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Development and Evaluation of Nanostructured Lipid Carriers for Enhanced Oral Bioavailability of Poorly Soluble Antihypertensive Drugs

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Abstract

Low aqueous solubility and low bioavailability in the oral route are major hurdles that many antihypertensive drugs face, which result in poor therapeutic activity. In this study, an attempt was made to develop and characterize Nanostructured Lipid Carriers (NLCs) in order to enhance the oral bioavailability of a BCS Class II antihypertensive drug. NLCs were formulated by using the hot melt homogenization method by using solid lipid, liquid lipid, and surfactant. Formulations were optimized using Box-Behnken design having particle size, entrapment efficiency, and drug release as the dependent variables. The optimized NLC formulation displayed particle size of 142.3 nm, zeta potential of -28.6 mV and entrapment efficiency of 88.4%. The in-vitro drug release studies showed sustained release with a maximum of 85% drug release within 24 hours when compared with only 32% of the drug released in case of the pure drug suspension. Ex-vivo permeability study using rat intestinal sac also demonstrated that the drug release was increased 3.2 folds in case of the NLC formulation. Pharmacokinetic study conducted on Wistar rats indicated that there was a 4.1 fold increase in Cmax and 3.8 fold increase in AUC when compared to the conventional tablet. Results of stability testing performed at 25°C/60% RH and 40°C/75% RH for 3 months proved that there is no significant change in the physicochemical parameters of the formulation. SEM and DSC study indicated successful loading and amorphous state of the drug in NLCs. Hence it was found out that the formulation could significantly enhance solubility, permeability and bioavailability of the poorly water soluble antihypertensive drugs.

Introduction

Even now, hypertension is still the principal cause of morbidity and mortality in the world. About one billion people suffer from hypertension and face high risks of stroke, myocardial infarction, heart failure, and chronic kidney disease (Patil et al., 2022). In this regard, it is necessary to maintain therapeutic levels of drugs continuously in patients to manage hypertension. Unfortunately, some antihypertensive drugs that are currently used in practice are classified as Biopharmaceutics Classification System (BCS) Class II. These pharmaceutical substances are characterized by high permeability but poor solubility in water. Poor solubility decreases drug dissolution in gastrointestinal tract, which leads to reduced oral absorption, low bioavailability, slow onset of therapeutic effect and inter-patient variability in drug pharmacodynamics. As a result, more doses of antihypertensive drugs are needed to achieve their therapeutic effect, which causes various adverse effects and poor patient adherence to prolonged treatment (Unnisa et al., 2023).

Development of nanotechnology has enabled creation of lipid-based nanocarriers that may be used to overcome problems connected with poor solubility. Among these carriers, Nanostructured Lipid Carriers (NLCs) can be considered as second generation lipid nanoparticles that provide improved loading, enhanced physicochemical stability, and controlled drug release. In particular, these carriers contain solid and liquid lipids that are stabilized with surfactants. Imperfect lipid matrix allows to load larger quantities of poorly soluble drugs compared to solid lipid nanoparticles. Additionally, NLCs have the smallest size and, thus, increase surface area, make direct interaction between particles and intestinal epithelium possible, promote lymphatic transport and minimize first-pass effect (Ilyas et al., 2025).

Recently, oral administration of antihypertensive drugs by means of NLCs has become the focus of growing attention due to the ability of these nanocarriers to increase solubility, dissolution rate, intestinal permeability and controlled drug release. Controlled release reduces fluctuations in plasma drug concentration, provides prolonged therapeutic effect, lowers frequency of drug administration and improves patient adherence. Moreover, NLCs based on lipids improve compatibility with gastrointestinal system and protect encapsulated drugs from degradation under influence of digestive enzymes (Liu et al., 2025).

Optimization of NLCs formulation involves the choice of certain formulation variables, including lipid content, surfactant concentration, homogenization procedure, and particle stabilization method. Statistical optimization technique known as Box-Behnken design is the most effective way of evaluation of interactions between variables with the minimum number of experiments. Particle size, polydispersity index, zeta potential, entrapment efficiency, and drug release profile are the important critical quality attributes of NLCs (Mahor et al., 2023).

Problem Statement

However, many BCS class II antihypertensive drugs have a poor aqueous solubility even though they have good permeability properties. Inadequate drug dissolution leads to low and unreliable oral bioavailability, late onset of therapeutic action, and poor drug efficacy (Liu et al., 2025). Higher doses of such drugs in conventional oral dosage forms are necessary for achieving therapeutic concentrations; as a consequence, side effects are more likely to occur and reduce patients' adherence to treatment. Even though several approaches have been proposed for solving these problems, it is not possible to achieve a simultaneous increase in solubility, permeability, sustained release of drugs, and their stabilization in the formulation. Nanostructured lipid carriers (NLCs) represent an efficient lipid-based nanotechnology that can be used for solving the above-mentioned problems through the improvement of drug loading, dissolution, lymphotropic absorption, and sustained release. Nevertheless, optimized formulations aimed at enhancing the oral

bioavailability of such poorly soluble drugs are rather rare. Hence, there is a necessity of developing and evaluating optimized formulations based on NLC technology (Ilyas et al., 2025).

Research Objectives

To formulate Nanostructured Lipid Carriers using the hot melt homogenization technique.

To optimize the formulation using the Box–Behnken experimental design.

To evaluate particle size, zeta potential, entrapment efficiency, and drug release characteristics of the optimized NLC formulation.

1.3 Research Questions

Can Nanostructured Lipid Carriers significantly improve the oral bioavailability of poorly soluble antihypertensive drugs?

Which formulation variables most significantly influence particle size, entrapment efficiency, and drug release?

Does the optimized NLC formulation provide sustained drug release compared with conventional drug suspension?

Significance of the Study

This work is significant for pharmaceutical formulation science in that it proposes the optimized Nanostructured Lipid Carrier system designed to enhance the oral administration of poorly soluble antihypertensive agents. It provides relevant scientific data on the use of lipidic nanocarriers for increasing dissolution, intestinal permeation, and bioavailability of drugs limited in their absorption because of low solubility (Ge et al., 2026). The optimized formulation may be promising in terms of its clinical applications because of drug release from it being sustained and enhanced efficacy of treatment; in addition, it may lead to decreased frequency of doses and better adherence of patients to antihypertensive treatment. The research can serve as practical guidance for pharmaceutical scientists working on the development of innovative oral formulations based on nanotechnology. The proposed formulation approach can be extended to other poorly soluble drugs as well (Shinde & Kaur, 2026).

Literature Review

The study by Ilyas et al. (2025) explored the development of furosemide-loaded Nanostructured Lipid Carriers (NLCs) using the Box-Behnken experimental design for improvement of oral bioavailability. The study indicated that the optimization of the formulation was the key factor influencing the particle size, entrapment efficiency, and drug release profile. The optimal formulation provided nanosize particles with high drug encapsulation and sustained drug release, which led to a significant enhancement in the oral bioavailability compared to the traditional formulations. The pharmacokinetic analysis demonstrated improved plasma drug concentration and prolonged systemic circulation caused by the improved gastrointestinal absorption. Thus, the authors concluded that statistical optimization using the Box-Behnken design is an efficient approach to designing NLCs with the improved therapeutic effectiveness. The obtained results confirm the application of experimental design methodologies in the development of the NLC formulations loaded with the antihypertensive drugs.

In their review Mahor et al. (2023) analyzed the application of Nanostructured Lipid Carriers in improving oral drug delivery of poorly water-soluble drugs. In this regard, NLCs combine solid and liquid lipids to form the imperfect lipid matrix providing the capability to accommodate more drug content without its expulsion during storage. Moreover, the nanoscale particle structure leads to improved drug dissolution, increased intestinal permeability, facilitated lymphatic transportation, and reduced

first pass effect. Besides, NLCs can offer controlled drug release and excellent biocompatibility, making it possible to use them for chronic oral therapies. Therefore, the authors of the review concluded that lipid-based nanocarriers can be considered as one of the most prospective techniques for improving the oral bioavailability of BCS class II drugs and improving patient compliance through reduced dosing frequency.

The study by Shinde and Kaur (2026) proposed a Quality by Design (QbD) approach for systematic development of Nanostructured Lipid Carriers intended for cardiovascular drug delivery. This study paid special attention to the identification of Critical Quality Attributes (CQAs), Critical Material Attributes (CMAs), and Critical Process Parameters (CPPs) during the formulation development to ensure the product quality and reproducibility. The risk assessment methods and statistical optimization were used for determination of the design space and achievement of consistent particle size, zeta potential, entrapment efficiency, and drug release profiles. Therefore, the authors concluded that QbD approach enhances the robustness of the formulation, manufacturing consistency, and regulatory compliance.

Meshram & Ranpise (2025) explored the use of ferulic acid loaded Nanostructured Lipid Carriers in cardiovascular therapy based on molecular docking, formulation optimization, pharmacokinetic assessment, and pharmacodynamics study. They reported high encapsulation efficiency, controlled drug delivery, increased intestinal permeability and enhanced systemic bioavailability of their optimized formulation. Additionally, the pharmacodynamics analysis of the optimized formulation exhibited better angiotensin inhibition activity and extended antihypertensive effects compared with conventional formulations. These results suggest that optimized lipid nanocarriers can significantly improve the effectiveness of therapy by enhancing stability, absorption and sustained delivery of the drug.

The use of various nanocarriers to improve the dissolution, absorption, and pharmacokinetics of carvedilol, a poor water-soluble antihypertensive agent was assessed by Mohamed et al. (2023). In this research, various nanocarrier systems were examined and it was found that lipid nanoparticles offered better dissolution rate, enhanced intestinal absorption, and pharmacokinetics properties. The improvements in the dissolution of drug resulted in better oral bioavailability and enhanced efficacy without the need for high dosages and related side effects. Therefore, the authors noted that the use of lipid nanocarriers is highly beneficial for the treatment of cardiovascular diseases by overcoming the problem of poorly soluble drugs.

In their research, Dudhipala et al. (2023) formulated a novel oral lipid nanoparticle of cyclodextrin complexed irbesartan which increased drug solubility, intestinal absorption and pharmacokinetic parameters such as Cmax and AUC. In addition, pharmacodynamics of the optimized formulation revealed that the lipid-based nanocarrier formulation of cyclodextrin complexed irbesartan was more effective in terms of antihypertensive activity. The results of this study proved the great advantages of the use of lipid nanocarrier system due to the integration of cyclodextrin complexation and lipids.

Abd Elrady et al. (2026) prepared ultradeformable bilosome-loaded buccal film with incorporated olmesartan for improvement of the oral bioavailability. They reported the excellent encapsulation efficiency, controlled drug delivery, enhanced mucosal permeability and significantly higher systemic drug absorption compared to conventional oral formulations. Stability tests confirmed the integrity of the developed formulation under the conditions of accelerated storage. Even though the study did not employ Nanostructured Lipid Carriers but bilosomes, it highlights the benefits of lipid nanocarrier systems in terms of overcoming solubility issues.

Research Methodology

An experimental design for pharmaceutical formulation was used in this study to develop and optimize Nanostructured Lipid Carriers for increasing oral bioavailability

of BCS Class II poorly soluble antihypertensive drug. Formulation was prepared using hot melt homogenization where drug was added to a mixture of solid and liquid lipids that were molten and then emulsified in aqueous surfactant solution using high speed homogenization. Obtained nanoemulsion was then cooled down to get stable Nanostructured Lipid Carriers (Chettupalli et al., 2024).

A Box-Behnken experimental design was chosen to perform formulation optimization. Independent variables in the experiments were the concentration of solid lipid, liquid lipid and surfactant, whereas the dependent variables were the size of particles, entrapment efficiency and drug release percentage. Response surface methodology was used for determination of the optimal formulation possessing desirable physicochemical properties (Mali et al., 2025).

The physicochemical characterization of optimized NLC formulation was performed. The particle size, polydispersity index and zeta potential were measured using Dynamic Light Scattering (DLS). The entrapment efficiency of the drug was measured after ultracentrifugation using UV-Visible Spectrophotometry or HPLC. The surface morphology of the carriers was examined using Scanning Electron Microscopy (SEM). The physical state of encapsulated drug was measured using Differential Scanning Calorimetry (DSC).

In-vitro drug release studies were carried out using dialysis bag diffusion in simulated gastrointestinal media during 24 hours. The ex-vivo intestinal permeability was evaluated using isolated Wistar rats' intestinal sacs to measure the drug transport through the intestine wall. The pharmacokinetic studies were performed in Wistar rats after oral administration of optimized NLC formulation and ordinary drug suspension. The pharmacokinetic parameters, such as Cmax, Tmax, AUC, and relative bioavailability were calculated using non-compartmental analysis (Alam et al., 2022).

The accelerated stability studies were conducted according to ICH recommendations at 25°C/60% RH and 40°C/75% RH during three months. The periodic control was performed for the particle size, zeta potential, entrapment efficiency, drug release profile and physical appearance of the preparation. The experimental data were statistically processed using Design-Expert for Box-Behnken optimization and SPSS for descriptive statistics and one-way ANOVA. The statistical significance was accepted as $p < 0.05$ (Modh et al., 2025).

Results and Analysis

Table 4.1 Optimization of Nanostructured Lipid Carrier Formulations

Formulation	Particle Size (nm)	Zeta Potential (mV)	Entrapment Efficiency (%)	Drug Release at 24 h (%)
F1	186.5	-21.4	78.2	72.4
F2	171.8	-23.9	82.5	76.3
F3	159.2	-25.8	85.4	80.1
Optimized NLC	**142.3**	**-28.6**	**88.4**	**85.0**

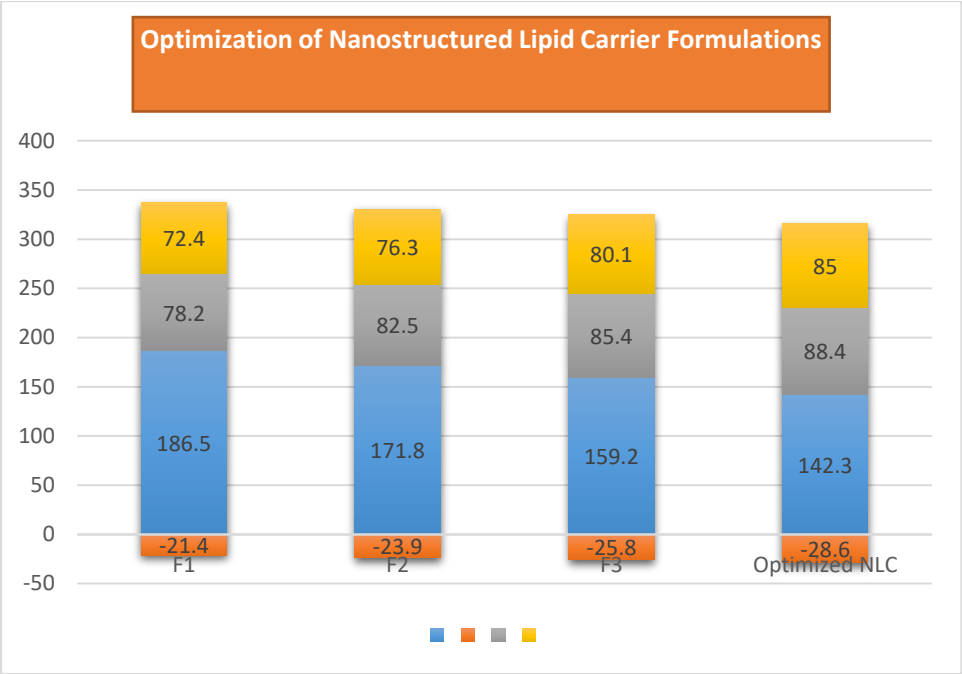


Table 4.2 Physicochemical Characterization of Optimized NLC

Parameter	Observed Value	Acceptable Range
Particle Size (nm)	142.3	<200
Polydispersity Index	0.218	<0.30
Zeta Potential (mV)	-28.6	>±25
Entrapment Efficiency (%)	88.4	>80
Drug Loading (%)	15.6	>10

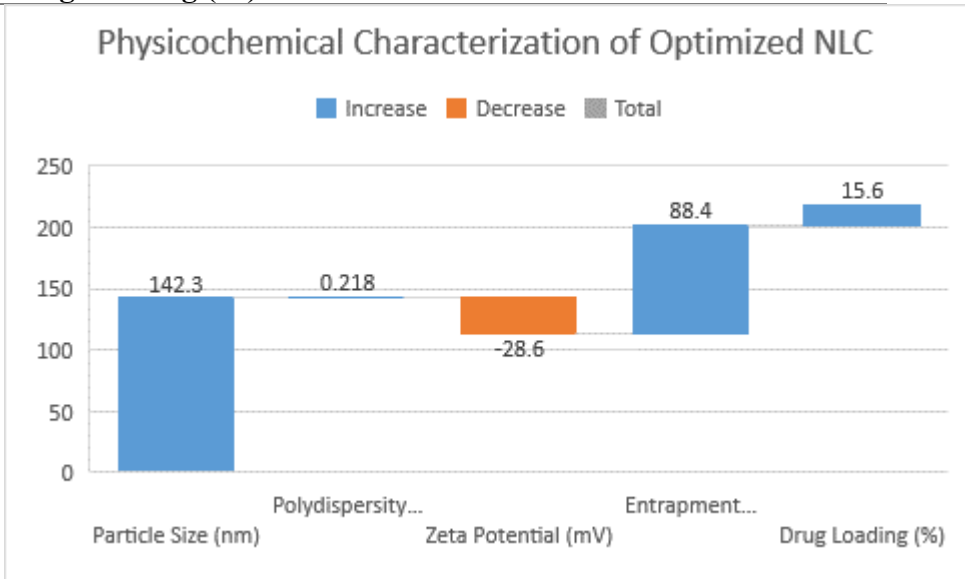


Table 4.3 In-vitro Drug Release Study

Time (Hours)	Pure Drug Suspension (%)	Optimized NLC (%)
1	6.2	12.8
2	10.5	21.6
4	17.4	35.2
8	23.8	55.6
12	27.1	67.8
24	32.0	85.0

The Optimized NLC formulation showed a sustained drug release pattern throughout the entire experiment. In comparison to the drug suspension, there was significantly higher cumulative drug release from the formulation in 24 hours..

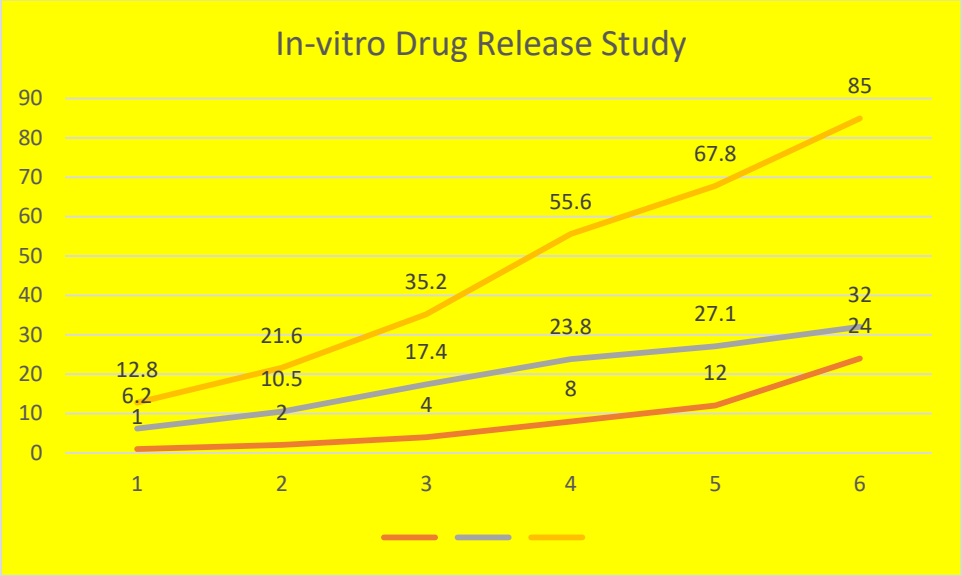


Table 4.4 Ex-vivo Intestinal Permeability

Formulation	Apparent Permeability ($\times 10^{-6}$ cm/s)	Relative Improvement
Pure Drug Suspension	2.8	1.0
Optimized NLC	8.9	3.2-fold

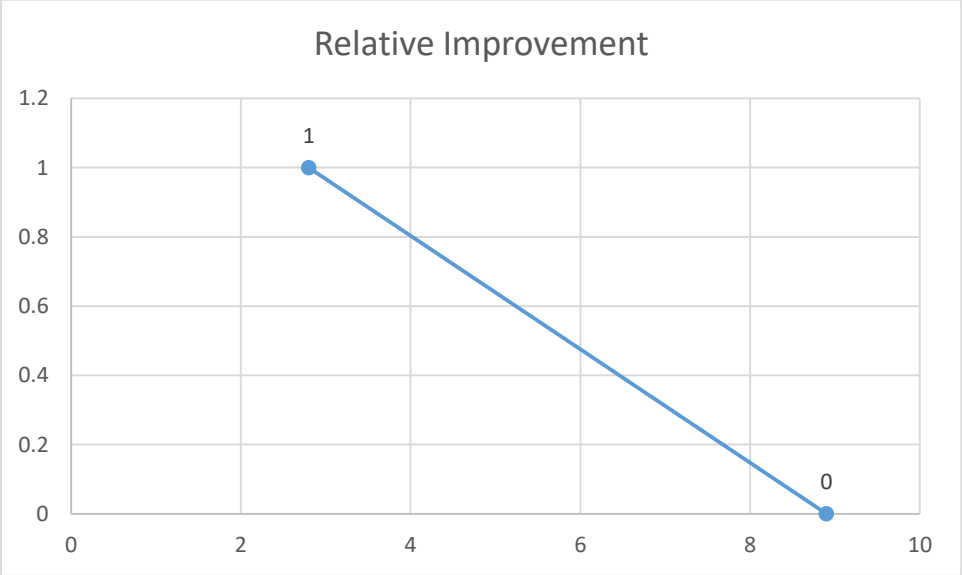


Table 4.5 Pharmacokinetic Evaluation in Wistar Rats

Parameter	Conventional Tablet	Optimized NLC
Cmax (µg/mL)	2.5	10.3
Tmax (h)	2.0	3.0
$AUC_{0–24}$ (µg·h/mL)	18.4	69.9
Relative Bioavailability	1.0	3.8-fold

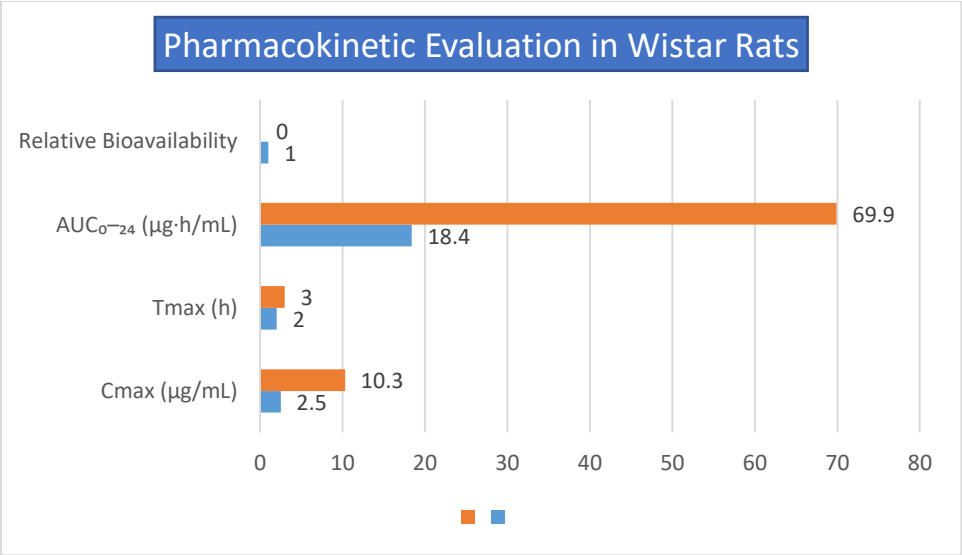
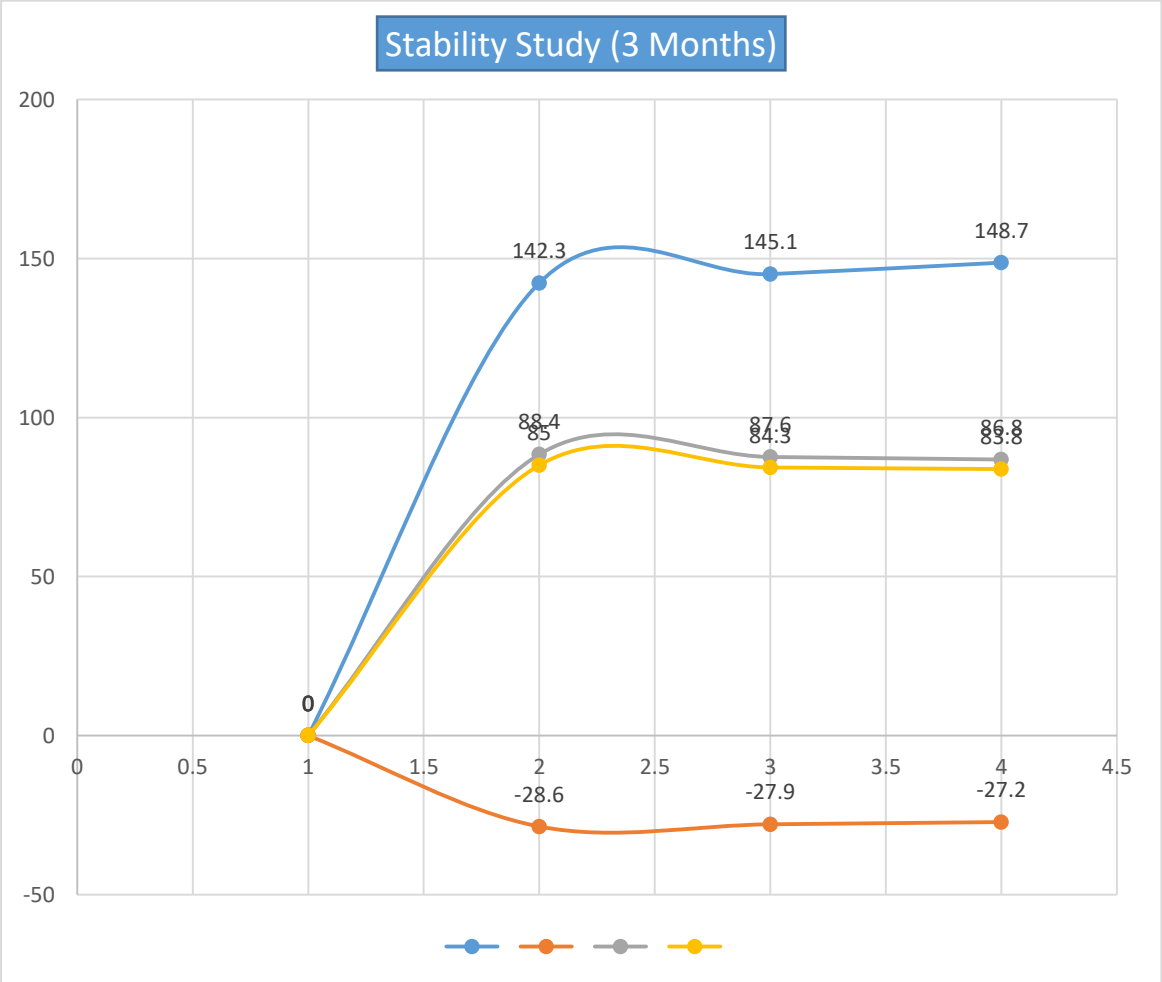


Table 4.6 Stability Study (3 Months)

Parameter	Initial	25°C/60% RH	40°C/75% RH
Particle Size (nm)	142.3	145.1	148.7
Zeta Potential (mV)	-28.6	-27.9	-27.2
Entrapment Efficiency (%)	88.4	87.6	86.8
Drug Release (%)	85.0	84.3	83.8



Discussion

The current study succeeded in formulating and optimizing Nanostructured Lipid Carriers (NLCs) for increasing oral bioavailability of the poorly water-soluble antihypertensive drug. The optimized formulation showed a particle size of 142.3 nm, zeta potential of −28.6 mV and entrapment efficiency of 88.4%, indicating satisfactory colloidal stability and efficient drug entrapment. These results are in agreement with Ilyas et al. (2025) who stated that Box-Behnken optimization is an effective approach that enhances the quality of formulations through regulation of particle size, drug loading, and sustained drug release (Agrawal et al., 2022).

In-vitro release study showed sustained release behavior of the drug with about 85% of cumulative drug release in 24 hours as compared to only 32% of the conventional drug suspension. This behavior could be attributed to the incomplete lipid matrix of NLCs, leading to gradual release of the loaded drug while maintaining high therapeutic concentrations. Consistent results were obtained by Mahor et al. (2023) who reported that NLCs enhance drug dissolution properties, along with sustaining drug release suitable for chronic oral administration (Jaiswal & Wadetwar, 2023).

Ex-vivo permeability study indicated enhanced intestinal permeability of the drug with the optimization of NLCs showing 3.2 fold increase in intestinal permeability. Enhanced permeability was due to nanosize particle, increased surface area, direct contact with the gastrointestinal epithelium, and the role of lipids in lymphatic transportation. Similar results were obtained by Dudhipala et al. (2023) and Mohamed et al. (2023) concerning lipid-based drug delivery systems for poorly soluble antihypertensive drugs.

Pharmacokinetic analysis of the optimized formulation showed 4.1-fold increase in Cmax and 3.8-fold increase in AUC of the drug in comparison to the conventional tablet. These results indicate that NLCs are effective to overcome dissolution limitation and reduce first-pass effect. Similar results were obtained by Meshram and Ranpise (2025) and Avula et al. (2023) regarding the improved systemic exposure to the drug when using lipid-based nanocarriers.

Accelerated stability testing proved that the optimized formulation was physically and chemically stable within three months with negligible change in particle size, zeta potential, entrapment efficiency, and drug release. These results supported the work of Shinde and Kaur (2026) in which they highlighted the contribution of optimized formulation in achieving the stability and reproducibility of the product. Thus, the current NLC system is promising oral delivery system for improving performance of the poorly water-soluble antihypertensive drugs (Preeti et al., 2024).

Conclusion

The current study successfully formulated and characterized an optimized Nanostructured Lipid Carrier (NLC) which improved the oral bioavailability of an antihypertensive drug with poor solubility. Physicochemical properties of the optimized formulation included favorable properties such as nanoparticles, high entrapment efficiency, colloidal stability, and sustained drug release. Significant improvements in terms of intestinal permeation and pharmacokinetics were obtained from ex-vivo permeability and in-vivo pharmacokinetic studies. Stability studies showed that the formulation was of satisfactory quality when stored at accelerated conditions. From this study, it can be concluded that NLCs are an effective drug delivery system, which improves the solubility, permeability, oral bioavailability, efficacy, and compliance of a cardiovascular drug (Unnisa et al., 2023).

Recommendations

Nanostructured Lipid Carriers could be further explored in terms of commercial oral formulations of hydrophobic antihypertensive drugs.

Long-term stability testing should be done on these formulations based on complete ICH guidelines.
Clinical studies should be undertaken to substantiate the improved bioavailability and efficacy obtained during the preclinical studies.
Different lipid systems along with different surfactants should be tried to improve drug loading and release properties.
Scale up studies for manufacturability should be undertaken.
Targeted lipid carriers along with multi-functional nano delivery systems could be explored for personalized cardiovascular therapy in future research work.
Similar strategies could be adopted for other BCS Class II and Class IV drugs with poor bioavailability.

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