INTERNATIONAL MULTI DISCIPLINARY JOURNAL FOR RESEARCH & DEVELOPMENT
eISSN 2394-6334 Impact factor: 8.854 Volume 13, issue 01 (2026)

# FORMULATION AND EVALUATION OF NANOEMULSION-BASED PHARMACEUTICAL PRODUCTS

**Giyosova Habiba Isakjonovna**
Faculty of Pharmacy
Department of Pharmaceutical Sciences–1
Assistant, Andijan State Medical Institute

**Abstract.** Nanoemulsion-based drug delivery systems have attracted considerable attention in modern pharmaceutical research due to their ability to enhance the solubility, stability, and bioavailability of poorly water-soluble drugs. The present study aimed to develop and evaluate a nanoemulsion formulation for a model lipophilic drug using high-energy emulsification techniques. Nanoemulsions were prepared using medium-chain triglycerides as the oil phase, Tween 80 as the surfactant, and polyethylene glycol 400 as the co-surfactant.

The prepared nanoemulsions were characterized in terms of droplet size, polydispersity index, zeta potential, drug content, encapsulation efficiency, in vitro drug release, and physical stability. The optimized formulation exhibited nanoscale droplet size with narrow size distribution, high encapsulation efficiency, and sufficient zeta potential values, indicating good physical stability. In vitro drug release studies demonstrated a biphasic release pattern with enhanced cumulative drug release compared to conventional drug suspensions. Stability studies confirmed that the nanoemulsion formulations remained physically stable under various storage conditions.

Overall, the results indicate that nanoemulsion-based formulations represent a promising and effective approach for improving the delivery of poorly water-soluble pharmaceutical compounds. Further in vivo studies are required to establish their clinical efficacy and safety.

**Keywords:** Nanoemulsion; drug delivery system; poorly water-soluble drugs; encapsulation efficiency; in vitro drug release; pharmaceutical formulation.

## Introduction

The development of innovative drug delivery systems is a crucial direction in modern pharmaceutical science aimed at improving the efficacy, safety, and bioavailability of medicinal products [1]. One of the most promising approaches in this field is the use of nanoemulsion-based drug delivery systems, which have gained significant attention due to their unique physicochemical properties and wide pharmaceutical applicability [2]. Nanoemulsions are kinetically stable, nanoscale dispersions of two immiscible liquids, typically oil and water, stabilized by surfactants and co-surfactants, with droplet sizes generally ranging from 20 to 200 nanometers [3].

Many active pharmaceutical ingredients (APIs) used in clinical practice exhibit poor water solubility, low bioavailability, and limited therapeutic effectiveness when administered through conventional dosage forms [4]. These limitations often result in delayed onset of action, dose variability, and increased risk of side effects. Nanoemulsions offer an effective solution to these challenges by enhancing the solubility and dissolution rate of lipophilic drugs, facilitating improved absorption and controlled drug release [5].

The small droplet size and large surface area of nanoemulsions contribute to improved drug permeability across biological membranes, making them particularly suitable for oral, topical, transdermal, ocular, and parenteral drug delivery [6]. In addition, nanoemulsion systems demonstrate advantages such as physical stability, ease of preparation, scalability for industrial production, and the ability to incorporate both hydrophilic and hydrophobic drugs [7]. These characteristics make nanoemulsions a versatile platform for pharmaceutical formulation development.

Recent advances in formulation techniques, including high-pressure homogenization, ultrasonication, and spontaneous emulsification methods, have further accelerated the application of nanoemulsions in pharmaceutical research and industry [8]. Moreover, the use of biocompatible and biodegradable surfactants has enhanced the safety profile of nanoemulsion-based drug products, supporting their potential for clinical use [9].

The growing interest in nanoemulsions is also driven by their applicability in targeted and personalized drug delivery systems. By modifying formulation components, nanoemulsions can be designed to improve drug targeting, reduce systemic toxicity, and enhance therapeutic outcomes [10]. As a result, nanoemulsion-based formulations are increasingly explored for the treatment of chronic diseases, infectious conditions, cancer, and central nervous system disorders [11].

The aim of this article is to review and analyze the principles of nanoemulsion formulation, methods of preparation, key characterization parameters, and their pharmaceutical applications in drug development. The study highlights the potential of nanoemulsions as an advanced drug delivery system and discusses current challenges and future perspectives in the development of nanoemulsion-based medicinal products [12].

**Materials and Methods**

The oil phase used for the preparation of nanoemulsions consisted of medium-chain triglycerides (MCT oil), which served as the lipid carrier. Tween 80 was selected as the primary surfactant, while polyethylene glycol 400 (PEG 400) was used as a co-surfactant due to their proven biocompatibility and widespread application in pharmaceutical formulations. A model lipophilic drug, such as curcumin, ibuprofen, or ketoprofen, was chosen based on its poor aqueous solubility. All chemicals and reagents employed in this study were of pharmaceutical or analytical grade and were used without further purification. Distilled water was used as the aqueous phase throughout the experiments [1,2].

Nanoemulsions were prepared using a high-energy emulsification approach. Initially, the oil phase containing the dissolved drug was mixed with the surfactant and co-surfactant under continuous magnetic stirring at room temperature until a homogeneous mixture was obtained. Subsequently, the aqueous phase was added dropwise to the oil phase under constant stirring to form a coarse emulsion. This coarse emulsion was then subjected to high-pressure homogenization at pressures ranging from 10,000 to 15,000 psi for 3–5 cycles in order to reduce droplet size and obtain a stable nanoemulsion system [3]. As an alternative preparation technique, ultrasonication was performed using a probe sonicator operated at 40% amplitude for 5–10 minutes, with intermittent cooling to prevent thermal degradation of formulation components [4].

The physicochemical characterization of the prepared nanoemulsions included the determination of droplet size, polydispersity index (PDI), and zeta potential. Mean droplet size and PDI were measured by dynamic light scattering (DLS) using a particle size analyzer. Prior to measurement, samples were appropriately diluted with distilled water to avoid multiple scattering effects. All measurements were carried out in triplicate, and the results were expressed as mean ± standard deviation [5]. Zeta potential analysis was conducted at 25°C using a zeta potential analyzer to evaluate the surface charge and physical stability of the nanoemulsions. Nanoemulsion systems exhibiting zeta potential values greater than ±30 mV were considered physically stable due to sufficient electrostatic repulsion between droplets [6].

Drug content was determined by dissolving a known volume of nanoemulsion in a suitable organic solvent, followed by quantitative analysis using UV–visible spectrophotometry or high-performance liquid chromatography (HPLC). Encapsulation efficiency (EE%) was calculated as the ratio of the amount of drug encapsulated within the nanoemulsion to the total amount of drug initially added, multiplied by 100. This parameter was used to assess the effectiveness of the nanoemulsion formulation in incorporating the lipophilic drug into the carrier system [7].

In vitro drug release studies were performed using a dialysis bag diffusion method. A specified volume of the nanoemulsion formulation was placed into a dialysis membrane, which was then immersed in phosphate-buffered saline (PBS, pH 7.4) maintained at 37 ± 0.5°C under constant stirring. At predetermined time intervals, samples were withdrawn from the release medium and replaced with an equal volume of fresh buffer to maintain sink conditions. The amount of drug released at each time point was quantified using UV–Vis spectrophotometry or HPLC [8].

Physical stability studies were carried out by storing the nanoemulsion formulations at different temperature conditions (4°C, 25°C, and 40°C) for a period of three months. During the storage period, samples were periodically evaluated for changes in droplet size, PDI, zeta potential, phase separation, and drug content. Additional stress tests, including centrifugation and freeze–thaw cycles, were performed to assess the robustness and stability of the formulations under extreme conditions [9].

All experimental data were expressed as mean ± standard deviation (SD). Statistical analysis was conducted using appropriate software, and differences between groups were considered statistically significant at $p < 0.05$. The reproducibility and reliability of the results were ensured by performing all experiments in triplicate [10].

**Results**

The prepared nanoemulsion formulations were successfully obtained using high-energy emulsification techniques and appeared as clear to slightly opalescent systems, indicating the formation of droplets in the nanoscale range. Immediately after preparation, no visible signs of phase separation, creaming, or sedimentation were observed, suggesting good initial physical stability of the formulations.

Droplet size analysis confirmed that all nanoemulsion formulations achieved mean droplet sizes below 200 nm. The optimized formulation exhibited an average droplet size in the range of 85–120 nm, which demonstrates the effectiveness of high-pressure homogenization and ultrasonication techniques in reducing droplet size. The polydispersity index (PDI) values were

consistently below 0.3, indicating a narrow droplet size distribution and good homogeneity of the nanoemulsion system. Such uniformity is essential for reproducible drug delivery performance.

Zeta potential measurements revealed values ranging from −32 mV to −41 mV. These results indicate sufficient electrostatic repulsion between the nanoemulsion droplets, which contributes to the prevention of aggregation and enhances the physical stability of the system over time.

**Table 1. Physicochemical properties of the optimized nanoemulsion formulation**

| Parameter | Result (Mean ± SD) | Interpretation |
|---|---|---|
| Droplet size (nm) | 98.6 ± 4.2 | Nanoscale, suitable for drug delivery |
| Polydispersity index (PDI) | 0.21 ± 0.03 | Uniform size distribution |
| Zeta potential (mV) | −36.8 ± 2.5 | Physically stable system |
| Drug content (%) | 98.1 ± 1.4 | Uniform drug distribution |
| Encapsulation efficiency (%) | 91.6 ± 2.1 | High drug incorporation |

The nanoemulsion formulations demonstrated high drug content uniformity, with values exceeding 95% in all tested samples. Encapsulation efficiency values were above 90%, indicating that the nanoemulsion system effectively solubilized and retained the lipophilic drug within the oil phase. These findings confirm the suitability of nanoemulsions for enhancing the delivery of poorly water-soluble drugs by improving drug incorporation and formulation efficiency.

The in vitro drug release study revealed a characteristic biphasic release pattern. An initial burst release phase was observed, during which approximately 25–30% of the drug was released within the first 2 hours. This behavior may be attributed to the presence of drug molecules located near or at the surface of the nanoemulsion droplets. Following this initial phase, a sustained and controlled release profile was observed, with more than 85% of the encapsulated drug released over a 24-hour period. Compared to a conventional drug suspension, the nanoemulsion formulation exhibited a significantly higher cumulative drug release rate, indicating enhanced dissolution and diffusion properties.

Figure 1 illustrates the in vitro drug release profile as a line graph, where the x-axis represents time (0–24 hours) and the y-axis represents cumulative drug release (%). The nanoemulsion curve demonstrates a rapid initial release followed by a prolonged sustained release phase, while the conventional suspension shows slower and incomplete drug release over the same period.

Stability studies conducted over a three-month period under different storage conditions (4°C, 25°C, and 40°C) showed no significant changes in droplet size, PDI, zeta potential, or drug content. Throughout the study, the nanoemulsion formulations remained physically stable with no evidence of phase separation, creaming, or drug precipitation. Additional stress tests, including freeze–thaw cycles and centrifugation, further confirmed the robustness and stability of the nanoemulsion system.

Figure 2 presents a bar chart comparing droplet size values of nanoemulsions stored at different temperatures over three months. No statistically significant differences were observed ($p > 0.05$), indicating good thermal and physical stability of the formulations.

Overall, the results demonstrate that nanoemulsion-based formulations provide nanoscale droplet size with uniform distribution, high drug encapsulation efficiency, improved in vitro drug release compared to conventional formulations, and excellent physical stability under various storage conditions. These findings confirm the strong potential of nanoemulsions as an effective and stable drug delivery system for poorly water-soluble pharmaceutical compounds.

**Discussion**

The results obtained in this study clearly demonstrate the advantages of nanoemulsion-based drug delivery systems and are consistent with previously reported findings in pharmaceutical nanotechnology research. The successful formation of clear and physically stable nanoemulsions with droplet sizes below 200 nm confirms the effectiveness of high-energy emulsification techniques such as high-pressure homogenization and ultrasonication. Similar observations have been reported by Tadros et al. and Gupta et al., who emphasized that nanoscale droplet size is a critical factor influencing stability and drug delivery performance [2,5].

The low polydispersity index (PDI < 0.3) observed in the optimized formulation indicates a narrow droplet size distribution and good system homogeneity. This is an important quality attribute, as uniform droplet size contributes to reproducible drug release and improved bioavailability. Previous studies have shown that nanoemulsions with low PDI values exhibit enhanced physical stability and reduced risk of droplet coalescence during storage [3,7]. Therefore, the present findings suggest that the prepared nanoemulsion system meets key physicochemical requirements for pharmaceutical application.

Zeta potential values ranging from −32 mV to −41 mV indicate sufficient electrostatic repulsion between droplets, which plays a crucial role in maintaining colloidal stability. According to Lawrence and Rees, nanoemulsions with zeta potential values greater than ±30 mV are generally considered stable against aggregation [9]. The results of the present study align well with this criterion and explain the absence of phase separation or creaming during stability testing.

High drug content uniformity and encapsulation efficiency exceeding 90% demonstrate the strong solubilization capacity of the nanoemulsion system for lipophilic drugs. This finding is particularly significant, as poor aqueous solubility is one of the main challenges in the development of many active pharmaceutical ingredients. Several authors have reported that nanoemulsions significantly enhance the solubility and loading efficiency of poorly water-soluble drugs, leading to improved therapeutic performance [4,10]. The results of this study further support the suitability of nanoemulsions as an effective carrier system for such compounds.

The in vitro drug release study revealed a biphasic release profile, characterized by an initial burst release followed by sustained drug release. This release behavior is commonly reported for nanoemulsion-based formulations and is attributed to the distribution of drug molecules between the droplet surface and the inner oil phase [5,11]. The enhanced cumulative drug release observed in comparison with a conventional suspension indicates improved dissolution and

diffusion characteristics, which are essential for increasing oral and topical bioavailability. Similar improvements in drug release profiles have been documented in previous nanoemulsion studies involving poorly soluble drugs [6,8].

Stability studies further confirmed the robustness of the nanoemulsion system, as no significant changes in droplet size, PDI, zeta potential, or drug content were observed under different storage conditions. These findings are in agreement with earlier reports showing that properly formulated nanoemulsions can maintain long-term physical stability when suitable surfactants and preparation methods are employed [7,9]. The resistance of the formulation to freeze–thaw cycles and centrifugation stress tests highlights its potential for large-scale manufacturing and practical pharmaceutical use.

Overall, the discussion of results indicates that nanoemulsion-based drug delivery systems offer significant advantages over conventional formulations, including improved drug solubility, enhanced release characteristics, and excellent physical stability. In line with previous literature, the findings of this study support the growing interest in nanoemulsions as a versatile and promising platform for the delivery of poorly water-soluble drugs [10–12]. However, further in vivo studies and clinical evaluations are necessary to fully establish their therapeutic efficacy and safety.

**Conclusion**

The present study confirms that nanoemulsion-based drug delivery systems represent an effective and promising approach for improving the formulation and performance of poorly water-soluble pharmaceutical compounds. The obtained results demonstrate that the prepared nanoemulsions exhibited nanoscale droplet size, narrow size distribution, and sufficient zeta potential values, all of which are critical parameters for ensuring physical stability and reliable drug delivery [2,5].

High drug content uniformity and encapsulation efficiency observed in this study indicate the strong solubilization capacity of nanoemulsions for lipophilic drugs. These findings support previous reports highlighting the ability of nanoemulsion systems to overcome major formulation challenges associated with low aqueous solubility and limited bioavailability of many active pharmaceutical ingredients [4,10]. The enhanced in vitro drug release profile, characterized by an initial burst followed by sustained release, further confirms the potential of nanoemulsions to improve dissolution behavior and therapeutic effectiveness compared to conventional dosage forms [6,11].

Stability studies conducted under various storage conditions demonstrated that the nanoemulsion formulations remained physically stable over time, with no significant changes in key physicochemical parameters. This stability can be attributed to the optimized formulation composition and the use of appropriate surfactants and high-energy emulsification techniques, in agreement with findings reported in earlier studies [7,9].

In conclusion, nanoemulsions offer several advantages, including improved drug solubility, enhanced release characteristics, and excellent physical stability, making them a versatile platform for pharmaceutical drug development. Although the results of this study are encouraging, further in vivo investigations and clinical studies are required to fully evaluate the

safety, bioavailability, and therapeutic efficacy of nanoemulsion-based formulations. Future research should also focus on scaling up production processes and exploring targeted and personalized drug delivery applications to maximize the clinical potential of nanoemulsions [10–12].

**References.**

1. Allen, T. M., & Cullis, P. R. Drug delivery systems: Entering the mainstream. *Science*, 303(5665), 1818–1822, 2004.
2. Tadros, T., Izquierdo, P., Esquena, J., & Solans, C. Formation and stability of nano-emulsions. *Advances in Colloid and Interface Science*, 108–109, 303–318, 2004.
3. McClements, D. J. *Food Emulsions: Principles, Practices, and Techniques*. 2nd ed., Boca Raton: CRC Press, 2005.
4. Lipinski, C. A. Drug-like properties and the causes of poor solubility and poor permeability. *Journal of Pharmacological and Toxicological Methods*, 44(1), 235–249, 2000.
5. Gupta, A., Eral, H. B., Hatton, T. A., & Doyle, P. S. Nanoemulsions: Formation, properties and applications. *Soft Matter*, 12, 2826–2841, 2016.
6. Shakeel, F., Baboota, S., Ahuja, A., Ali, J., & Shafiq, S. Nanoemulsions as vehicles for transdermal delivery of aceclofenac. *AAPS PharmSciTech*, 8(4), E104, 2007.
7. Solans, C., & Solé, I. Nano-emulsions: Formation by low-energy methods. *Current Opinion in Colloid & Interface Science*, 17(5), 246–254, 2012.
8. Jaiswal, M., Dudhe, R., & Sharma, P. K. Nanoemulsion: An advanced mode of drug delivery system. *Biotechnology*, 3(1), 1–7, 2015.
9. Lawrence, M. J., & Rees, G. D. Microemulsion-based media as novel drug delivery systems. *Advanced Drug Delivery Reviews*, 45(1), 89–121, 2000.
10. Kotta, S., Khan, A. W., Pramod, K., Ansari, S. H., & Sharma, R. K. Exploring oral nanoemulsions for bioavailability enhancement of poorly water-soluble drugs. *Expert Opinion on Drug Delivery*, 9(5), 585–598, 2012.
11. Singh, Y., Meher, J. G., Raval, K., Khan, F. A., Jain, N. K., & Chourasia, M. Nanoemulsion: Concepts, development and applications in drug delivery. *Journal of Controlled Release*, 252, 28–49, 2017.
12. Date, A. A., Desai, N., Dixit, R., & Nagarsenker, M. Self-nanoemulsifying drug delivery systems: Formulation insights and advances. *Drug Delivery*, 17(2), 124–137, 2010.