International Journal of Multidisciplinary Research and Growth Evaluation.

Formulation and Characterization of Saquinavir Nano Emulsion

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Article Info

ISSN (Online): 2582-7138
Impact Factor (RSIF): 7.98
Volume: 07
Issue: 01
Received: 12-11-2025
Accepted: 14-12-2025
Published: 16-01-2026
Page No: 449-454

Abstract
The objective of the present study was to formulate and characterize an optimal stable Nano emulsion formulation of Saquinavir with an aim to increase its bioavailability. The components for the formulation of Nano emulsion were olive and Clove oil selected as the oil phase, surfactants namely Tween 40 and the co-surfactants, Ethanol were selected. Different concentrations of oil and surfactant, which formed nanoemulsions were selected basedon the thermodynamic stability and dispersibility test. Optimized formulation was selected for *in vitro* study on thebasis of higher drug release, optimum globule size, minimum lower viscosity, and overalllower surfactant concentration and co-surfactant. The diffusion of drug from Nano emulsion for the all the prepared formulations. Thusoptimized nanoemulsion could be used effectively to improve the bioavailability of poorly water-soluble drugs toimprove their bioavailability. The nanoemulsion were optimized optical transparency, viscosity measurement, determination of pH, measurement of globule size, zeta potential, drug content, invitro diffusion study, stability study.

DOI: https://doi.org/10.54660/.IJMRGE.2026.7.1.449-454

Keywords: Saquinavir, FTIR Studies, Oil, Surfactants, Co-Surfactants, Homogenization Method, *In vitro* Drug Release Studies

Introduction

Nanoemulsions kinetically stable dispersions of oil and water stabilized by surfactant and co-surfactant with droplet sizes typically in the 20–200 nm range offer an attractive delivery strategy to overcome these problems. [1] Their extremely small droplet size provides a very large interfacial area for drug solubilization, improves apparent drug solubility, and can enhance oral absorption via improved dissolution, increased intestinal permeability, and lymphatic uptake that bypasses first-pass hepatic metabolism. [2] In addition, nanoemulsions can be formulated to be physically stable, scalable for manufacturing, and compatible with both hydrophobic and lipophilic drug loading strategies. Proper selection of oil phase, surfactant/co-surfactant system and process parameters is critical to obtain a nanoemulsion with high drug loading, small and uniform droplet size, low polydispersity, and long-term stability. [3] Saquinavir is a first-generation HIV-1 protease inhibitor that played a pivotal role in transforming HIV infection from a fatal illness into a manageable chronic condition. [4] Despite its clinical importance, saquinavir suffers from very low aqueous solubility and poor oral bioavailability due to extensive first-pass metabolism and P-glycoprotein–mediated efflux. [5] These pharmacokinetic limitations necessitate high doses and frequent administration, which can reduce patient adherence and increase the risk of dose-related adverse effects. [6] This study aims to develop and optimize a saquinavir-loaded nanoemulsion and to comprehensively characterize its physicochemical properties and in-vitro performance.

Materials

Saquinavir was procured from Hetero Labs, Hyderabad. Clove oil and Tween 40 were obtained from Synpharma Research Labs, Hyderabad. Other chemicals and the reagents used were of analytical grade.

Methodology

Fourier transform infrared spectroscopy

Any potential interaction between drug and excipients can affect the physical or chemical properties of drug, bioavailability and stability of dosage form. Hence, it is important to check and confirm that the selected formulation components are in good compatibility with drug and do not compromise its stability and safety. The principle involved in the IR spectroscopy is measuring the energy difference between the excited and ground states of a molecule. Fourier transformed infrared spectroscopy (FTIR) analysis used for identifying the functional groups with their means of attachment thus helps assess the drug excipients interaction in terms of polymerization, cross-linking as well as drug loading in the formulation. FTIR was carried out to evaluate the interaction of excipients with the drug. For pure powdered drug KBR pellet method was used and for physical mixture, polished sodium chloride salt plates were used to check the interaction between the components of the formulation. [7]

Formulation development [8]

Oil Phase Preparation

Dissolve Saquinavir in the Clove oil using gentle heating (~40–50°C) and stirring.

Add Tween 40 and PEG to the oil phase and mix thoroughly.

Pre-emulsion Formation

Slowly add the aqueous phase (water) to the oil phase under high-speed homogenization using a mechanical stirrer at 10,000–15,000 rpm for 10–15 minutes to form a coarse emulsion.

High-Pressure Homogenization

Pass the coarse emulsion through a high-pressure homogenizer (e.g., 15,000 psi) for 3–7 cycles.

This process reduces droplet size to 20–200 nm, forming a Nano emulsion.

Cooling and Storage

Allow the Nano emulsion to cool to room temperature.

Store in a light-protected, airtight container at 4–8°C.

Table 1: Composition of Nano emulsion

F. no	Drug	Clove oil	Tween 40	PEG	Water
F1	100	2.5	2	2	Q.S
F2	100	5	4	2	Q.S
F3	100	7.5	6	2	Q.S
F4	100	10	8	2	Q.S
F5	100	12.5	10	2	Q.S
F6	100	15	12	2	Q.S

Characterization

pH measurements: The pH is important in case of ophthalmic dosage forms as eyes are sensitive to pH changes and the pH of the prepared Nano emulsions was measured by digital pH meter (DPH 504, Global electronics, India) [9]

Viscosity: The viscosity was measured to determine rheological properties of formulations. Brookfield Rheometer viscometer at 30˚C with a CPE 61 spindle at 30 rpm was used to serve this purpose. Results were taken in triplicate and the average was taken in to consideration. [10]

Particle Size analysis: The small size of emulsion globules is responsible for its stability and also contributes to the improved ocular absorption. Particularly droplets with Nano size elevate the interfacial area thereby facilitate the drug diffusion to the targeted tissues at greater rates which results in the enhanced clinical efficacy of the drug substance. Hence, it is of utmost importance to verify whether the prepared emulsions are in the required Nano size range or not. Mean globule size, surface charge (Zeta potential) and size distribution of the nanoemulsions (PDI) were determined by photon correlation spectroscopy using a Zetasizer S-90 1000 HS (Malvern Instruments, UK) at 25ºC and 90º angle. The samples were prepared by diluting at a ratio of 1:500 with water before the measurement. [11]

Zeta Potential: The zeta potential reflects the surface charge of the particles, which is influenced by changes in the interface with the dispersing medium, due to the dissociation of functional groups on the particle's surface or due to the adsorption of ionic species present in the aqueous dispersion medium as well as the solvation effect. This parameter is determined using Doppler techniques to measure the particle velocity as a function of voltage, thus the zeta potential is calculated from the electrophoretic mobility of particles in a respective solvent. [12]

SEM Analysis: Morphological evaluation of Saquinavir Nano emulsion was conducted by scanning electron microscopy. The samples were placed over a copper grid coated with carbon film and air-dried, and then were stained with 0.1% phosphotungstic acid. Finally, the samples were air dried and then observed with an H-7650 Scanning electron microscope. [13]

Drug entrapment efficiency: The accuracy of the method of preparation and excipient interference can be predicted by estimating drug content. A small fixed volume of nanoemulsion was taken and diluted with methanol. Then the samples were analyzed by using Uv spectrophotometer and the concentrations were calculated from the calibration curve. [14]

***In vitro* drug release study:** The drug release from the NEs was studied by utilizing vertical Franz diffusion cell of 20mm internal diameter and 15 ml receiver capacity. The donor and receiver compartments were separated by the dialysis membrane of 12,000 Da. The dissolution medium of pH 7.4 was prepared. 1ml of the test formulation was filled in the donor compartment whereas 15ml of the 7.4 phosphate buffer was filled in the receiver compartment. 1ml of 7.4 phosphate buffer with a dose equivalent amount of drug was served as control. The setup was kept under continuous stirring with a Teflon-coated magnetic bar up on a magnetic stirrer at 100 rpm maintaining a constant temperature of 37±0.5ºC. 1ml sample was collected from the receiver compartment and replaced with the same amount of fresh 7.4 phosphate buffer at every predetermined time points. The concentration of drug in samples was analyzed using UV. [15]

Stability studies: Storage stability was studied by storing the lyophilized Nanoemulsion samples at 4°C and room temperature for 3 months. In addition, Saquinavir stability in

the Nano emulsion was examined by determining the amount of parent drug remaining after specific storage periods. [16]

Results and Discussion

Drug - excipient compatibility studies

Compatibility studies were performed using IR spectrophotometer. The IR spectrum of pure drug and physical mixture of drug and excipients were studied. The peaks obtained in the spectra of each formulation correlates with the peaks of drug spectrum. This indicates that the drug was compatible with the formulation components.

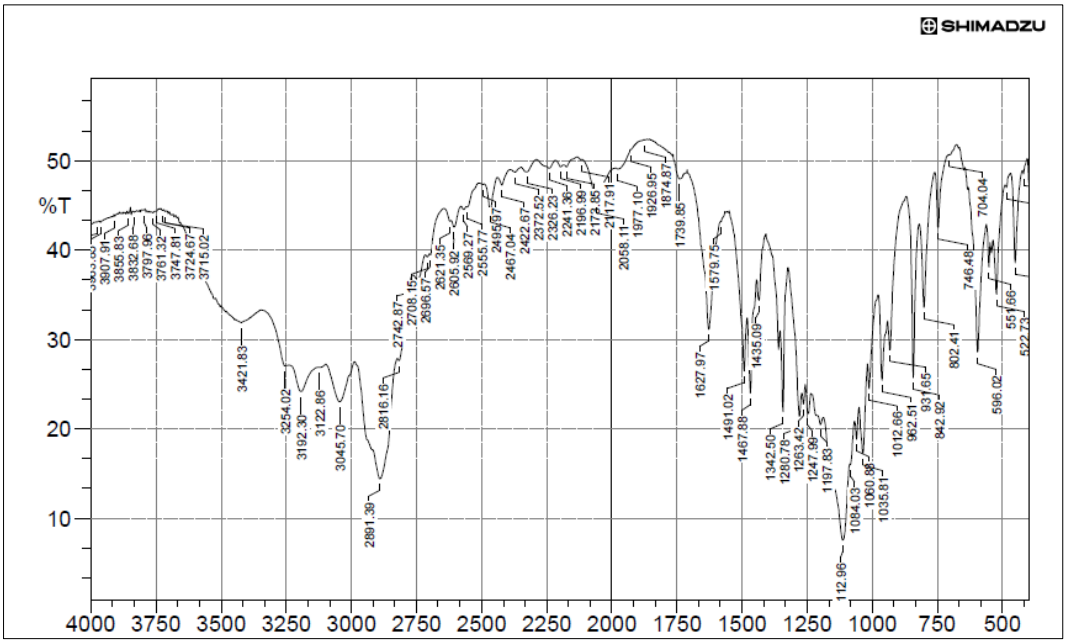

Fig 1: FT-IR Sample for Pure drug

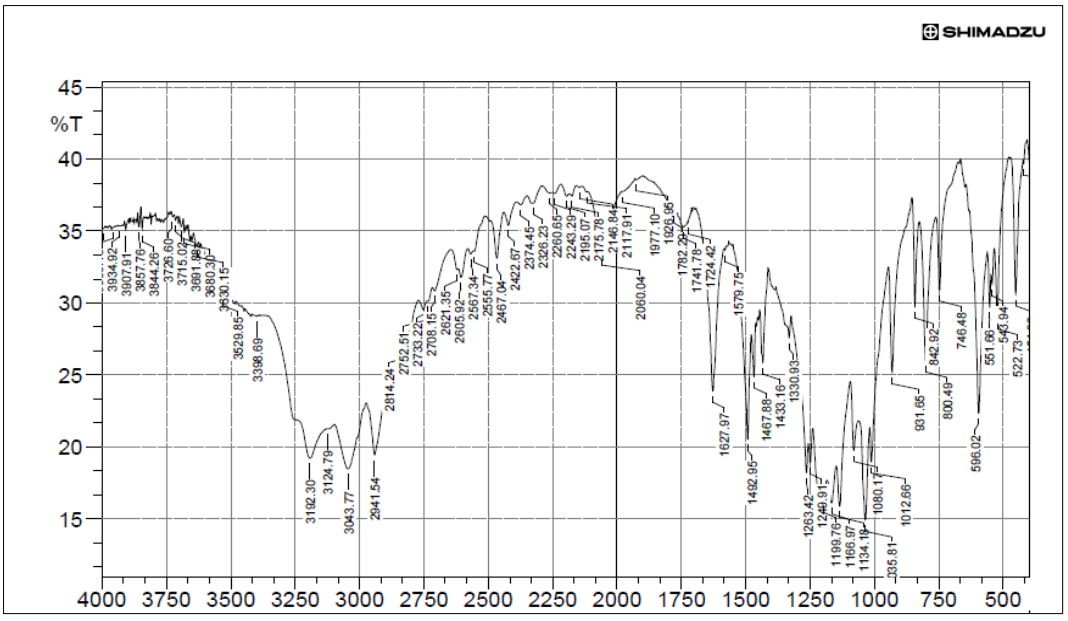

Fig 2: FT-IR Sample for Optimized formulation

Evaluation parameters:

Table 2: Drug entrapment efficiency of all formulation

F.no	Drug entrapment efficiency	pH	Viscosity
F1	79.68	5.48	0.759
F2	81.26	5.30	0.755
F3	80.19	5.26	0.769
F4	83.66	5.55	0.788
F5	82.50	5.24	0.758
F6	81.55	5.46	0.765

The entrapment efficiency for the prepared formulation was in the range of 79.68 to 83.66%. The entrapment efficiency increased progressively with increasing the concentration of oils which could be attributed to the formation of larger nanoemulsion that entrapped more amount of drug. Nanoemulsion were found to be the finest among all with a entrapment efficiency of 83.66%.

Viscosity: Increase in viscosity can affect the penetration of formulation through skin. Viscosity of formulation is affected by the sonication amplitude. Lower the viscosity better is the permeation. According to our optimum formulation result viscosity i.e. 0.788 is in good range, so we can assure that our formulation have good permeation due to ideal viscosity range.

pH: pH of formulation has important role for compatibility of formulation with skin. Our formulation has pH value of 5.55 that is compatible to pH of our skin.

Clarity test for NE: Nano emulsions have to be clear in appearance. Formulations we prepared were having difficulty in giving clarity to formulation. Various formulations with different surfactant to oil concentration yielding turbidity except F4 showed little clarity than turbidity so we increased the time of sonication from 10 to 15 minutes and yet not clear. We prepared four more formulations in order to obtain clear results but we changed sonication from continuous to periodic sonication. Periodic sonication yields better result in clarity. It shows that sonication has effect on transparency of Nano emulsion.

Determination of globule size and morphology: Sample was coated with gold and allowed the SEM to capture the images at a temperature of - 120^0c and voltage of 5kV.

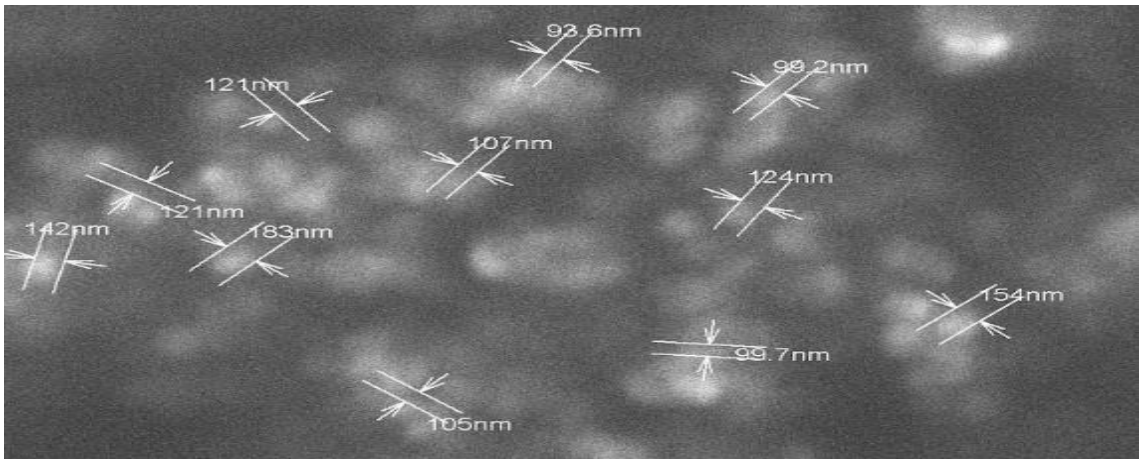

Fig 3: SEM analysis of Optimized Nano emulsion

The SEM photomicrographs of the nanoparticles are shown in Figures, the morphology of the prepared different types of nanoemulsion was found to be almost spherical in shape and have rough surface. The mean particle size of the different formulations of the prepared Nano emulsion was between 99.2 to 183 nm, it was observed that the particle size increase with increasing in the concentration of oil and surfactant ratio as shown in the formulations that contain the highest ratio of oil.

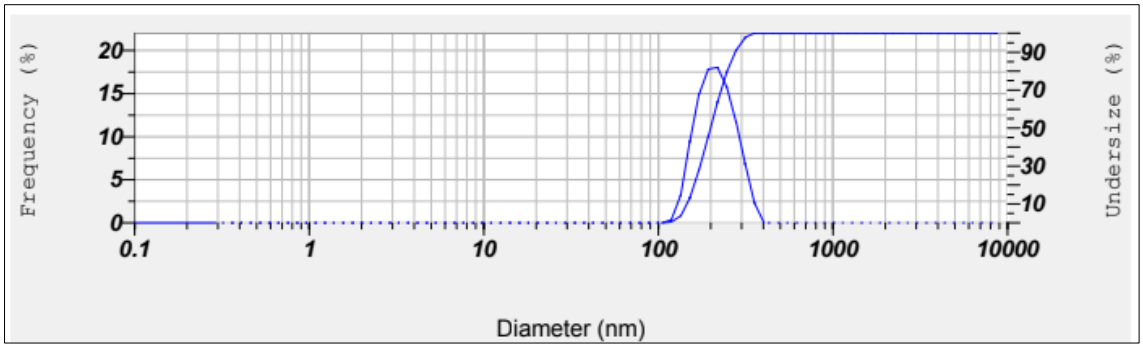

Fig 4: Particle size analysis of Optimized Nano emulsion

Zeta potential

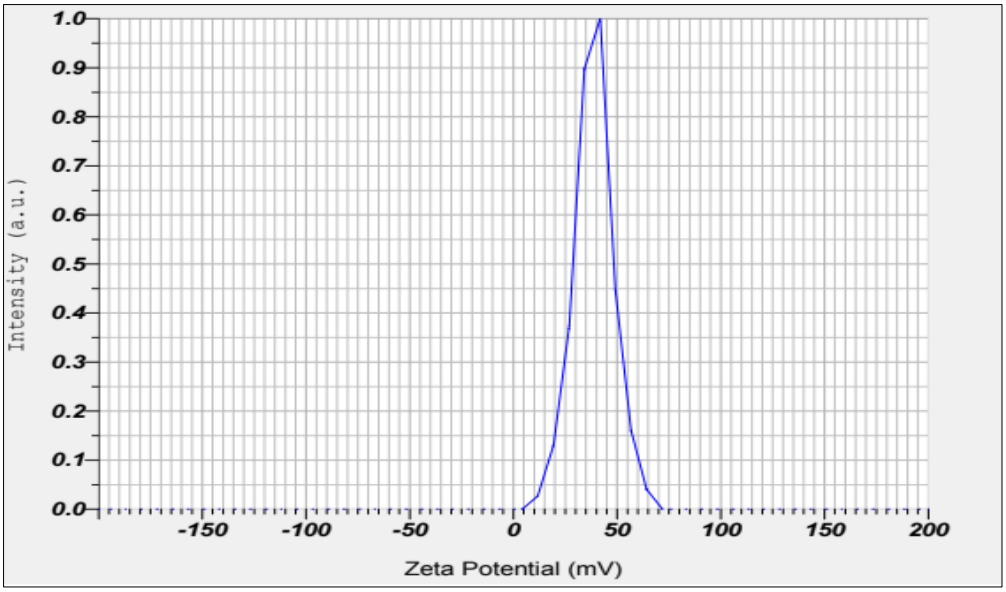

Fig 5: Zeta potential of Saquinavir nanoemulsion

Table 3: Evaluation Studies of Saquinavir Nano emulsion particle size and Zeta potential

F. No	Particle size (nm)	Zeta potential
F1	225	-29.3
F2	201	-25.6
F3	195	-22.7
F4	183	-27.1
F5	142	-26.3
F6	121	-27.5

In vitro drug release studies:

Table 4: Results of Saquinavir Nano emulsion of all formulations

Time(hr.)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
1	17.12	18.15	19.25	19.62	19.28	16.98
2	24.69	31.98	36.88	37.55	32.25	29.23
3	39.86	45.86	47.55	44.78	40.87	41.68
4	47.96	52.68	58.75	50.27	52.39	50.36
5	59.45	67.85	69.38	65.28	63.96	61.85
6	70.25	71.25	75.86	72.85	70.83	69.94
7	81.26	80.45	84.40	84.64	83.60	83.86
8	93.68	94.50	95.28	97.98	94.85	92.63

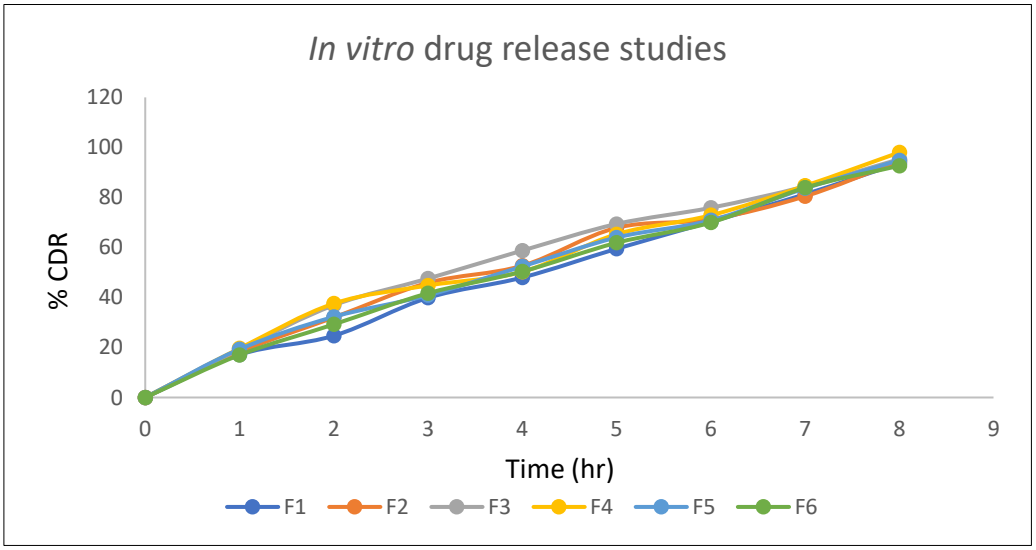

Fig 6: Drug release studies of (F1-F6) formulations

Among the four types of nanoemulsion highest amount of release percentage i.e., 97.98% was found for Saquinavir Nano emulsion.

Stability studies

Optimized formulations F4 was selected for accelerated stability studies as per ICH guidelines. The patches were observed for drug release for a period of three months.

Table 5: Stability studies of optimized formulations at 40 ± 2 ^{0}C and 75 ± 5% RH for 3 months

Formulation Code	Initial	1st Month	2nd Month	3rd Month	Limits as per Specifications
F-4	97.98	96.53	95.89	94.60	Not less than 85%
F-4	97.98	96.42	95.76	94.55	Not less than 85%
F-4	97.98	96.35	95.12	94.33	Not less than 85%

Conclusion

To conclude this study, Formulations with different ratios were prepared with Clove oil as an oil phase and API, the surfactant used as Tween 40. Purified water was used as an aqueous phase throughout the study. The most compatible NE formulation was with Tween 40 with periodic sonication gave an optimum result among other formulations. This optimum formulation was then tested for its characterization such as droplet size and zeta potential for stability of our Nano emulsion system and was accepted depending on findings and result. The final formulation as clove oil-based Nano emulsion for the treatment of HIV or AIDS, but according to the good results obtained from the whole study, we can ensure the effectiveness of our NE formulation. From above result concluded that Nanoemulsions significantly increase the solubility of Saquinavir, allowing for more efficient drug delivery. Improved bioavailability, Due to the small droplet size and large surface area, Nano emulsions facilitate better absorption, potentially enabling alternative routes of administration. Nanoemulsions can provide sustained or targeted release of Saquinavir, which may reduce dosing frequency and enhance patient compliance. Targeted delivery through Nano emulsions may reduce off-target effects and minimize systemic toxicity.

References

1. Solans C, Izquierdo P, Nolla J, Azemar N, Garcia-Celma MJ. Nano-emulsions. Curr Opin Colloid Interface Sci. 2005;10(3-4):102-10.
2. Tadros T, Izquierdo P, Esquena J, Solans C. Formation and stability of nano-emulsions. Adv Colloid Interface Sci. 2004;108-109:303-18.
3. McClements DJ. Nanoemulsions versus microemulsions: terminology, differences, and similarities. Soft Matter. 2012;8:1719-29.
4. Shakeel F, Baboota S, Ahuja A, Ali J, Shafiq S. Nanoemulsions as vehicles for transdermal delivery of aceclofenac. AAPS PharmSciTech. 2007;8(4):E1-9.
5. Porter CJH, Trevaskis NL, Charman WN. Lipids and lipid-based formulations: optimizing the oral delivery of lipophilic drugs. Nat Rev Drug Discov. 2007;6:231-48.
6. Pouton CW. Formulation of poorly water-soluble drugs for oral administration: physicochemical and physiological issues and the lipid formulation classification system. Eur J Pharm Sci. 2006;29(3-4):278-87.
7. Sznitowska M, Zurowska-Pryczkowska K, Janicki S, Jarvinen T. Miotic effect and irritation potential of pilocarpine prodrug incorporated into a submicron emulsion vehicle. Int J Pharm. 1999;184:115-20.
8. Patel HC, Parmar G, Seth AK, Patel JD, Patel SR. Formulation and evaluation of o/w nanoemulsion of ketoconazole. Int J Pharm Sci. 2013;4(4):338-51.
9. Patel R, Patel ZK, Patel KR, Patel MR. Formulation and evaluation of micro emulsion based gel of ketoconazole. Int J Universal Pharm Bio Sci. 2014;3(2):93-111.
10. Shinde PB. Component screening of miconazole nitrate nanoemulsion. Asian J Biomed Pharm Sci. 2013;3(19):33-40.
11. Ravi Shankar, Tiwari V. Formulation and evaluation of ketoconazole nanoemulsion gel for topical delivery. Am J PharmTech Res. 2015;5(5):445-62.
12. Kavitha K, Kanagathara N. Optimization and solubilisation study of novel nanoemulsion formulation for 5-fluorouracil by applying pseudoternary phase diagram. Asian J Pharm Clin Res. 2014;7(2):137-9.
13. Ping L, Ghosh A, Wagner RF, Krill S, Joshi YM, Serajuddin ATM. Effect of combined use of nonionic surfactant on formation of oil-in-water microemulsions. Int J Pharm. 2005;288:27-34.
14. Ahuja A, Ali J, Baboota S, Faisal MS, Shakeel F, Shafiq S. Stability evaluation of celecoxib nanoemulsion containing Tween 80. Thai J Pharm Sci. 2008;32:4-9.
15. Singh KK, Vingkar SK. Formulation, antimalarial activity and biodistribution of oral lipid nanoemulsion of primaquine. Int J Pharm. 2008;347:136-43.
16. Sharma SN, Jain NK. A text book of professional pharmacy. 1st ed. Delhi: Vallabh Prakashan; 1985. p. 201.
17. Edresi S, Baie S. Formulation and stability of whitening VCO-in-water nanocream. [Journal name not fully provided in query; assuming based on context] 2009;373(48):174-8.

How to Cite This Article

Mukund P, Chakradhar DMK, Goud EP, Sanjana KM, Himabindu, Aman MA, Haindavi S. Formulation and characterization of saquinavir nano emulsion. Int J Multidiscip Res Growth Eval. 2026;7(1):449–454. doi:10.54660/IJMRGE.2026.7.1.449-454.

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