizes) indicating relatively greater heterogeneity. This visualization complements the traditional particle size metrics because it sheds light onto the internal structure of the size population, which thus supports a more sturdy determination of the quality of the formulation adulation important for a conclusive evaluation of material colloidal consistency. Table 5 presents numerical changes in physicochemical parameters of the optimized formulation over storage.

Fig. 4 shows the time dependence of droplet size evolution of optimized nanoemulsion formulation wherein different storage conditions are employed. This trajectory-based visualization gives insight into the dynamic regular behavior of the system by tracking gradual changes in droplet size that would become comparable to isolated

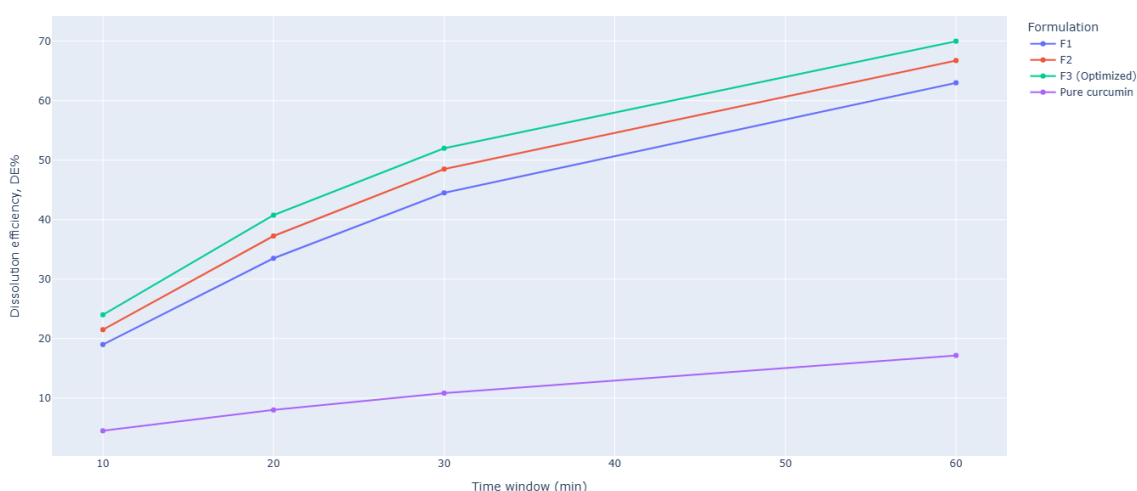


Fig. 2. Dissolution efficiency (denoted as DE%) profiles of nanoemulsion formulations of curcumin (F1, F2 and optimized formulation of F3) versus pure curcumin in different time windows (10-60 min), showing dependence of formulation enhancement of dissolution performances.

check points for stability of the system.

The formulation shows a low variation in droplet size for room temperature condition indicating good physical stability during evaluated storage time. In contrast, storage under elevated temperature conditions is linked with progressive increase in droplet size which is suggestive of temperature-induced destabilization mechanisms such as increased droplet coalescence or faster interfacial rearrangement. Through this visualization, stability as a continuous process, described in time, and allows to better distinguish between storage environments that are stable and stress-sensitive and complements descriptors of stability as expressed in literature tables.

Fig. 5 reports the integrative comparison of formulation performance using a composite index that incorporates the important dissolution and stability related attributes into one quantitative index. This visualization allows quick and easy

distinction between these formulations through the summarization of the multidimensional performance outcomes in a unified formulation.

The optimized formulation (F3) displays the highest index value representing the best combination between increased dissolution efficiency and physicochemical stability. Formulation F2 shows intermediate performance while F1 shows comparatively less overall performance. By combining several quality attributes in one index, this method facilitates the objective formulation ranking and helps to reinforce conclusions from results of individual dissolution, particle size, and stability analyses.

The present findings support the use of nanoemulsion-based delivery system as an efficient means of overcoming the dissolution-related limitations of curcumin such as poor aqueous solubility and poor dissolution characteristics [24]. In accordance with the recent literature

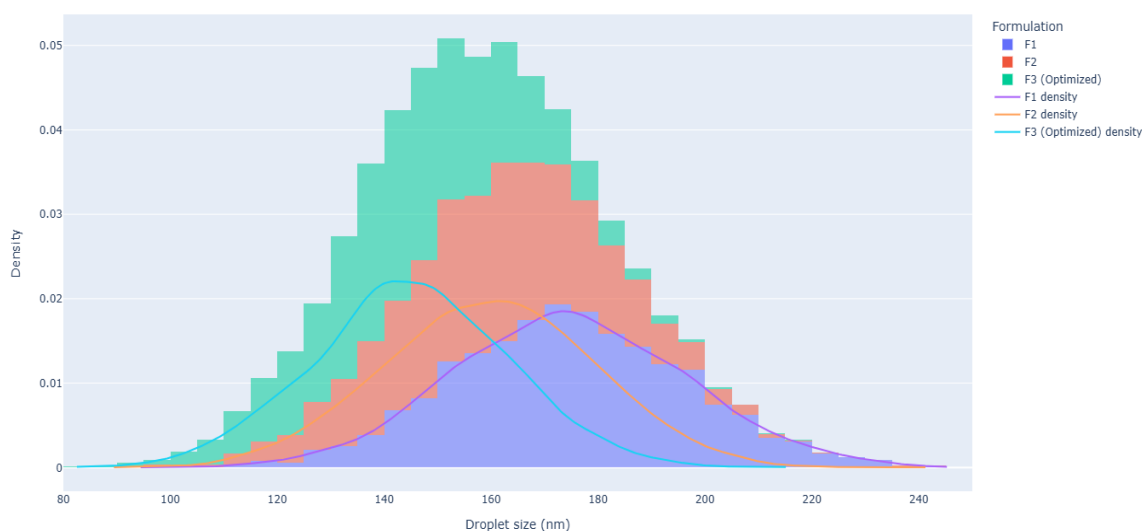


Fig. 3. Particle size distribution density profiles of curcumin nanoemulsions formulations (F1, F2, and optimized formulation F3) showing varies with the homogeneity and the distribution of droplet size beyond the mean values.

Table 5. Changes in physicochemical parameters of the optimized curcumin nanoemulsion during storage at room temperature.

Time (days)	Droplet size (nm)	PDI	Zeta potential (mV)
0	145 ± 18	0.21 ± 0.04	-32.6 ± 4.1
7	147 ± 17	0.22 ± 0.03	-31.9 ± 3.8
14	149 ± 16	0.23 ± 0.04	-31.4 ± 3.6
30	151 ± 15	0.24 ± 0.05	-30.8 ± 3.9

on nanoemulsion drug delivery, the optimized formulation exhibited a good combination of nanoscale droplet size, excellent size distribution, and enhanced dissolution compared with pure curcumin, which is in line with the mechanistic expectation that a smaller droplet size will provide higher interfacial area and keep the drug in a more readily available dispersed/solubilized state [23].

From a physicochemical viewpoint, the above

improvement in the quality of the formulation can be supported by consideration of the role of both droplet size and PDI as major keys to characterize the uniformity and reproducibility with the dispersion, and zeta potential, as supportive evidence for interfacial stabilization [25]. These attributes are typically considered as fundamental quality indicators in the development of nanoemulsions due to their contribution to the

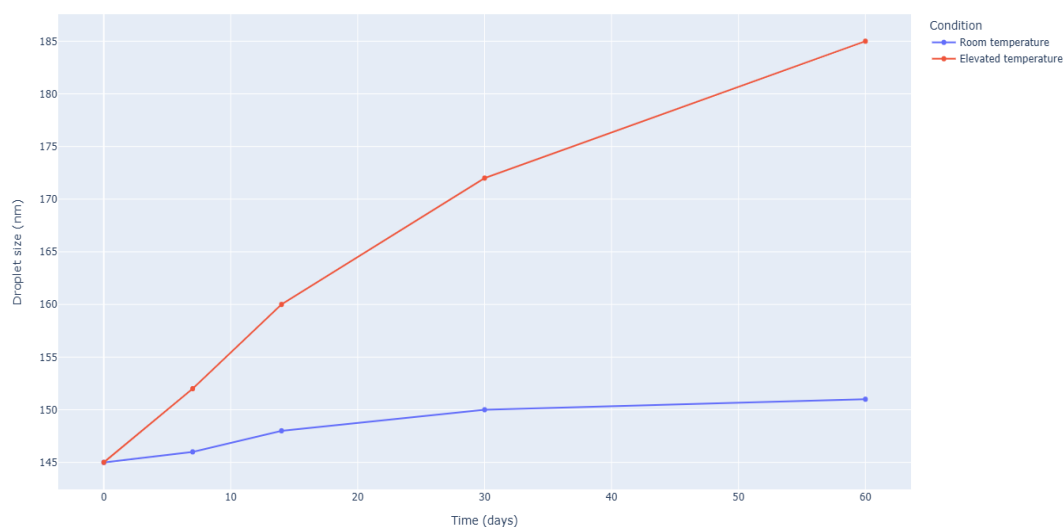


Fig. 4. The temporal variation of the droplet size of the optimal curcumin nanoemulsion kept at varying temperatures, which depicts the behavior of the nanoemulsion in terms of stability over time.

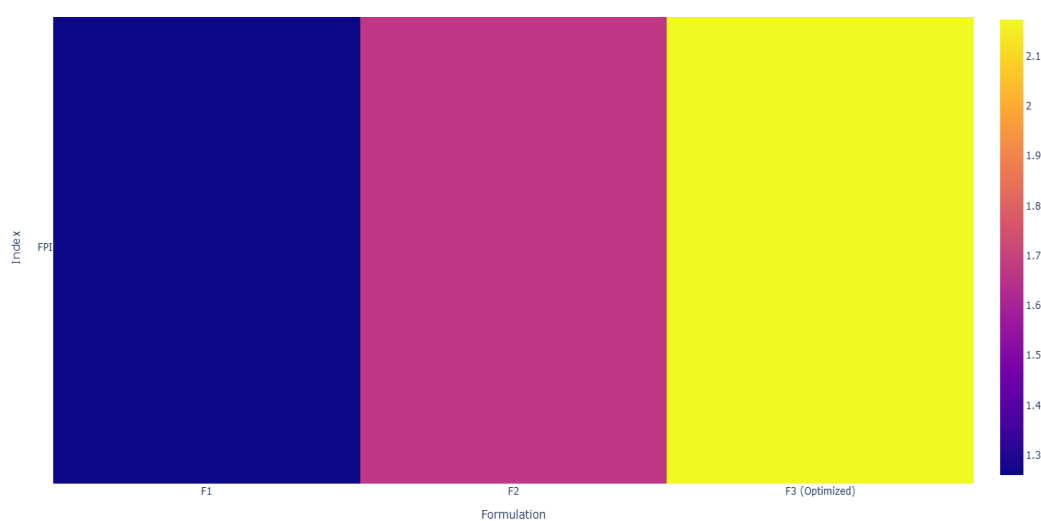


Fig. 5. Comparative visualization of the Formulation Performance Index (FPI) of curcumin nanoemulsion formulations (F1, F2 and optimized F3) incorporating the dissolution performance and physicochemical stability qualities into one composite indicator.

characteristics of droplet interactions, aggregation propensity and handling/storing performance [26].

The dissolution efficiency (DE%) visualization method afforded an integrative picture of the performance of the release within time windows as opposed to the utilization of single point comparisons [27]. This is in line with dissolution profile comparison literature, whereby model-independent measures (including DE%) are adopted to summarise the overall dissolution behaviour and elaborate the interpretation by providing evidence for differences between multiple formulations [28].

Stability tracking further suggested conditional behavior between the conditions, showing better size keeping under standard storing and increase in size at higher temperature [29]. This trend is following well-recognized temperature sensitivity from emulsion systems, whereby increased thermal energy can accelerate the growth mechanism of the droplet system and diminish the robustness of the droplets' interfaces over the course of time, respectively. The use of long-term and accelerated conditions is also in keeping with normal stability testing principles which have been used to assess the robustness of formulations [30].

Overall, combining the physicochemical, dissolution, and stability evidence supports the selection of the optimized nanoemulsion as the most balanced formulation among those investigated among the tested systems, and also, the visualization framework reinforces formulation ranking by reflecting multidimensional and performance by capturing multidimensional performance instead of testing for isolated parameters [31].

CONCLUSION

The present study successfully developed and evaluated a nanoemulsion-based drug delivery system for curcumin using Capryol® 90, Tween® 80, and PEG 400. The optimized formulation demonstrated desirable physicochemical characteristics, including nanoscale droplet size, narrow polydispersity, and adequate electrostatic stability, which collectively indicate high formulation uniformity and dispersion stability. Importantly, the nanoemulsion significantly enhanced the in vitro dissolution performance of curcumin compared with the unformulated drug, as reflected by markedly increased dissolution

efficiency and reduced mean dissolution time. The results indicate that displaying curcumin in a pre-solubilized nano-dispersed form is good in overcoming intrinsic solubility constraints and enhancing better dissolution actions. Stability tests also showed that the optimized formulation achieved acceptable physicochemical integrity in the normal storage conditions, although the droplet size increased faster by high temperatures, suggesting that storage control conditions are important to ensure stability over the long term. Formulation perspective The visualization framework and the multidimensional performance assessment were more integrative and it reinforced the ranking in formulation and validated the optimized nanoemulsion as the most balanced system among the systems studied.

These findings justify the use of nanoemulsions to deliver curcumin and other water-insoluble drugs by mouth as a promising approach to oral delivery. The proposed studies in future should involve in vivo pharmacokinetic analysis, gastrointestinal digestion modeling, and stability studies over a long period of time to validate the clinical translatability of the formulation developed. Also, Quality-by-Design (QbD) optimization and scale-up feasibility study could further assist in regulatory development and pharmaceutical applicability of curcumin nanoemulsion systems.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interests regarding the publication of this manuscript.

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