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Formulation and Evaluation of Self-Nanoemulsifying Drug Delivery System (SNEDDS) of Pravastatin

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Abstract:
The present study was undertaken to develop and evaluate a Self-Nanoemulsifying Drug Delivery System (SNEDDS) of Pravastatin to enhance its intestinal permeability, dissolution rate, and oral bioavailability. Pravastatin, a BCS Class III drug, exhibits high aqueous solubility but poor permeability, leading to variable and limited oral absorption. To overcome this limitation, lipid-based SNEDDS formulations were designed using different combinations of oils, surfactants, and co-surfactants. Preformulation studies, including solubility analysis, melting point determination, UV spectroscopy, and FTIR, confirmed the physicochemical characteristics and compatibility of the drug with selected excipients. Nine SNEDDS formulations (F1–F9) were prepared and evaluated for droplet size, polydispersity index (PDI), zeta potential, self-emulsification efficiency, drug content, and in vitro dissolution behavior. The results indicated that all formulations formed stable nanoemulsions upon dilution. Among them, formulation F5 exhibited optimal characteristics with the smallest droplet size, low PDI, satisfactory zeta potential, and superior drug release profile. The in vitro dissolution study demonstrated significantly enhanced drug release compared to conventional systems, indicating improved solubilization and potential for enhanced absorption. Overall, the developed SNEDDS formulations successfully improved the biopharmaceutical performance of Pravastatin, suggesting that this approach can be an effective strategy for enhancing oral delivery of poorly permeable drugs.
Keywords: SNEDDS, Pravastatin, Nanoemulsion, Bioavailability enhancement, BCS Class III drug, Lipid-based drug delivery system, Oral drug delivery, Dissolution improvement.

Introduction

Cardiovascular diseases (CVDs) remain one of the leading causes of morbidity and mortality worldwide and are strongly associated with dyslipidemia, hypercholesterolemia, and atherosclerosis. Elevated levels of low-density lipoprotein cholesterol (LDL-C) and triglycerides contribute significantly to the development of coronary artery disease, myocardial infarction, and stroke. Statins are considered the first-line therapeutic agents for the management of hyperlipidemia because of their ability to inhibit 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase, the rate-limiting enzyme involved in cholesterol biosynthesis. Among the available statins, Pravastatin is widely prescribed due to its proven efficacy in reducing plasma cholesterol levels and lowering cardiovascular risk.[1-3]

Pravastatin is a hydrophilic statin that exhibits good safety and tolerability profiles compared with several lipophilic statins. It is commonly used in the treatment of primary hypercholesterolemia, mixed dyslipidemia, and prevention of cardiovascular complications. However, despite its therapeutic importance, Pravastatin demonstrates certain biopharmaceutical limitations that reduce its overall clinical effectiveness. According to the Biopharmaceutics Classification System (BCS), Pravastatin is categorized as a Class III drug, characterized by high aqueous solubility but poor intestinal permeability. Drugs belonging to this class often exhibit limited membrane transport across the gastrointestinal epithelium, leading to variable oral absorption and suboptimal bioavailability.[4-6]

The oral bioavailability of Pravastatin is reported to be relatively low due to poor permeability through the intestinal membrane and extensive hepatic first-pass uptake. Although the drug dissolves readily in gastrointestinal fluids, its absorption across the intestinal barrier remains restricted. Consequently, only a limited fraction of the administered dose reaches systemic circulation, resulting in fluctuations in therapeutic response. The low permeability characteristics of Pravastatin necessitate the development of advanced drug delivery systems capable of improving intestinal transport and enhancing oral absorption.

In recent years, lipid-based drug delivery systems have gained considerable attention for improving the oral delivery of poorly absorbed drugs. Among these approaches, Self-Nanoemulsifying Drug Delivery Systems (SNEDDS) have emerged as a promising strategy for enhancing drug dissolution, permeability, and bioavailability. SNEDDS are isotropic mixtures of oils, surfactants, and co-surfactants that spontaneously form fine oil-in-water nanoemulsions upon gentle agitation in gastrointestinal fluids. The resulting nano-sized droplets provide a large interfacial surface area that promotes rapid drug release and improved absorption.[7-8]

SNEDDS offer several advantages over conventional dosage forms, including improved solubilization capacity, enhanced drug stability, ease of manufacture, reduced variability in absorption, and improved therapeutic performance. The nano-sized droplets formed after dilution facilitate intimate contact with the intestinal membrane, thereby enhancing membrane permeation and drug transport. In addition, certain surfactants and lipid excipients used in SNEDDS can alter membrane fluidity and inhibit efflux transporters, further contributing to improved intestinal absorption. These properties make SNEDDS particularly suitable for drugs with permeability-related limitations such as Pravastatin. The formulation of SNEDDS involves careful selection of suitable oils, surfactants, and co-surfactants based on their drug solubilization ability, emulsification efficiency, and compatibility. Oils play a critical role in dissolving lipophilic portions of the drug and promoting lymphatic transport, while surfactants reduce interfacial tension and facilitate spontaneous emulsification. Co-surfactants enhance the flexibility of the interfacial film and improve the stability of the nanoemulsion system. Optimization of component ratios is generally carried out using pseudo-ternary phase diagrams, which help identify the nanoemulsion region capable of producing stable and transparent emulsions.[9-10]

Evaluation of SNEDDS formulations involves several critical parameters such as self-emulsification efficiency, droplet size, polydispersity index (PDI), zeta potential, optical clarity, thermodynamic stability, and drug content uniformity. Droplet size is considered one of the most important characteristics because smaller droplets provide larger surface area and improved drug absorption. Similarly, low PDI values indicate uniform droplet distribution and better formulation stability. Thermodynamic stability studies including heating-cooling cycles, centrifugation, and freeze-thaw tests are essential to ensure the physical stability of the developed formulation under different storage conditions.

Apart from improving dissolution behavior, SNEDDS have shown considerable potential in enhancing intestinal permeability and oral bioavailability of BCS Class III drugs. The lipidic components and surfactants present in the system can improve paracellular transport and membrane fluidization, thereby facilitating enhanced drug permeation across the intestinal epithelium. Furthermore, the nanoemulsion droplets protect the drug from degradation in the gastrointestinal environment and maintain the drug in a solubilized state throughout the absorption process. Several research studies have demonstrated the successful application of SNEDDS in improving the bioavailability of various poorly absorbed drugs. Enhanced dissolution rate, increased permeability, and superior pharmacokinetic performance have been observed with SNEDDS formulations compared to conventional tablets or suspensions. Therefore, the development of Pravastatin-loaded SNEDDS represents a promising approach to overcome the limitations associated with poor intestinal permeability and inconsistent oral absorption.[11-12]

The present study is focused on the formulation and evaluation of a Self-Nanoemulsifying Drug Delivery System of Pravastatin with the objective of enhancing its intestinal permeability, dissolution behavior, and therapeutic efficacy. The study involves screening of suitable excipients, preparation of pseudo-ternary phase diagrams, formulation optimization, and comprehensive characterization of the developed SNEDDS. In addition, in-vitro dissolution and permeation studies are carried out to investigate the ability of the developed system to improve oral absorption and bioavailability of Pravastatin. Stability studies are also performed to assess the physical and chemical stability of the optimized formulation under suitable storage conditions. The successful development of Pravastatin-loaded SNEDDS may provide an efficient oral delivery platform for improving the therapeutic performance of this important antihyperlipidemic drug.

Materials and Methods

Materials

Pravastatin was used as the active pharmaceutical ingredient in the present study. Sorbitan monostearate (Span 60), Cremophor EL, glycerol, polyethylene glycol 400 (PEG 400), garlic oil, cinnamon oil, and olive oil were used as formulation excipients for the preparation of the Self-Nanoemulsifying Drug Delivery System (SNEDDS). All chemicals and reagents used during the study were of analytical grade.

Instruments and Equipment

The study was carried out using various analytical and pharmaceutical instruments including an analytical balance, digital pH meter, hot air oven, UV–Visible spectrophotometer, FTIR spectrophotometer, magnetic stirrer, centrifuge, dissolution apparatus, agitator, and melting point apparatus.

Characterization of Pravastatin

Organoleptic Evaluation

The organoleptic properties of Pravastatin were evaluated by visual inspection. Parameters such as color, appearance, texture, and physical state were examined to confirm the identity and purity of the drug sample.

Determination of Melting Point

The melting point of Pravastatin was determined by the capillary tube method using a melting point apparatus. A small quantity of powdered drug was filled into a sealed capillary tube and heated gradually.

The temperature at which the sample started melting was recorded as the melting point.

Solubility Study

The solubility behavior of Pravastatin was investigated in different solvents. Approximately 1 g of drug was added to varying volumes of solvents, and the extent of dissolution was observed visually to determine the solubility characteristics of the drug.

Determination of λmax

For UV spectrophotometric analysis, 10 mg of Pravastatin was dissolved in suitable diluent to prepare a stock solution of 1 mg/mL.

Further dilution was carried out to obtain a concentration of 10 µg/mL. The prepared solution was scanned over the wavelength range of 200–400 nm using a UV–Visible spectrophotometer, and the wavelength showing maximum absorbance (λmax) was recorded.

FTIR Analysis

Fourier Transform Infrared (FTIR) spectroscopy was performed to identify the characteristic functional groups and evaluate possible drug–excipient interactions. The sample was placed directly on the sample holder, and spectra were recorded over the required scanning range.

Formulation of Pravastatin-Loaded SNEDDS The Pravastatin-loaded SNEDDS formulations were prepared by a simple mixing and sonication method. Accurately weighed quantities of Pravastatin were transferred into a clean and dry beaker. The selected oil phase was added, and the mixture was stirred to facilitate complete dissolution of the drug in the oil medium. Thereafter, the required quantities of surfactant and co-surfactant were added gradually with continuous stirring to obtain a homogeneous mixture.

The formulation mixture was heated to approximately 40°C using a magnetic stirrer with hot plate to improve solubilization and achieve a clear isotropic system. The prepared mixture was then subjected to ultrasonication for 15 minutes to improve nanoemulsification characteristics and reduce globule size. The final SNEDDS formulations were transferred into airtight glass containers and stored at room temperature for 24 hours to observe any signs of instability such as precipitation or phase separation.

Table 1: Formulation Batches

Sr. No.	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	Pravastatin	10	10	10	10	10	10	10	10	10
2.	Polyethylene Glycol	10	15	10	15	`10	--	--	--	--
3.	Glycerol	--	--	--	--	--	20	10	15	20
4.	Cremophor EL	--	--	--	--	--	60	70	50	60
5.	Cinnamon Oil	10	15	10	15	15	--	--	--	--
6.	SPAN 60	60	70	80	60	50	--	--	--	--
7.	Garlic Oil	--	--	--	--	--	5	10	10	10
8.	Olive oil	--	--	--	--	--	5	10	15	10

Evaluation of Liquid SNEDDS

Visual Examination and Self-Emulsification Efficiency

The prepared SNEDDS formulations were visually examined after dilution with distilled water and stored at 37 ± 0.5°C for 24 hours.

The diluted formulations were evaluated for clarity, precipitation, phase separation, and physical stability. For self-emulsification assessment, 1 mL of formulation was introduced into 100 mL distilled water maintained at 37°C under gentle stirring at 100 rpm.

The time required for spontaneous formation of a clear or slightly bluish nanoemulsion was recorded.

Drug Content Determination

Drug content analysis was carried out by diluting 1 mL of SNEDDS formulation with suitable solvent followed by UV spectrophotometric analysis at the selected wavelength.

The drug concentration was determined using the previously prepared calibration curve.

Robustness to Dilution Study

The robustness to dilution study was performed by diluting the formulations with different volumes of distilled water (10 mL, 50 mL, and 100 mL). The diluted samples were stored for 24 hours and observed for precipitation, creaming, cracking, or phase separation.

Measurement of Droplet Size, Polydispersity Index, and Zeta Potential

The globule size, polydispersity index (PDI), and zeta potential of the prepared nanoemulsions were measured using Dynamic Light Scattering (DLS) technique with a Zetasizer Nano instrument (ZEN3600, Malvern Instruments, UK). The formulations were diluted with distilled water in the ratio of 1:1000 (v/v) and mixed gently. The diluted samples were placed in disposable cuvettes and analyzed at room temperature. Each sample was evaluated in triplicate to ensure reproducibility.

In Vitro Drug Diffusion Study

The in vitro diffusion study was performed using the dialysis membrane diffusion technique. The dialysis membrane was pre-soaked and one end was tied securely. About 1 mL of SNEDDS formulation mixed with 0.5 mL phosphate buffer (pH 6.8) was placed inside the membrane, and the other end was sealed to form a dialysis bag. The dialysis bag was immersed in phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C with continuous stirring at 100 rpm. Samples were withdrawn at predetermined time intervals and replaced with fresh dissolution medium to maintain sink conditions. The collected samples were analyzed using a UV–Visible spectrophotometer to determine the amount of drug diffused from the SNEDDS formulation over time.

Results and Discussion

Analytical Evaluation of Pravastatin

Organoleptic Properties

The organoleptic evaluation of Pravastatin was carried out to confirm its physical identity and purity. The drug sample was observed as a light yellow crystalline powder, which was comparable with the reported characteristics of Pravastatin. The crystalline nature of the drug indicated its purity and suitability for formulation development.

Melting Point Determination

The melting point of Pravastatin was determined using the capillary tube method. The observed melting point was found to be 171.3°C, which corresponded exactly with the reported standard value. This confirmed the purity and identity of the drug sample and indicated the absence of major impurities or degradation products.

Solubility Study

The solubility profile of Pravastatin was investigated in different solvents and buffer systems. The drug was found to be soluble in ethanol, slightly soluble in pH 6.8 phosphate buffer and pH 1.2 buffer, and poorly soluble in water.The poor aqueous solubility and limited dissolution behavior in physiological media may contribute to reduced oral absorption and inconsistent bioavailability. The results justified the need for development of a lipid-based drug delivery system such as SNEDDS to improve dissolution and absorption characteristics.

Determination of λmax

The UV spectrophotometric analysis of Pravastatin showed maximum absorbance at 239 nm in ethanol. This wavelength was selected for further analytical estimations including calibration curve preparation, drug content analysis, and diffusion studies.

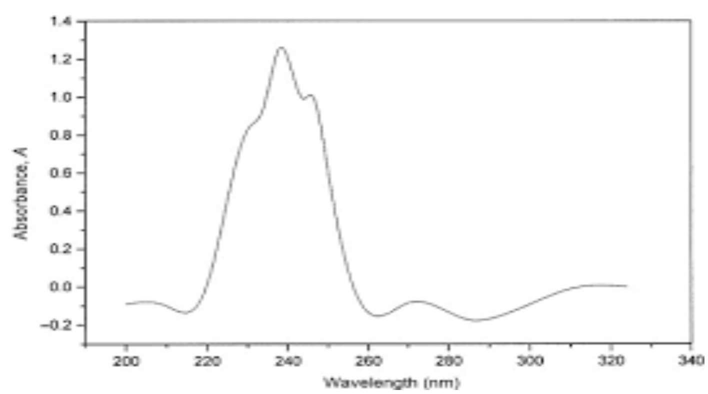

Figure 1: UV Spectra of Pravastatin

The sharp absorption peak at 239 nm confirmed the suitability of the analytical method for accurate quantitative estimation of Pravastatin in subsequent experiments.

FTIR Spectroscopy: FTIR spectroscopy was performed to identify the characteristic functional groups of Pravastatin and confirm its structural integrity. The obtained spectrum showed characteristic peaks corresponding to hydroxyl groups, aliphatic C–H stretching, C–O stretching, and imidazole ring vibrations.

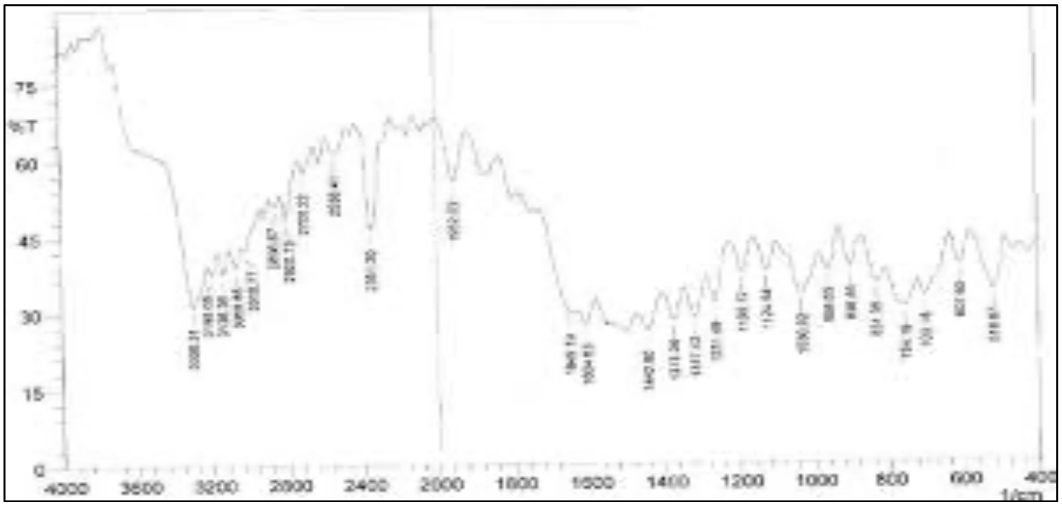

Figure 2: FTIR Spectrum of Pravastatin

The presence of all characteristic peaks indicated that the drug retained its chemical integrity and no significant structural alteration occurred during analysis. The FTIR results confirmed the authenticity and purity of the drug sample.

Preformulation Studies

Screening of Components

Solubility Study of Oils

Among the tested oils, cinnamon oil showed the highest solubility for Pravastatin (104.73 mg/mL), followed by garlic oil and olive oil. Higher drug solubility within the oil phase is important for maximizing drug loading capacity and maintaining the drug in a solubilized state after dilution.

Table 2: Solubility studies (Oils)

Sr. No.	Oils	Solubility (mg/mL)
1	Cinnamon Oil	104.73
2	Garlic Oil	87.62
3	Olive oil	76.34

The superior solubilization capacity of cinnamon oil suggested its suitability as a potential oil phase for SNEDDS formulation.

Garlic oil and olive oil also demonstrated appreciable solubility and could support stable nanoemulsion formation.

Solubility Study of Surfactants

Among the evaluated surfactants and co-surfactants, SPAN 60 exhibited the highest solubility (159.38 mg/mL), indicating excellent drug solubilization capability. PEG 400 and glycerol also demonstrated satisfactory solubilization properties.

Table 3: Solubility studies (Surfactants)

Sr. No.	Surfactants	Solubility (mg/mL)
1	PEG 400	84.35
2	SPAN 60	159.38
3	Glycerol	89.05

The high solubility provided by SPAN 60 may contribute significantly toward efficient nanoemulsion formation and improved drug dispersion within the formulation.

Emulsification Study:

The emulsification efficiency of the selected surfactants and co-surfactants was evaluated based on percentage transparency and number of inversions required for emulsification. PEG 400 demonstrated the highest transparency (98.63%) with fewer inversions, indicating excellent emulsify cation performance and formation of a clear nanoemulsion system.

High transparency reflects formation of fine droplets with uniform distribution.

Table 4: Emulsification study

Sr. No.	Surfactants/ Co-surfactant	% Transparency	No. of inversions
1	PEG 400	98.63	30
2	SPAN 60	63.26	50
3	Glycerol	89	25

SPAN 60 exhibited lower transparency despite a higher number of inversions, suggesting comparatively less efficient emulsification behavior.

Glycerol showed moderate emulsification efficiency. The results indicated that PEG 400 possessed superior emulsification characteristics and could effectively contribute to the spontaneous formation of stable nanoemulsions.

Evaluation of Liquid SNEDDS

Droplet Size Analysis: Droplet size plays a critical role in determining the efficiency of SNEDDS formulations because smaller droplets provide larger surface area for drug release and absorption.

Table 5: Evaluation parameters of liquid SNEDDS

Sr. No.	Formulation	Droplet Size in nm	PDI	Zeta
1	F1	90±6.43	0.62	-17.73 ± 5.86
2	F2	86±4.65	0.55	-15.64 ± 7.48
3	F3	70±4.23	0.57	-14.74 ± 1.76
4	F4	63±3.65	0.51	-14.37 ± 3.13
5	F5	52±3.98	0.47	-13.96 ± 2.98
6	F6	102±8.45	0.76	-16.67 ± 4.56
7	F7	93±7.12	0.53	-15.45 ± 5.45
8	F8	66±5.23	0.44	-18.34 ± 4.66
9	F9	74±6.64	0.48	-14.65 ± 4.86

Among all formulations, F5 exhibited the smallest droplet size (52 ± 3.98 nm), indicating efficient nanoemulsion formation and potential enhancement of drug absorption. Smaller droplet size facilitates rapid dispersion in gastrointestinal fluids and improves dissolution behavior. In contrast, F6 showed the largest droplet size (102 ± 8.45 nm), which may reduce the rate of emulsification and drug release.

Polydispersity Index (PDI): The PDI values ranged from 0.44 to 0.76, indicating varying levels of droplet size uniformity among formulations. Lower PDI values represent narrow particle size distribution and better formulation homogeneity.

Formulations F8 and F5 exhibited the lowest PDI values (0.44 and 0.47 respectively), indicating uniform droplet distribution and improved physical stability. On the other hand, F6 exhibited the highest PDI value (0.76), suggesting broader size distribution and comparatively lower uniformity.

Zeta Potential

Zeta potential analysis was performed to evaluate the physical stability of the nanoemulsion systems. All formulations exhibited negative zeta potential values ranging from −13.96 mV to −18.34 mV.

Formulation F8 showed the highest absolute zeta potential value (−18.34 ± 4.66 mV), indicating comparatively better electrostatic stabilization and reduced tendency toward aggregation. Although F5 exhibited slightly lower zeta potential, its small droplet size and low PDI contributed to overall formulation stability.

Overall, formulations F5 and F8 demonstrated superior nanoemulsion characteristics due to smaller droplet size, lower PDI values, and acceptable zeta potential.

Evaluation of Solid SNEDDS

Drug Loading Efficiency

Drug loading efficiency is an important parameter that reflects the capacity of the formulation to incorporate and retain the drug effectively within the SNEDDS matrix. All formulations demonstrated high drug loading efficiency ranging from 92.34% to 97.75%, indicating efficient incorporation of Pravastatin into the solid SNEDDS system.

Table 6: Drug Loading Efficiency

Sr. No.	Formulation	Drug Loading Efficiency Pravastatin
1	F1	95.36±0.24
2	F2	94.24±0.85
3	F3	95.23±0.73
4	F4	93.52±0.45
5	F5	92.73±0.23
6	F6	94.66±0.23
7	F7	96.58±0.64
8	F8	97.75±0.56
9	F9	92.34±0.87

Formulation F8 exhibited the highest drug loading efficiency (97.75 ± 0.56%), suggesting superior entrapment capability and effective compatibility between the drug and formulation components.

High drug loading efficiency is beneficial because it ensures uniform drug distribution and improved therapeutic performance. The high loading efficiencies observed in all formulations confirmed the suitability of the selected excipients and formulation strategy for development of stable solid SNEDDS.

Dissolution Study

The dissolution study demonstrated significant differences in drug release behavior among the developed formulations.

Formulations F5 and F6 exhibited the highest cumulative drug release profiles, achieving approximately 97% drug release within 8–12 hours. Among all batches, F5 demonstrated particularly rapid and enhanced dissolution behavior due to its smaller droplet size and improved nanoemulsion characteristics.

Table 7: Dissolution Study of Pravastatin

Batch	% CDR @ 1hr	% CDR @ 2hr	% CDR @ 4hr	% CDR @ 8hr	% CDR @ 12hr
F1	25.14	49.51	64.89	76.84	96.84
F2	24.61	37.22	49.78	77.59	92.56
F3	24.33	38.33	46.33	78.13	95.22
F4	22.17	29.65	42.09	74.28	87.26
F5	32.89	48.23	72.31	97.75	97.75
F6	36.1	51.03	74.89	97.34	97.34
F7	23.49	37.22	49.78	77.59	94.56
F8	25.33	38.33	46.33	78.13	96.22
F9	29.26	35.18	42.09	74.28	92.31

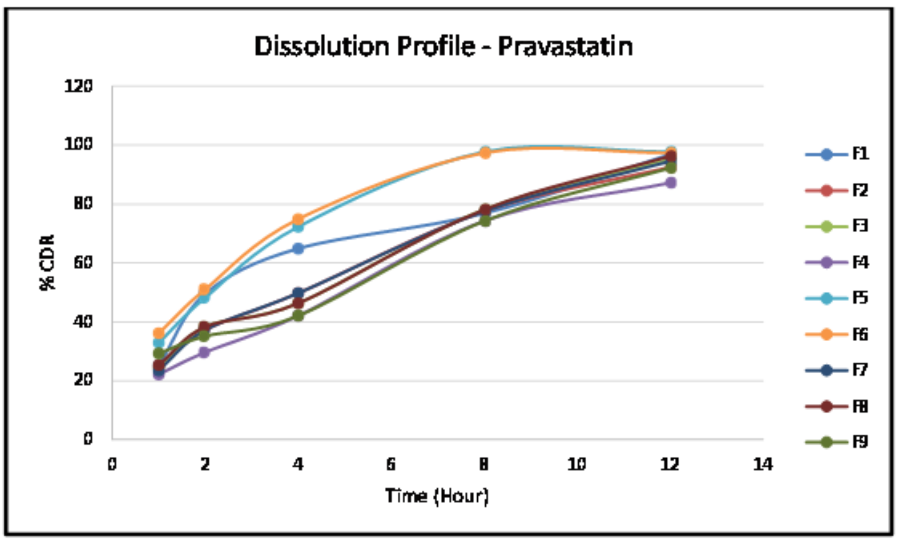

Figure 3: Dissolution Study of Pravastatin

The enhanced dissolution observed in F5 may be attributed to:

- Reduced droplet size
- Improved surface area for dissolution
- Efficient self-emulsification behavior
- Uniform droplet distribution
- Effective drug solubilization within the lipid matrix

In comparison, formulations such as F4 and F9 showed relatively lower dissolution profiles, possibly due to larger droplet size and less efficient emulsification characteristics. The overall dissolution results confirmed that the SNEDDS approach successfully improved the dissolution behavior of Pravastatin. Enhanced dissolution may contribute to improved intestinal absorption and oral bioavailability, thereby increasing the therapeutic efficacy of the drug. Based on the overall evaluation parameters including droplet size, PDI, zeta potential, drug loading efficiency, and dissolution performance, formulation F5 was identified as the optimized SNEDDS formulation for Pravastatin.

Conclusion

The present study successfully developed and evaluated a Self-Nanoemulsifying Drug Delivery System (SNEDDS) of Pravastatin to enhance its dissolution, intestinal permeability, and oral bioavailability.

Preformulation and compatibility studies confirmed the suitability of selected excipients and showed no significant drug–excipient interaction. The formulation studies demonstrated the successful formation of stable nanoemulsions with desirable physicochemical properties.

Among all formulations, F5 showed the best performance with the smallest droplet size, low PDI, good zeta potential, and highest drug release, indicating improved solubilization and dissolution behavior.

Overall, SNEDDS significantly improved the in vitro performance of Pravastatin, suggesting its potential to enhance oral absorption and therapeutic efficacy. Further in vivo studies are recommended to confirm bioavailability enhancement.

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