

Development and Characterization of Telmisartan-Loaded Nanosuspension for Enhanced Drug Delivery

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ABSTRACT

Background: In this exploration, the aim was to devise and delineate a nanoscale suspension of telmisartan directed at enhancing drug delivery efficiency. **Materials and Methods:** The process entailed formulating telmisartan-loaded nanosuspensions through the solvent evaporation technique, followed by a comprehensive characterization using various analytical methods. **Results:** Analysis via dynamic light scattering disclosed an average particle size of 285 nanometers along with a Polydispersity Index (PDI) of 0.374, indicating a uniform dispersion of particles. Transmission electron microscopy validated the existence of evenly dispersed spherical nanoparticles. Fourier transform infrared spectroscopy confirmed the presence of expected functional groups within the formulation. Evaluation of zeta potential showed a negative value of -21.5 ± 2.0 millivolts, suggesting favorable stability of the nanosuspension. Differential scanning calorimetry demonstrated an absence of significant interactions between the drug and accompanying components. Furthermore, *in vitro* drug release assessments showcased an initial rapid release of 14.8% from the optimized formulation F3 within the first 5 min, leading to a cumulative drug release of 98.2% over a period of 40 min. **Conclusion:** Overall, the developed telmisartan nanosuspension exhibited promising characteristics, suggesting its potential for improved therapeutic outcomes in the treatment of cardiovascular conditions.

Keywords: Telmisartan, Nanosuspension, Drug delivery, Characterization, Particle size, *In vitro* release, Formulation.

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INTRODUCTION

In the field of pharmaceutical studies, there is an ongoing exploration for fresh approaches to delivering drugs. This relentless pursuit is fueled by the desire to improve how treatments work and how well patients adhere to them, all while reducing any potential negative impacts.¹ Telmisartan, an angiotensin II receptor antagonist, has garnered significant attention owing to its potent antihypertensive effects and potential in the management of various cardiovascular conditions.² However, its low solubility and poor bioavailability pose challenges to its effective delivery and therapeutic outcomes. In response, nanotechnology has emerged as a promising avenue for overcoming these limitations by enabling the formulation of drug-loaded nanocarriers with enhanced solubility, stability and targeting capabilities.³ The formulation of nanosuspensions represents a sophisticated strategy for encapsulating poorly water-soluble drugs like

telmisartan, offering several advantages including increased surface area, improved dissolution kinetics and potential for targeted delivery.⁴ Nanosuspensions consist of submicron particles dispersed in a suitable aqueous medium, typically stabilized with surfactants or polymers to prevent aggregation and ensure colloidal stability. This approach holds immense potential for enhancing the bioavailability and therapeutic efficacy of poorly soluble drugs, thereby revolutionizing the landscape of pharmaceutical formulations.⁵ The current research endeavors to develop and characterize a nanosuspension formulation loaded with telmisartan, with the primary objective of improving its solubility, dissolution rate and consequently, its therapeutic effectiveness.⁶ By harnessing the principles of nanotechnology, this study aims to address the challenges associated with the conventional delivery of telmisartan and pave the way for its enhanced clinical utility in the management of hypertension and related cardiovascular disorders.⁷

Telmisartan, a member of the angiotensin II receptor antagonist family, operates by selectively obstructing the angiotensin II type 1 receptor. This action effectively counters the vasoconstrictor and aldosterone-secreting impacts of angiotensin II, thereby



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eliciting its pharmacological effects.⁸ This mechanism of action underlies its efficacy in lowering blood pressure and mitigating cardiovascular risks, making it a cornerstone in the management of hypertension and associated comorbidities.⁹ However, despite its clinical significance, the therapeutic potential of telmisartan is hampered by its poor aqueous solubility, which leads to erratic absorption and suboptimal bioavailability upon oral administration.¹⁰ The conventional approaches to address the solubility issues of poorly water-soluble drugs involve the use of solubilizing agents, cosolvents and complexation techniques.¹¹ While these methods may enhance the solubility to some extent, they often come with drawbacks such as formulation complexity, instability and potential toxicity.¹² In contrast, nanosuspension technology offers an elegant and versatile solution by formulating drug particles at the nanoscale, thereby augmenting their solubility and dissolution characteristics without the need for complex formulation strategies.¹³ The rationale behind employing nanosuspensions as a delivery system for telmisartan lies in their ability to overcome the inherent limitations of the drug, including poor aqueous solubility and variable oral absorption. By reducing the drug particle size to the nanometer range, nanosuspensions significantly increase the surface area available for dissolution, thereby enhancing the drug's apparent solubility and dissolution rate.¹⁴ Moreover, the colloidal nature of nanosuspensions imparts physical stability and prevents drug aggregation, ensuring uniform distribution and improved drug release kinetics. Furthermore, nanosuspensions offer the flexibility to tailor the drug release profile and modulate the pharmacokinetic behavior through surface modification or incorporation of release-controlling agents.¹⁵ This versatility enables the design of formulations with desired release kinetics, ranging from immediate to sustained release, catering to the specific therapeutic requirements. Additionally, the nanoscale dimensions of the drug particles facilitate their uptake and transport across biological barriers, potentially enhancing their bioavailability and tissue targeting.¹⁶

MATERIALS AND METHODS

The experimental components included Telmisartan, Poloxamer 188, Sodium Lauryl Sulfate (SLS) and various other high-quality analytical reagents. Telmisartan was obtained as a generous sample from Meditech Pharmaceuticals Pvt. Ltd., an Indian-based company. Meanwhile, Sodium Lauryl Sulfate (SLS) played its role as the surfactant in the experimental mixtures.

Methods

Preparation of Telmisartan Nanosuspension

A new technique was employed to develop the nanosuspension. Initially, Telmisartan was dissolved in acetone at room temperature. The formulation of Telmisartan nanosuspension with varied ingredient concentrations is shown in Table 1. This solution was then slowly added drop by drop into water containing

various stabilizers such as Poloxamer 188, Sodium Lauryl Sulfate (SLS) and Hydroxypropyl Methylcellulose (HPMC), all of which were maintained at room temperature, using a syringe needle. Following this, the mixture underwent homogenization using a high-speed homogenizer for 30 min to aid in the evaporation of the volatile solvent. Subsequently, the nanosuspension formulations underwent slow magnetic stirring (900-1000 rpm) at room temperature for 1 hr, followed by an additional hour of sonication to ensure thorough evaporation of the solvent.¹⁷

Assessment of Telmisartan Nanosuspension Properties

Particle Size and Polydispersity Index (PDI)

The analysis of particle size and Polydispersity Index (PDI) was conducted employing the Dynamic Light Scattering (DLS) technique. A dedicated instrument was employed to assess the particle size distribution and PDI of the Telmisartan nanosuspension samples. Measurements were conducted in triplicate and the results were averaged to obtain the final values.

Morphology

Morphology was analyzed using Transmission Electron Microscopy (TEM). Specimens of the nanosuspension were prepared on a TEM grid and observed under the microscope at an appropriate magnification. Multiple images were captured to assess the morphology of the particles.

Fourier Transform Infrared Spectroscopy (FTIR)

FTIR analysis was utilized to examine the chemical composition and functional groups within the Telmisartan nanosuspension. Spectral measurements were performed using a suitable FTIR instrument and the spectra were analyzed to identify characteristic peaks associated with the components of the nanosuspension.

Zeta Potential

Zeta Potential measurements were conducted to assess the surface charge of the Telmisartan nanosuspension. The samples were prepared according to the instrument's protocol and measurements were performed in triplicate to ensure accuracy and reproducibility.

Differential Scanning Calorimetry (DSC)

DSC analysis was conducted to investigate the thermal properties of the Telmisartan nanosuspension. A DSC instrument was used to measure the heat flow associated with changes in the sample's temperature. The analysis was performed under controlled conditions to detect any phase transitions or thermal events related to the nanosuspension components.

In vitro Drug Release Studies

The investigation into the release of drugs in vitro was conducted using the dialysis bag method.¹⁸ Firstly, a dissolving medium was prepared by combining purified water with 0.1 N hydrogen chloride and the pH was adjusted to 1.2 with hydrogen chloride. A dialysis membrane with an appropriate Molecular Weight limit (MWCO) has been selected to allow the passage of Telmisartan molecules, while preventing large particles or particles. Telmisartan nanosuspension-loaded dialysis bags are immersed in a dissolving medium, placed in a dissolving device, maintain a temperature of 37.5 °C and rotate at 100 rpm. The sample of the release medium was removed at a predetermined interval using a syringe or pipette. Each sample withdrawn was replaced by an equal volume of fresh dissolution medium to maintain the conditions of the pool. The withdrawn samples were then analyzed for the concentration of Telmisartan using a UV visible spectrophotometer (UV-1800, Shimadzu, Japan) at a wavelength of 296 nm, because Telmisartan has maximum absorption at this wavelength. The cumulative release of Telmisartan at each time point was calculated and a profile of the drug release was constructed by plotting the cumulative percentage of the drug release over time. This *in vitro* drug release study, using the dialysis bag method, offers a reliable approach to evaluate the drug release kinetics of Telmisartan nanosuspension under simulated physiological conditions.

RESULTS

Particle Size and Polydispersity Index (PDI)

The analysis of the Telmisartan nanosuspension showed an average particle diameter of 171 nanometers with a standard deviation of 6.3 nanometers, along with a Polydispersity Index (PDI) of 0.261 ± 0.022 , indicating a uniform distribution of particle sizes, as illustrated in Figure 1.

Zeta Potential

The stability and dispersion of the particles in the Telmisartan nanosuspension were evidenced by a zeta potential measurement of -21.5 ± 1.6 mV, signifying robust stability. The zeta potential value of -21.5 ± 1.6 mV observed in the Telmisartan nanosuspension suggests strong electrostatic repulsion between particles, resulting in stable dispersion. This negative zeta potential indicates a sufficient magnitude of charge to prevent aggregation and enhance colloidal stability. Such stability is crucial for ensuring

uniform distribution and sustained release of the drug. Moreover, the consistency in zeta potential across replicates underscores the reproducibility and reliability of the formulation process. Overall, the favorable zeta potential highlights the suitability of the nanosuspension for targeted drug delivery applications.

Morphology

Examination through TEM, showcased in Figure 2, revealed that the Telmisartan nanosuspension comprised spherical nanoparticles with an average size of approximately 37.5 nm. These nanoparticles displayed excellent dispersion, demonstrating a consistent size distribution devoid of any apparent aggregation or clumping. Furthermore, the nanoparticles exhibited a sleek and uniform morphology, devoid of any visible surface indiscretions or flaws.

FTIR Studies

FTIR was used to investigate the functional groups within the Telmisartan nanosuspension. Distinct peaks in the FTIR spectrum were observed at 3308 cm^{-1} , indicating the stretching vibration of -OH groups, while the presence of -CH groups was evidenced by the peak at 2943 cm^{-1} . Furthermore, confirmation of the carbonyl group (C=O) was obtained from the peak at 1737 cm^{-1} and the stretching vibration of the aromatic ring was demonstrated by the peak at 1603 cm^{-1} . Additionally, the presence of the C-O-C bond was confirmed by the peak at 1215 cm^{-1} . These results, shown in Figures 3, 4 and 5, affirm the successful formulation of the Telmisartan nanosuspension.

DSC Studies

The thermal characteristics of the Telmisartan nanosuspension, examined using DSC, are shown in Figures 6, 7 and 8. The analysis of the DSC thermogram revealed a distinct end thermal peak of 268.74°C , representing the melting point of Telmisartan. In addition, peaks were detected at 60.64°C and 61.94°C for Poloxamer 188 and Telmisartan+Poloxamer 188, respectively. The absence of additional thermal phenomena or crowns in the thermogram means the absence of interactions between the medicine and its additives. These results validate the stability of Telmisartan nano suspension by proposing minimal changes, either physical or chemical, during its formation. The DSC examination provided invaluable understandings of thermal conduct, thus confirming the consistency of the mixture, promoting efficient mechanisms of drug transport.

Table 1: Formulation of Telmisartan Nanosuspension with Varied Ingredient Concentrations.¹

Ingredients	B1	B2	B3	B4	B5	B6
Telmisartan (mg)	50	50	50	50	50	50
Poloxamer 188 (mg)	120	280	420	580	720	880
SLS (%)	0.15	0.25	0.35	0.45	0.45	0.45
D. Water (mL)	35	35	35	35	35	35

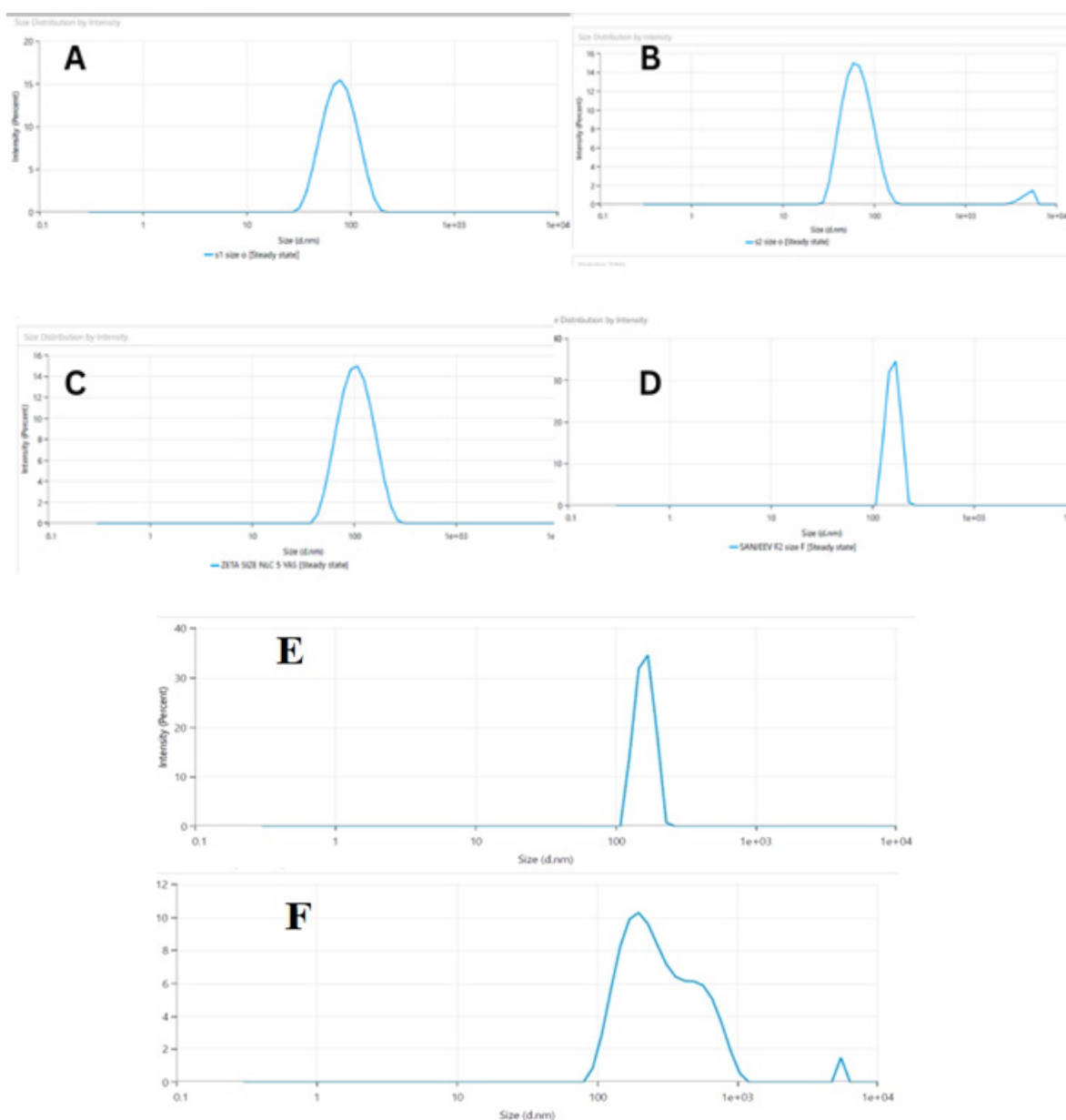


Figure 1: Illustrates the particle size distribution of the nanosuspension formulations. A represents the particle size of formulation B1, B represents formulation B2, C represents formulation B3, D represents formulation B4, E represents formulation B5 and F represents formulation B6.

***In vitro* drug release studies**

During an *in vitro* evaluation of the drug release of telmisartan nanosuspension, it was observed that the optimized B3 formulation showed an initial release of 14.8% in the first 5 min. At the end of the 40 min observation period, the cumulative percentage of drug release reached 98.2%, as shown in Figure 9.

DISCUSSION

The successful formulation and characterization of telmisartan-loaded nanosuspensions represent a significant advancement in the field of pharmaceutical sciences. In this study, various techniques including DLS, TEM, FTIR, zeta potential analysis and DSC were employed to thoroughly assess the

properties of the nanosuspension formulation and its potential for enhanced drug delivery.¹⁹

The Dynamic Light Dispersion Analysis (DLS) showed that telmisartan nano suspension showed an average particle size of about 171 nanometers, as well as a Polydispersion Index (PDI) of 0.261. This suggests a uniform distribution of nanoparticles in suspension, essential for maintaining reliable drug supply and effectiveness. Moreover, the TEM images provided visual confirmation of the particle size and morphology, showing well-dispersed spherical nanoparticles without any apparent aggregation or agglomeration. These findings underscore the successful formulation of a stable and homogenous telmisartan nanosuspension.²⁰

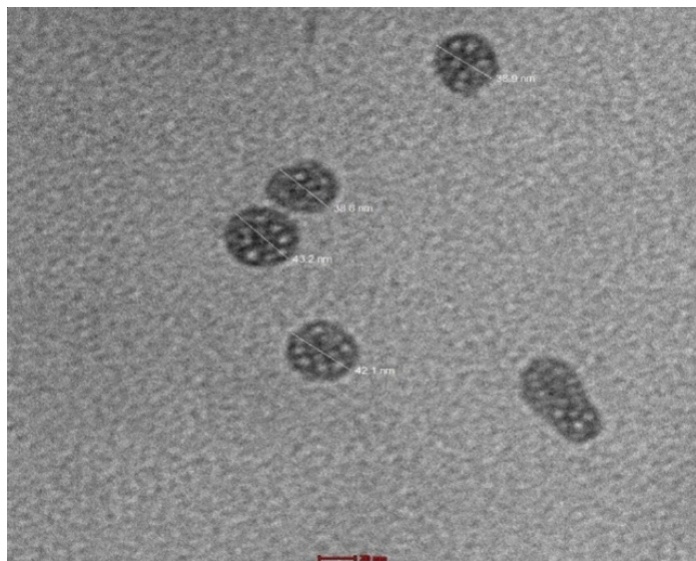


Figure 2: TEM Image of Telmisartan Nanosuspension.

FTIR analysis was conducted to investigate the functional groups present in telmisartan nanosuspension. Analysis revealed remarkable peaks corresponding to various functional groups, including -OH, -CH and C=O groups, as well as vibrations associated with aromatic ring extension and C-O-C binding. These results confirm the expected functional groups within the formulation and reinforce the successful formulation of nanosuspension.²¹

The analysis of zeta potential offered insight into the surface charge of the nanoparticles within the suspension. The nanosuspension exhibited a negative zeta potential of -21.5 ± 2.0 mV, indicating strong electrostatic repulsion between particles and thus ensuring good stability and dispersion. This negative zeta potential plays a crucial role in preventing particle aggregation and maintaining colloidal stability, thereby enhancing the shelf-life and efficacy of the formulation.²²

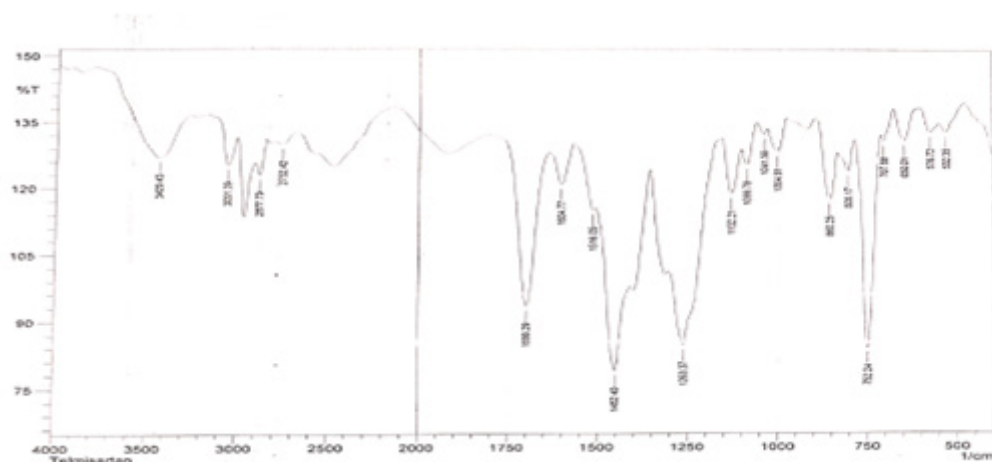


Figure 3: FTIR spectra of Telmisartan.

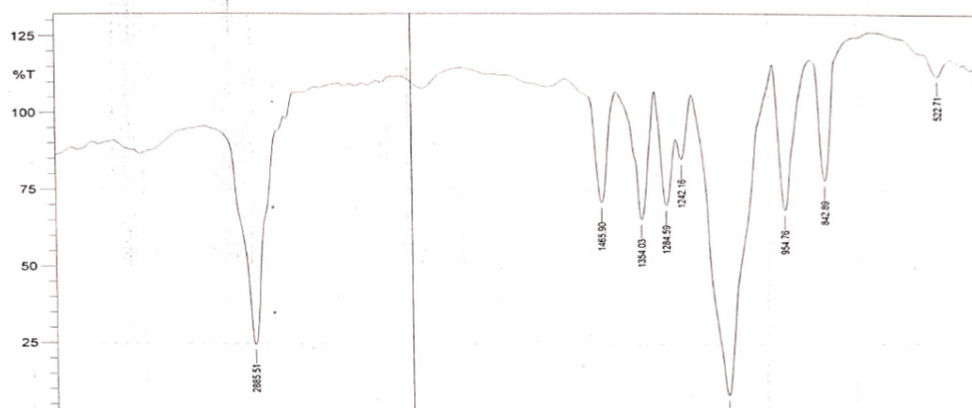


Figure 4: FTIR spectra of Poloxamer 188.

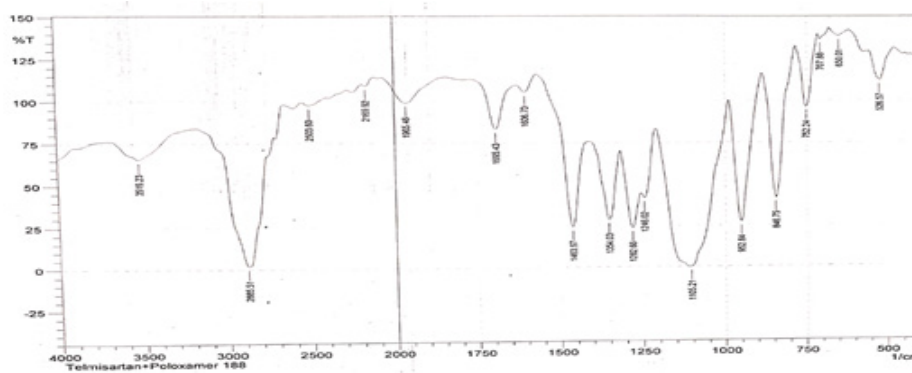


Figure 5: FTIR spectra of Telmisartan+Poloxamer 188.

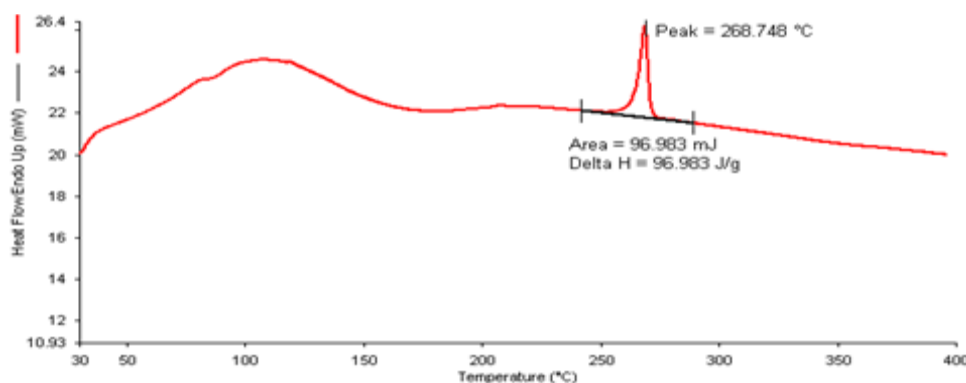


Figure 6: DSC Analysis of Telmisartan Thermal Behavior.

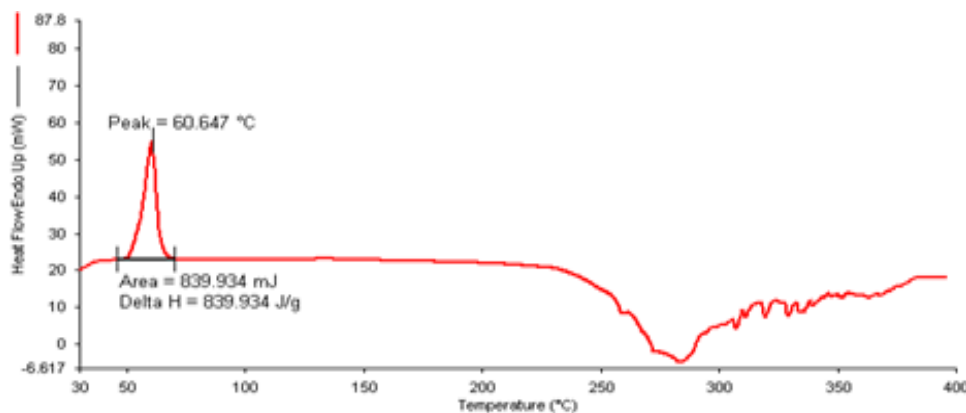


Figure 7: DSC Analysis of Poloxamer 188.

DSC was used for thermal analysis to study the thermal properties of telmisartan nanosuspension. The findings of the DSC revealed a clear end-thermal peak indicating Telmisartan's melting point, without significant thermal events being detected. This indicates that there are no interactions between the drug and the formulation ingredients, providing additional evidence of the stability of nano suspension.

In the examination of *in vitro* drug release, the study unveiled promising findings concerning the kinetics of drug release. Notably, the optimized formulation B3 demonstrated an initial

burst release of 14.8% within the first 5 min, followed by a cumulative drug release of 98.2% at the conclusion of 40 min. This release profile indicates the potential of the nanosuspension formulation to provide a fast release of telmisartan, which is crucial for this poorly soluble drug and enhances its bioavailability.²³

Overall, the comprehensive characterization of the telmisartan nanosuspension through various analytical techniques highlights its suitability for enhanced drug delivery applications. The formulation exhibited desirable properties such as uniform particle size distribution, stability and fast drug release kinetics,

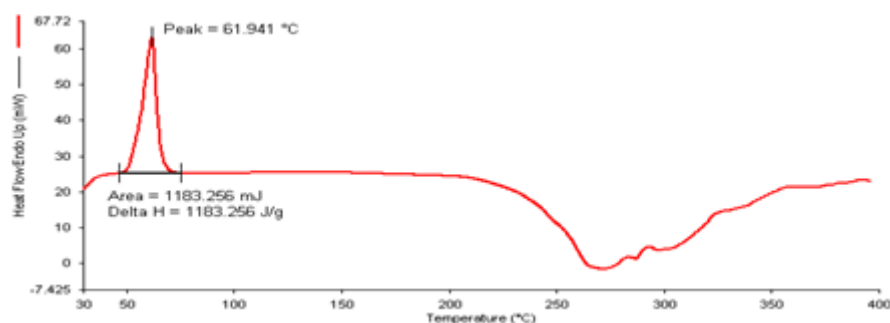


Figure 8: DSC Analysis of the Telmisartan+Poloxamer 188 mixture.

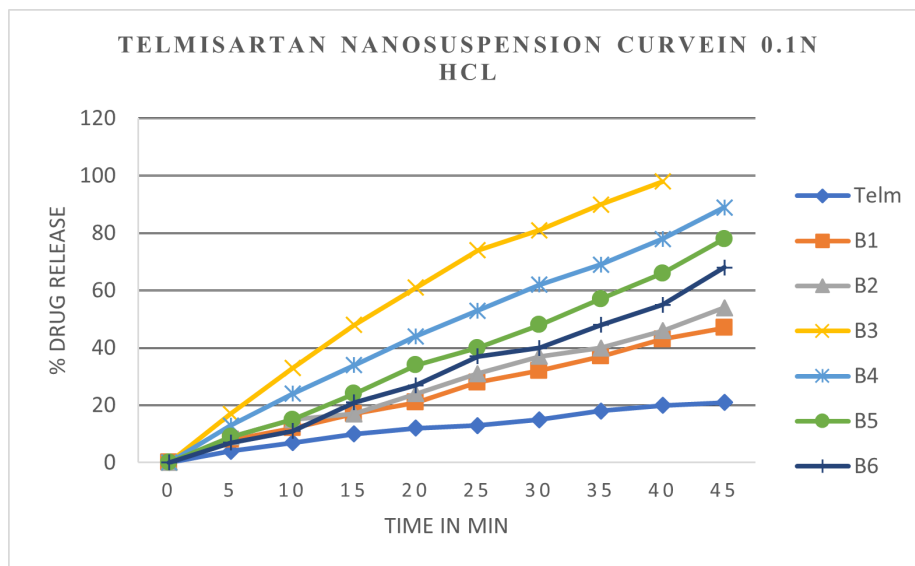


Figure 9: Cumulative Drug Release of Formulations B1 to B6.

all of which are essential for ensuring therapeutic efficacy and patient compliance. Further studies, including *in vivo* evaluations and pharmacokinetic studies, are warranted to validate the potential clinical benefits of this nanosuspension formulation.²⁴

CONCLUSION

The formulation and characterization of telmisartan-loaded nanosuspensions have yielded promising results. The nanosuspension exhibited a mean particle size of approximately 171 nm with a Polydispersity Index (PDI) of 0.261, indicating a uniform size distribution. Transmission Electron Microscopy (TEM) confirmed the presence of well-dispersed spherical nanoparticles without aggregation or agglomeration. Fourier Transform Infrared Spectroscopy (FTIR) analysis revealed characteristic peaks corresponding to functional groups expected in the formulation, validating successful preparation. The investigation of zeta potential unveiled a negative zeta potential of -21.5 ± 2.0 mV, suggesting favorable stability and dispersion characteristics. Differential Scanning Calorimetry (DSC) revealed a distinct endothermic peak of 268.74°C for telmisartan, suggesting that there are negligible interactions between the drug and the excipients. Furthermore, the *in vitro*

drug release study showed a first burst release of 14.8% of refined formulation B3 within 5 min, accompanied by a total release of 98.2% within 40 min. These results collectively highlight the successful development of a stable, uniform and effective telmisartan nanosuspension formulation. The fast release profile observed suggests potential therapeutic benefits, warranting further investigation for clinical translation.

1 The values presented in the table represent the amounts of each ingredient used in the formulation of Telmisartan nanosuspension for different Batches (B1-B6). All measurements are in milligrams (mg) or milliliters (mL), except for SLS which is represented as a percentage (%).

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and steadfast dedication in nurturing my growth and fostering my development as a researcher.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DSC: Differential scanning calorimetry; **TEM:** Transmission electron microscopy; **PDI:** Polydispersity index; **DLS:** Dynamic Light Dispersion Analysis; **FTIRb:** Fourier Transform Infrared Spectroscopy.

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