RESEARCH PAPER

Nanoformulation of Telmisartan-Loaded Liposome Using the Film Hydration Method

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ABSTRACT

Telmisartan is a Biopharmaceutics Classification System (BCS) Class II drug with high permeability but poor aqueous solubility, which limits its oral bioavailability. Liposomes are an effective nanocarrier system capable of improving the solubility of poorly water-soluble drugs through incorporation into the phospholipid bilayer. Therefore, liposomal formulation represents a promising approach to enhance the solubility and biopharmaceutical performance of telmisartan. Nanotechnology-based drug delivery systems offer an advanced approach to overcome solubility limitations of poorly water-soluble drugs by improving their dissolution behaviour and bioavailability. To Create and optimise telmisartan-loaded liposomal nanoparticles utilising the thin film hydration approach. The thin film hydration approach was used to create telmisartan liposomes utilising different ratios of 1,2-Dipalmitoyl-sn-glycero-3-phosphocholine (DPPC), 1,2-Dipalmitoyl-sn-glycero-3-phosphoethanolamine (DPPE), and cholesterol. A phosphate buffer (pH 6.8) was used to hydrate the thin film formed after the medication and lipids were dissolved in a chloroform:methanol mixture and evaporated. To minimise particle size, the resulting dispersion was subjected to sonication. The effects of independent variables (lipid concentration, drug-to-lipid ratio, and hydration volume) on vesicle size, polydispersity index (PDI), zeta potential, and entrapment efficiency were examined using a full factorial design using Design Expert® software. The particle size ranged from 156-74.4 nm, with a homogeneous distribution indicated by a PDI of ≤ 0.15, a polydispersity index (PDI) of 0.3 or lower is considered acceptable, indicating a homogeneous population of phospholipid vesicles, and the zeta potential values of the liposomal formulations ranged from -4.7 mV to -60.9 mV, indicate excellent colloidal stability. The entrapment efficiency (EE) and drug loading (DL) of the formulations ranged from 78.3% to 96.05% and from 7.67% to 19.58%, respectively, which indicate excellent encapsulation of drug. Telmisartan-loaded liposomal nanoparticles can be effectively formulated using the thin film hydration method. The use of Design-Expert® facilitated the identification of optimal formulation parameters, demonstrating the potential of liposomes to enhance the delivery of poorly soluble drugs like telmisartan.

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INTRODUCTION

Telmisartan is a selective angiotensin-II receptor blocker that lowers blood pressure. It diminishes the effects of angiotensin-II on blood vessels and aldosterone secretion by blocking the signals from the AT1 receptor in the adrenal gland and the smooth muscle vascular system [1]. TLM is a BCS class II drug that can't be delivered in many ways, as it doesn't dissolve well, its biodistribution is difficult to predict, and it has limited bioavailability [2].

Diverse methods have been employed to deliver water-insoluble drugs, including salt formation, co-solvency, surfactant solubilization, amorphous forms, solid dispersion, co-crystals, polymeric micelles, inclusion complexes, size reduction, solid lipid nanoparticles, polymeric nanoparticles, and liposomes [3]. Liposomes are nanoparticles with a bilayer membrane that are good at getting small chemicals into cells [4].

Over the past 15 years, liposome technology has made significant progress, accelerating the development of new medicinal liposomal applications. To work best, factors must be given as quickly as feasible [5]. Liposomes were initially characterised by British haematologist Dr Alec D. Bangham in 1964 at the Babraham Institute in Cambridge. Their discovery occurred when Bangham and R. W. Horne tested the institute's new electron microscope by applying negative stain to dehydrated phospholipids [6].

The design of liposomes aims to achieve optimised properties: Drug loading and regulation of drug release rate, managing the rapid elimination of liposomes, Intracellular drug delivery, Receptor-mediated endocytosis of ligand-targeted liposomes and triggered release, Delivery of nucleic acids and DNA [7].

Liposome structures are categorised into four types based on size and bilayer count: small unilamellar vesicles (SUV), large unilamellar vesicles (LUV), multilamellar vesicles (MLV), and multivesicular vesicles (MVV). Liposomes possess a monolayer phospholipid bilayer in a unilamellar configuration, whereas they exhibit an onion-like architecture in a multilamellar arrangement. MVV establish a multilamellar configuration with concentric phospholipid spheres, while several unilamellar vesicles are generated within bigger liposomes [8].

This study aimed to enhance the solubility of telmisartan by formulating and optimising liposomal formulations using Design-Expert® software to save time and costs.

MATERIALS AND METHODS

Materials

Telmisartan was purchased from Shanghai Maclin Biochemical Technology Co., Ltd. (Shanghai, China). 1,2-Dipalmitoyl-sn-glycero-3-phosphocholine (DPPC) was purchased from Suzhou Xinglin Pharmaceutical Technology Co., Ltd. (Suzhou, China). 1,2-Dipalmitoyl-sn-glycero-3-phosphoethanolamine (DPPE) was purchased

Table 1. Several formulations of Telmisartan-loaded liposomes.

Formula	DPPC (mg)	DPPE (mg)	Cholesterol
F1	40	20	4.5
F2	60	10	2
F3	40	20	4.5
F4	60	30	2
F5	60	30	7
F6	60	10	7
F7	20	30	2
F8	20	10	2
F9	60	10	7
F10	20	30	2
F11	20	10	7
F12	20	10	7
F13	20	10	2
F14	60	30	7
F15	20	30	7
F16	20	30	7
F17	60	10	2
F18	60	30	2

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from Shanghai Rhawn Technology CO., Ltd. (Shanghai, China).

Preparation of liposomes

This study involved the preparation of liposomes by the thin film hydration technique utilising a Heidolph rotary evaporator [9]. For the preparation of liposome formulations, various quantities of phospholipids (DPPE, DPPC) and cholesterol were used, as shown in Table 1. In a round-bottom flask, all lipids and the hydrophobic medicine are solubilised in a 2:3 mixture of methanol and chloroform [10]. The organic solvent was subsequently evaporated in a rotary flask above the lipid transition temperature under reduced pressure until a thin layer was produced[11][8]. Subsequently, the film was rehydrated by adding 10 ml of phosphate buffer. The flask was reintroduced to the rotary flask evaporator without vacuum above the phospholipid transition temperature until a white, milky suspension was obtained to disperse the film in the solution [12]. Ultrasonication was used to diminish the size of the liposomes and enhance their homogeneity, hence augmenting the stability of the nanoliposomes [13].

Characterisation of telmisartan liposomes

Measurement of particle size, polydispersity index

The particle size and polydispersity index of telmisartan liposomes were analysed using a Particle Size Analyser (ABT-9000 Nano Laser Particle Size Analyser) to determine the particle size and polydispersity index. [14]In drug delivery applications involving lipid-based carriers, such as liposome formulations, a polydispersity index (PDI) of 0.3 or lower is considered acceptable, indicating a homogeneous population of phospholipid vesicles [15].

Measurement of zeta potential

The Zeta sizer (HORIBA, scientific SZ100, Tokyo, Japan) was utilised to measure the surface charge of the samples. In this experiment, materials were diluted in deionised (DI) water, and subsequently, surface charge was measured using a zeta sizer. Analysis was performed at 25 ºC with a detection angle of 90 ºC[16].

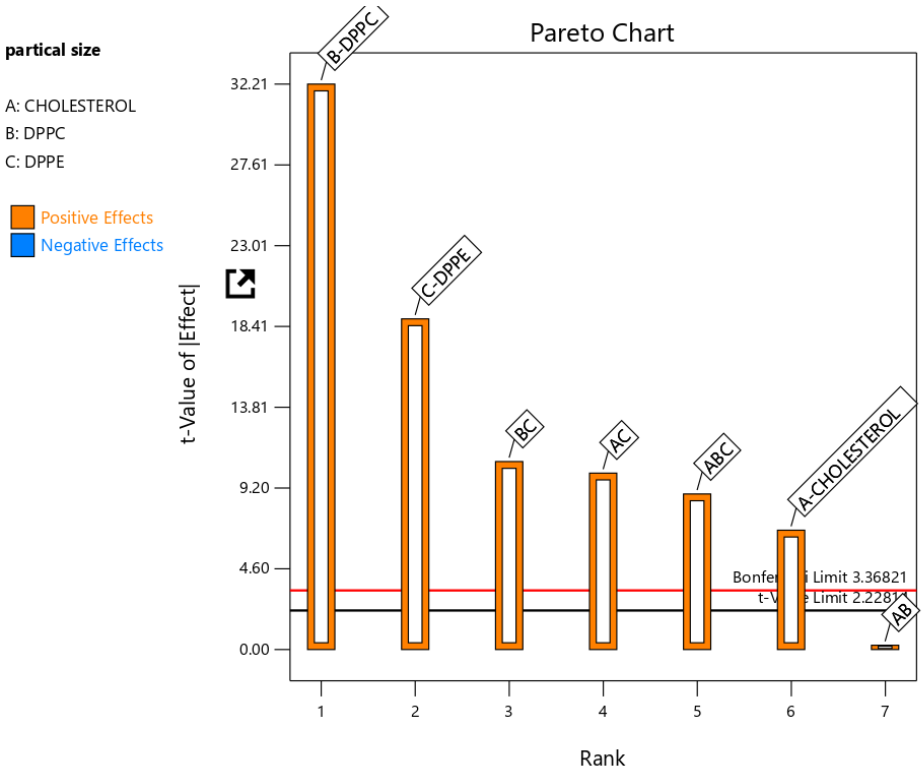

Fig. 1. Pareto chart showing the effects of DPPC, DPPE, and cholesterol on the particle size of telmisartan-loaded liposomes.

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Entrapment Efficiency and Drug Loading

The percentage of telmisartan calculated the entrapment efficiency (EE) and drug loading encapsulated in liposomes relative to the total amount of telmisartan (encapsulated and free) in the liposomes suspension. The entrapment efficiency and drug loading were assessed by isolating non-encapsulated telmisartan from the liposomal mixture using centrifugation. Two millilitres of liposome suspension were centrifuged at 1000 rpm for 10 minutes at 4 ºC. The supernatant was discarded, and liposomes were lysed with methanol to liberate the encapsulated medication. The drug amount was quantified using UV spectroscopy at 296 nm [17, 18].

The EE and LC were measured using Eq. 1 and Eq. 2.

$$\text{Entrapment efficiency} = \frac{\text{Entrapped drug(mg)}}{\text{Total drug added(mg)}} \times 100 \quad (1)$$

$$\text{Loading efficiency} = \frac{\text{Weight of entrapped drug(mg)}}{\text{Weight of liposome(mg)}} \times 100 \quad (2)$$

Fourier transform infrared spectroscopy

Several FTIR spectra were obtained using an FTIR spectrophotometer (Shimadzu, Japan) for pure telmisartan powder, a physical mixture, and the telmisartan-loaded liposomal formulation [19]. For each measurement, the sample was precisely incorporated into potassium bromide (KBr) powder and subsequently compacted into a disc comprising approximately 2% (w/w) of the sample. The spectra were obtained within the range of 4000–600 cm^{-1} at a resolution of 4 cm^{-1} [20].

Statistical analysis

A full factorial design was employed, utilising Design-Expert® version 13 (Stat-Ease Inc., USA), to systematically examine the effects of three independent variables DPPC, DPPE, and cholesterol on the physicochemical properties of telmisartan-loaded liposomes. The factorial design facilitated the assessment of both the individual impacts of each variable and their interaction effects on critical responses, including particle size, polydispersity index (PDI), entrapment efficiency (EE), drug loading (DL), and zeta potential. Statistical significance was determined by analysis of variance (ANOVA), while model suitability was verified through diagnostic visualisations, including Pareto charts and response surface plots. This method enabled the determination of an ideal formulation by optimising attractiveness, hence ensuring the efficient and economical construction of a stable liposomal system.

RESULTS AND DISCUSSION

Particle size and PDI

The influence of formulation variables

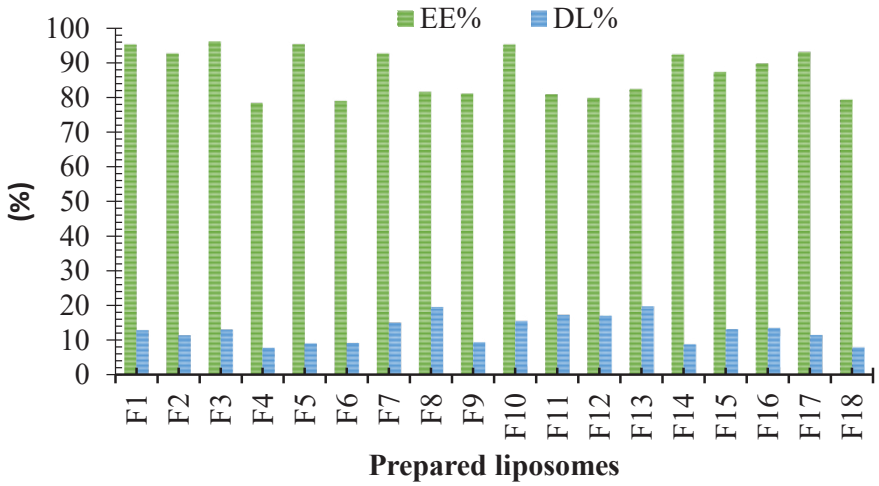

Fig. 2. Comparison of entrapment efficiency (EE) and drug loading (DL) of telmisartan-loaded liposomes for all prepared formulations (F1–F18), illustrating the impact of varying DPPC, DPPE, and cholesterol concentrations on encapsulation performance.

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A-Cholesterol, B-DPPC and C-DPPE on the particle size of telmisartan-loaded liposomes was analysed using a Pareto chart, as shown in Fig. 1. The data indicated that DPPC exerted the most pronounced positive influence on particle size, followed by DPPE and cholesterol. This signifies that increasing their concentrations results in bigger vesicle dimensions. Interaction variables, including AB, AC, BC, and ABC, had negligible effects and were statistically insignificant relative to the main effects.

Particle size was most affected by DPPC (factor B), shown in Fig. 1. Its t-value was higher than the Bonferroni threshold, indicating a statistically significant positive impact. This means that raising the level of DPPC causes the size of the particles to increase significantly [21].

Likewise, DPPE (factor C) exhibited a notable positive influence on particle size, as evidenced by its t-value exceeding the standard error line. However, it remained below the Bonferroni threshold, indicating moderate statistical significance [22]. Cholesterol (factor A) and all the investigated interaction terms (AB, AC, BC, and ABC), on the other hand, had t-values below the critical threshold, which means that they did not have a statistically significant effect on particle size within the studied range.

The findings indicate that phospholipid composition, specifically the concentrations of DPPC and DPPE, significantly influences the particle size of the prepared liposomes. In contrast, cholesterol content and interaction effects are minimal in this regard.

All prepared liposomal samples had low polydispersity index (PDI) values, consistently measuring below 0.15. This reflects a limited size distribution and elevated homogeneity of the synthesised nanoparticles. The low PDI values indicate the efficacy of the formulation process and imply that the chosen preparation parameters effectively generated homogenous liposomal populations, which is advantageous for improved stability and reproducibility. The use of probe sonication contributed significantly to achieving these low PDI values across all formulations [23].

Entrapment Efficiency and Drug Loading

The lipid composition significantly influenced the entrapment efficiency (EE%) and drug loading (DL%), particularly the ratios of cholesterol and DPPC/DPPE. The EE% values varied between 78% and 96%, with the highest entrapment observed at 4.5 mg cholesterol, 40 mg DPPC, and 20 mg DPPE (F3). Maintaining appropriate drug-to-lipid ratios ensures high encapsulation efficiency of hydrophobic drugs [24]. Inversely, the formulations exhibiting the lowest EE% (about 78%) (F4, F6) included either excessive cholesterol or insufficient phospholipids, corroborating previous studies that indicated an excess of cholesterol may alter bilayer fluidity, hence reducing its capacity to encapsulate substances [9].

The DL% values ranged from 7.7% to 19.4%,

Table 2. Characterisation results for telmisartan liposome formulations.

Formulation	Particle size (nm)	Polydispersity	Entrapment efficiency %	Drug loading%	Zeta potential
F1	84.1	0.04	95.18	12.775	-50
F2	112	0.071	92.56	11.287	-59.6
F3	83.9	0.033	96.05	12.89	-49.8
F4	127	0.074	78.3	7.676	-38.1
F5	156	0.01	95.25	8.901	-17.6
F6	96.4	0.042	78.885	9.067	-21.4
F7	84	0.077	92.56	14.929	-31.7
F8	74.7	0.06	81.49	19.402	-13.5
F9	97.7	0.034	81.015	9.312	-18.1
F10	83.5	0.086	95.15	15.346	-19.3
F11	83.2	0.135	80.815	17.194	-17.9
F12	80.6	0.09	79.73	16.963	-25.1
F13	76.5	0.087	82.26	19.585	-4.7
F14	152	0.015	92.265	8.622	-22.7
F15	90.7	0.132	87.25	13.022	-49.9
F16	95	0.068	89.71	13.389	-60.9
F17	110	0.146	92.975	11.338	-52.8
F18	120	0.108	79.235	7.768	-30.7

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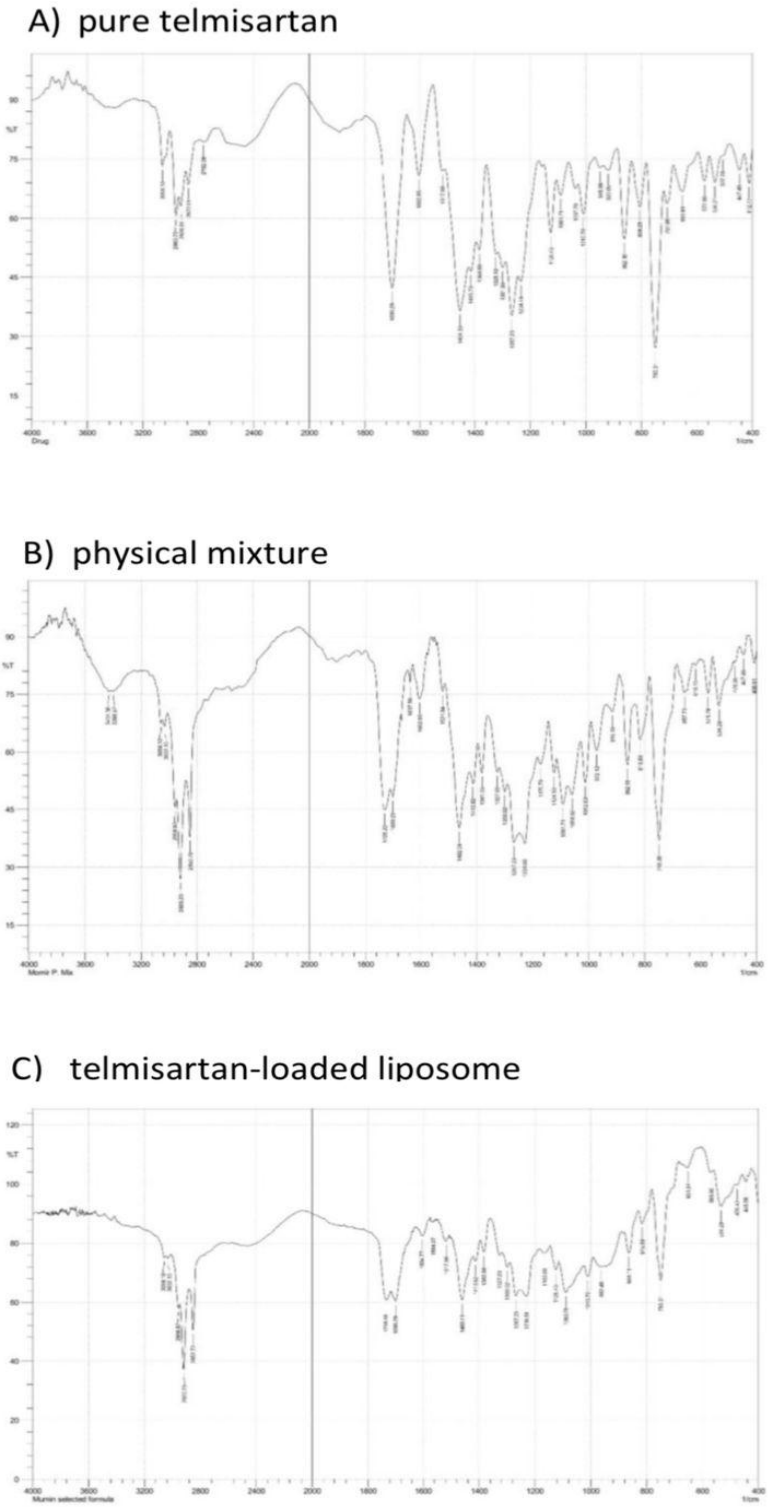

Fig. 3. The FTIR spectra of (a) pure telmisartan, (b) physical mixture of telmisartan with lipids and cholesterol, and (c) telmisartan-loaded liposomal formulation.

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demonstrating an inverse correlation with EE% across multiple trials. Elevated cholesterol levels increased encapsulation efficiency (EE%) but constrained drug loading percentage (DL%), presumably due to diminished aqueous core volume, while reduced cholesterol facilitated a greater DL% at the cost of EE%. This pattern corresponds with findings that elevated cholesterol levels lead to reduced medication loading and encapsulation efficiency [25]. Furthermore, it is typically advised to keep cholesterol levels below about 30% to optimise bilayer fluidity, stability, and effective drug loading in thin-film hydrated liposomal formulations [26].

Measurement of zeta potential

The zeta potential of the liposomal formulations ranged from –4.7 to –60.9 mV, indicating a consistently negative surface charge across all samples. Values below –30 mV indicate excellent colloidal stability, whereas values ranging from –4.7 to –15 mV denote moderate stability, which aligns with the documented ranges for DPPC/DPPE liposomes [15, 27]. The significant negative values can be ascribed to the presence of DPPE, which improves membrane packing and surface charge. In contrast, lower values may stem from elevated cholesterol levels, which are recognised to diminish charge mobility on the liposomal surface [26, 28].

Fourier transform infrared Spectroscopy

The FTIR analysis was performed on telmisartan powder to assess the drug's purity and to evaluate its compatibility with the phospholipids and cholesterol. The pure telmisartan's FTIR spectrum (Fig. 3) reveals specific absorption bands that attest to its structural integrity and the presence of functional groups. The broad band seen between 3380 and 3400 cm^{-1} is associated with the carboxylic acid group's O–H stretching vibration. The C–H stretching vibrations of the aliphatic and aromatic components are responsible for the peaks at 2958 cm^{-1} and 2872 cm^{-1}. While the peaks at 1602 cm^{-1} and 1507 cm^{-1} correspond to C=C aromatic stretching vibrations, a strong band at 1698–1702 cm^{-1} reveals the presence of the C=O stretching vibration from the carboxylic acid moiety. These findings are in agreement with Mahmood *et al.,* (2025), who reported characteristic FTIR peaks for pure telmisartan at 3392 cm^{-1} (O–H stretching), 2956 cm^{-1} (C–H stretching), 1697 cm^{-1} (C=O stretching) and 1604 cm^{-1} (C=C aromatic) [29]. The close match between the measured spectrum and the values in the literature shows that telmisartan is structurally sound and pure before it is made into liposomes.

The FTIR compatibility test was conducted to confirm that telmisartan is compatible with the other liposomal ingredients and to identify any potential chemical interactions. This was achieved by comparing the FTIR spectrum of pure carvedilol to the spectra of the physical mixture and the telmisartan-loaded liposome formulation. The physical mixture kept all of telmisartan's primary distinctive peaks, with no significant modifications or disappearances. This indicates that the medicine's molecular structure remained unchanged and that only physical blending occurred between the drug and the excipients. The fact that the C=O and aromatic C=C peaks remained unchanged also indicated that there was no chemical interaction or bond formation between the medication and the lipid matrix.

The FTIR spectrum of the telmisartan-loaded liposomal formulation, on the other hand, exhibited all the distinctive peaks of the drug. Still, the O–H and C=O stretching areas were slightly broader and shifted. The O–H band moved somewhat to about 3390 cm^{-1}, while the C=O stretching peak showed up close to 1701 cm^{-1}. These small changes point to the possibility of weak hydrogen bonding and van der Waals interactions between telmisartan molecules and the polar head groups of phospholipids (DPPC/DPPE). These interactions enable telmisartan to enter the liposomal bilayer without compromising the medication.

CONCLUSION

This research successfully formulated liposomes loaded with telmisartan through the thin film hydration technique and optimized them statistically using Design-Expert® software. The concentrations of DPPC, DPPE, and cholesterol were adjusted in a systematic manner to assess their impact on essential liposomal characteristics. The refined formulation showed an appropriate vesicle size with a narrow distribution, impressive entrapment efficiency, and an acceptable zeta potential, suggesting strong physical stability. The results demonstrated that the lipid composition is essential to determining the characteristics and effectiveness of liposomes. The formulated

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liposomal version of telmisartan showed better solubility and a possible increase in bioavailability, underscoring the reliability of the thin film hydration technique for encapsulating drugs that are poorly soluble in water. Future research may include *in vivo* antihypertensive assessments to validate the improved therapeutic efficacy of the formulated product.

CONFLICT OF INTEREST

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

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