ISSN 1998 – 409X

ORIGINAL ARTICLE

A Self-Microemulsifying Drug Delivery Approach for Improving the Solubility and Dissolution of Telmisartan

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Abstract

Background: Telmisartan is a poorly water-soluble drug belonging to Biopharmaceutics Classification System Class II, for which inadequate aqueous solubility and dissolution can limit oral drug absorption and bioavailability. Self-microemulsifying drug delivery systems (SMEDDS) offer a promising lipid-based approach for enhancing drug solubilization and dissolution. **Objectives:** The present study aimed to develop and optimize a telmisartan-loaded SMEDDS to enhance drug solubilization and improve its *in vitro* dissolution performance. **Materials and Methods:** The formulation development involved screening of different oils, surfactants, and co-surfactants based on their ability to solubilize Telmisartan and facilitate microemulsion formation. Oleic acid, Tween 80, and polyethylene glycol 400 were selected as the oil, surfactant, and co-surfactant, respectively. Pseudo-ternary phase diagrams were constructed to identify the microemulsion region, and SMEDDS formulations were prepared by the water-titration method. Ten formulations (F1-F10) were developed using different surfactant-to-co-surfactant (S-mix) and oil-to-Smix ratios. The formulations were evaluated for drug content, self-emulsification time, percentage transmittance, cloud point, electrical conductivity, viscosity, thermodynamic stability, droplet size, zeta potential, and *in vitro* drug release. Fourier-transform infrared spectroscopy (FTIR) was performed to assess potential drug–excipient incompatibility. **Results:** Among the developed formulations, F2 containing an S-mix ratio of 1:1 and an oil-to-Smix ratio of 1:5 demonstrated favorable physicochemical and performance characteristics. F2 showed a drug content of 98.15 ± 0.36%, percentage transmittance of 98.50 ± 1.33%, self-emulsification time of 1.31 min, cloud point of approximately 52°C, and electrical conductivity of 0.156 mS/cm. The mean droplet diameter was 28.36 nm, with a zeta potential of −25.5 mV. F2 exhibited enhanced *in vitro* drug release compared with the marketed Telmisartan formulation, achieving 94.38% release at 120 min and 97.34% at 150 min, compared with 78.49% release from the marketed formulation at 120 min. Thermodynamic stability studies, including freeze–thaw, heating–cooling, and centrifugation tests, showed no visible signs of instability. FTIR analysis did not indicate major incompatibility between Telmisartan and the formulation components. **Conclusion:** The developed Telmisartan SMEDDS, particularly formulation F2, demonstrated efficient self-emulsification, nanosized droplets, satisfactory physicochemical characteristics, and substantially improved *in vitro* dissolution compared with the marketed formulation. The findings suggest that SMEDDS is a promising lipid-based drug delivery approach for enhancing the solubilization and dissolution performance of poorly water-soluble Telmisartan.

Key words: Dissolution, oleic acid, polyethylene glycol 400, self-microemulsifying drug delivery system, self-microemulsifying drug delivery systems, solubility enhancement, telmisartan, tween 80

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Received: 22-08-2026
Revised: 23-09-2026
Accepted: 29-09-2026

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INTRODUCTION

Poor aqueous solubility is one of the major challenges encountered during the development of oral dosage forms. A drug must generally dissolve in gastrointestinal fluids before it can become available for absorption.[1] Consequently, inadequate aqueous solubility may result in slow dissolution, variable absorption, and reduced oral performance. Several formulation approaches have therefore been investigated for poorly water-soluble drugs, including micronization, salt formation, solid dispersion, cyclodextrin complexation, surfactant-based systems, nanosizing, and lipid-based drug delivery systems.[2,3] Self-microemulsifying drug delivery systems (SMEDDS) are isotropic mixtures consisting principally of an oil, surfactant, and co-surfactant or co-solvent. Upon exposure to aqueous gastrointestinal fluids and gentle agitation, these systems spontaneously form fine oil-in-water dispersions.[4,5] The resulting small droplets provide a large interfacial area and facilitate presentation of the drug in a solubilized or finely dispersed state. The efficiency of a SMEDDS depends strongly on the physicochemical properties of the drug and the selection and proportion of formulation components.[6] Drug solubility in the lipidic excipients, the self-emulsification region identified by phase-diagram studies, droplet size distribution, and formulation stability are important considerations during development.[7,8] Telmisartan was selected as a model poorly water-soluble drug for the present investigation. The project work was designed to investigate the ability of a lipid-based SMEDDS containing oleic acid, Tween 80, and polyethylene glycol 400 (PEG 400) to enhance Telmisartan solubilization and dissolution.

The project specifically proposed preformulation studies, solubility screening, selection of suitable formulation components, compatibility evaluation, formulation of Telmisartan SMEDDS, and assessment of the resulting formulations using *in vitro* characterization and dissolution studies.

MATERIALS AND METHODS

Materials

Telmisartan was used as the model drug. Oleic acid was selected as the oil phase, Tween 80 as surfactant, and PEG 400 as co-surfactant. Distilled water, methanol, hydrochloric acid, and other analytical reagents were used as required for the experimental investigations.

Preformulation studies

Preformulation evaluation included examination of the physical characteristics of Telmisartan, melting point determination, Fourier-transform infrared spectroscopy (FTIR) analysis, analytical method development, solubility studies, thin-layer chromatography and drug-excipient compatibility studies.[9,10] The project used ultraviolet (UV) spectrophotometry for quantitative estimation of Telmisartan. The reported analytical work included determination of the wavelength maximum and preparation of calibration curves in different media. The reported λ_{max} for Telmisartan in the experimental study was approximately 249.8 nm.

Solubility study

The solubility of Telmisartan was investigated in selected oils, surfactants and co-surfactants.

The investigated vehicles included Tween 80, PEG 400, PEG 600, oleic acid, olive oil and Tween 60. Excess drug was added to the respective vehicles and equilibrated under controlled conditions. Following centrifugation and filtration, the concentration of dissolved drug was determined spectrophotometrically.[11] Based on the reported solubility screening, oleic acid, Tween 80 and PEG 400 were selected for development of the SMEDDS.

Drug–excipient compatibility study

Compatibility between Telmisartan and the selected formulation components was assessed by visual observation, UV spectroscopic analysis, and FTIR spectroscopy.[12] The drug–excipient mixtures were monitored over the study period for changes in appearance. The reported mixtures remained visually stable without major color change or phase separation during the observation period. The project also reported acceptable assay values for the drug–excipient mixtures during the evaluation period.

Preparation of telmisartan SMEDDS

Telmisartan SMEDDS formulations were prepared using oleic acid, Tween 80, and PEG 400. The drug concentration was maintained at 10 mg/mL in the formulation.[13] Tween 80 and PEG 400 were mixed to form the surfactant/co-surfactant mixture (Smix). Telmisartan was incorporated into the selected lipidic mixture and mixed until the drug was completely dissolved. The formulations were stored at room temperature before characterization.

In vitro release

The quantitative *in vitro* release test was performed in 0.1 N HCl as a dissolution medium. SMEDDS were placed in gelatine capsule during the release period to compared to release profile with the traditional dosage form, and the percent drug dissolved at different time intervals was calculated.[14,15]

Table 1: Drug excipient compatibility study

S. No.	Time (days)	Appearance study		
		Telmisartan+Oleic acid	Telmisartan+Tween 80	Telmisartan+PEG 400
1	0	Clear colorless liquid	Slightly yellowish liquid	Clear colorless liquid
2	7	Clear colorless liquid	Slightly yellowish liquid	Clear colorless liquid
3	15	Clear colorless liquid	Slightly yellowish liquid	Clear colorless liquid
4	30	Clear colorless liquid	Slightly yellowish liquid	Clear colorless liquid
5	60	Clear colorless liquid	Slightly yellowish liquid	Clear colorless liquid
6	90	Clear colorless liquid	Slightly yellowish liquid	Clear colorless liquid

Table 2: Composition design of Telmisartan SMEDDS formulations

Formulation	Smix ratio (Tween 80:PEG 400)	Oil: Smix ratio
F1	1:1	1:4
F2	1:1	1:5
F3	1:1	1:6
F4	1:1	1:7
F5	2:1	1:4
F6	2:1	1:5
F7	2:1	1:6
F8	3:1	1:4
F9	3:1	1:5
F10	3:1	1:6

SMEDDS: Self-microemulsifying drug delivery systems, PEG 400: Polyethylene glycol 400

Table 3: Drug content of Telmisartan SMEDDS

Formulation	Drug content (%)
F1	93.34±0.29
F2	**98.15±0.36**
F3	88.62±0.48
F4	74.10±0.25
F5	86.64±0.22
F6	89.72±0.43
F7	90.36±0.35
F8	94.87±0.22
F9	79.53±0.32
F10	72.60±0.21

SMEDDS: Self-microemulsifying drug delivery systems. F2 showed the highest reported drug content among the investigated formulations. F2 showed the highest reported drug content among the investigated formulations

RESULTS

Organoleptic properties

Telmisartan was found white in color, odorless, and amorphous powder, which complies all parameters with IP.

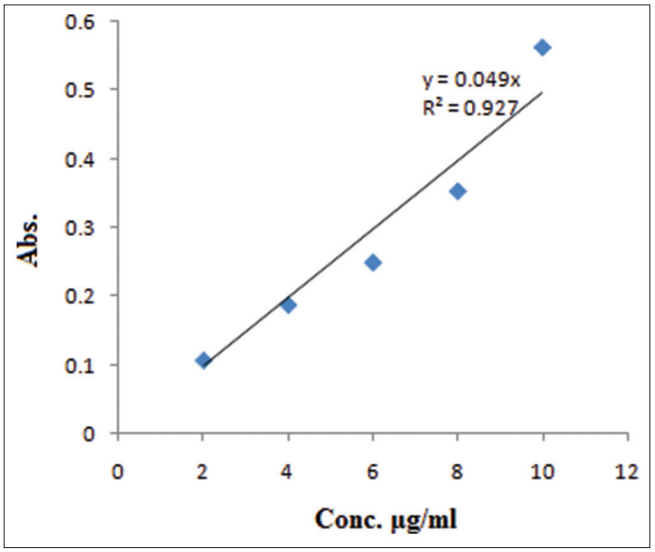


Figure 1: Calibration curve of Telmisartan in distilled water

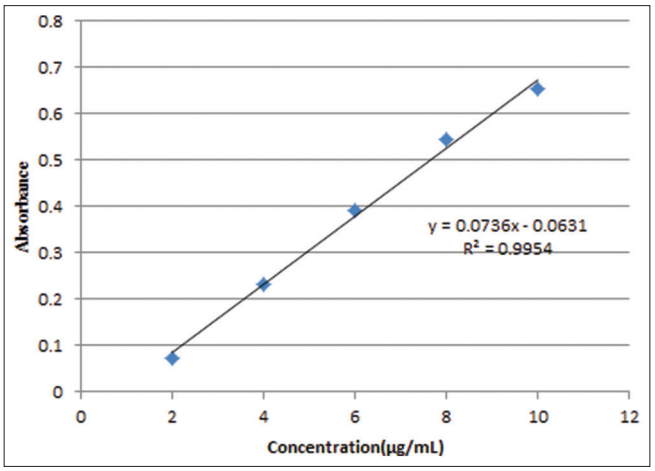


Figure 2: Calibration curve of Telmisartan in 0.1 N HCl

UV spectrophotometric analysis

Construction of calibration curve of telmisartan in distilled water

The drug exhibited an absorption maximum at 276 nm. A linear relationship between the concentration and

Table 4: Self-emulsification characteristics

Formulation	Time (min)	Observation
F1	1.23	Clear dispersion
F2	**1.31**	Clear dispersion
F3	1.41	Slightly clear
F4	1.47	Clear dispersion
F5	1.43	Clear dispersion
F6	1.32	Slightly clear
F7	2.11	Clear dispersion
F8	2.16	Slightly clear
F9	2.14	Clear dispersion
F10	2.23	Slightly clear

Values in bold represent F2 rapidly produced a clear dispersion without visible drug precipitation.

Table 5: Percentage transmittance

Formulation	Transmittance (%)
F1	94.26±1.75
F2	**98.50±1.33**
F3	86.34±2.04
F4	81.67±1.33
F5	76.31±2.43
F6	94.42±2.12
F7	90.15±1.05
F8	83.25±1.56
F9	92.18±1.40
F10	95.36±1.51

Bold text highlights value that F2 exhibited the highest percentage transmittance, indicating formation of a comparatively clear dispersion.

Table 6: FTIR characteristics of Telmisartan SMEDDS

Functional group	Observed frequency (cm^{-1})
O–H stretching	3628
C–H stretching	2867
C=O	1733
Ar–CH	1456
C=N	1248
Ar C=C	1566
C–O–C	1296
CH_2–CH	2843

FTIR: Fourier-transform infrared spectroscopy, SMEDDS: Self-microemulsifying drug delivery systems

absorbance of telmisartan was established over the examined concentration range (2–10 g/mL).

The calibration curve of Telmisartan in distilled water was found to be linear in the range of 2–10 µg/mL, and the coefficient of regression was found 0.927 as shown in Figure 1.

Table 7: *In vitro* cumulative drug release

Time (min)	F2 SMEDDS (%)	Marketed formulation (%)
15	29.18	20.67
30	46.10	36.42
45	61.37	46.34
60	71.48	58.78
90	84.37	73.65
120	**94.38**	78.49
150	**97.34**	82.37

SMEDDS: Self-microemulsifying drug delivery systems. Bold values indicate highest percentage of drug release as compared to marked formulation.

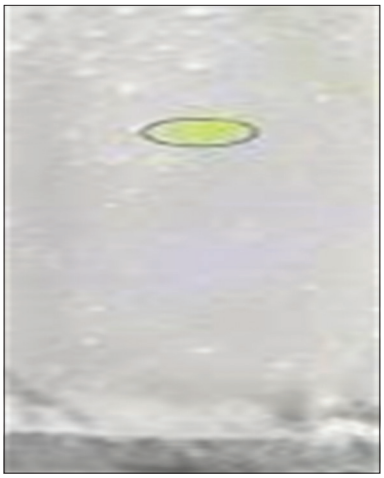


Figure 3: Thin-layer chromatography of the drug

Construction of calibration curve of telmisartan in 0.1 N HCl

The calibration curve of Telmisartan in 0.1 N HCl was found to be linear in the range of 2–10 µg/mL, and the coefficient of regression was found 0.995 (Figure 2).

Mobile phase: Methanol: Tolune (4:6v/v). The Rf value of Telmisartan was found to be 0.54. The Figure 3 shows only one spot of Telmisartan, from this, it can be concluded that there was an absence of impurities.

Drug – excipients compatibility study

Appearance study of drug and excipient mixture does not show any colour change (Figure 4), that indicate drug and excipient mixture was chemically stable (Table 1).

Pseudo-ternary phase diagram

Pseudo-ternary phase diagrams were constructed to identify the microemulsion region as shown in Figure 5. Oleic acid was used as the oil phase, and Tween 80/PEG 400 mixtures were evaluated at different surfactant-to-co-surfactant ratios.

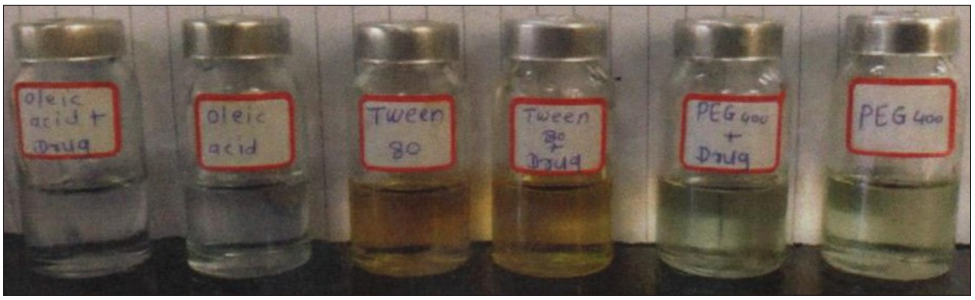


Figure 4: Appearance study of Telmisartan and excipient mixture from day 1 to 90

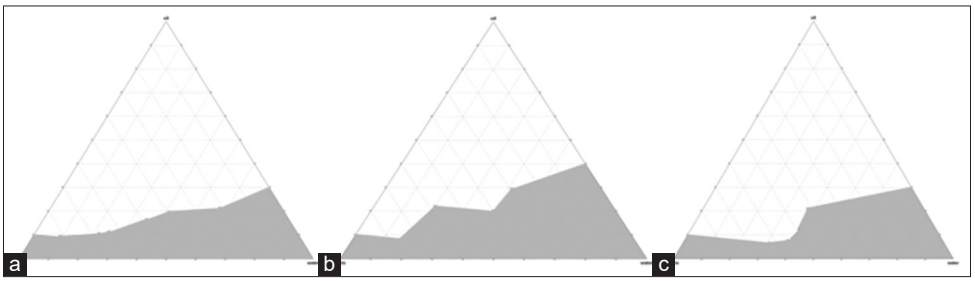


Figure 5: Phase diagram of oleic acid-tween 80-polyethylene glycol 400 (PEG 400) system indicating microemulsion existence region with Tween80/PEG 400 ratio of (a) 1:1 (b) 2:1 (c) 3:1

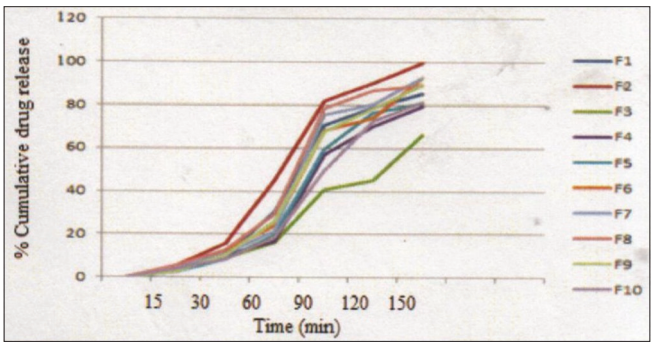


Figure 6: *In vitro* dissolution study of F1-F10 self-microemulsifying drug delivery systems formulations

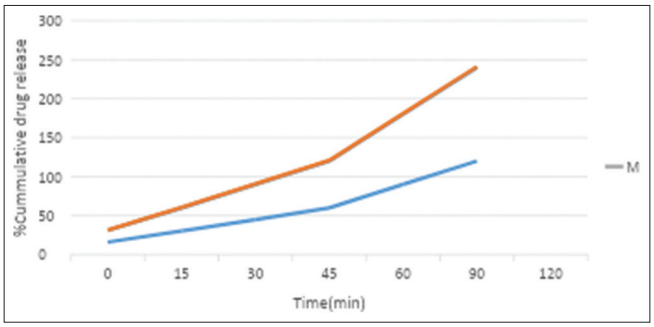


Figure 7: *In vitro* dissolution study of F2 self-microemulsifying drug delivery systems and marketed tablet formulations

The investigated Smix ratios included 1:1, 2:1, and 3:1. The mixtures were gradually titrated with water and visually evaluated. Clear and isotropic systems were considered to represent the microemulsion region. The study selected the 1:1 Tween 80/PEG 400 Smix ratio as the most suitable system for subsequent formulation development.

Formulation design

As shown in Table 2, Ten formulations were prepared by varying the oil-to-Smix ratio and Smix composition.

The formulation design and experimental evaluation were based on the project formulation scheme.

Evaluation of SMEDDS

Drug content

Drug content was determined by extracting Telmisartan from the SMEDDS and analyzing the resulting solution by UV spectroscopy. The reported drug-content values for F1–F10 are shown in Table 3.

Self-emulsification time

Self-emulsification behavior was evaluated following dispersion of the formulations in aqueous media under controlled agitation (Table 4).

Percentage transmittance

Percentage transmittance was measured at 650 nm to assess the optical clarity of the resulting microemulsion (Table 5).

Cloud point

The cloud point represents the temperature at which the clarity of the diluted formulation changes because of

temperature-dependent behavior of the non-ionic surfactant system. The cloud point of F2 was reported as approximately 52 ± 1.025°C, which was above physiological temperature and therefore indicated acceptable thermal behavior under the conditions investigated.

Electrical conductivity

Electrical conductivity was measured to provide information regarding the nature of the resulting microemulsion. The project results indicated formation of an oil-in-water type system, consistent with water serving as the continuous phase after dilution. For F2, the reported conductivity was 0.156 mS/cm.

Viscosity

Viscosity was determined using a Brookfield viscometer. The reported viscosity of F2 was approximately 2022 cps in the detailed formulation evaluation, although the abstract of the project reports 202 cps.

Thermodynamic stability

The formulations were subjected to freeze–thaw cycling, heating–cooling cycles, and centrifugation. No visible phase separation or other major physical instability was reported for the evaluated formulations (Figure 4). The formulations therefore passed the preliminary thermodynamic stability screening.

Droplet size and polydispersity

- The optimized F2 formulation was analyzed following dilution
- The reported mean droplet diameter was: 28.36 nm
- The reported polydispersity index was: 1.000
- The small measured droplet diameter supports formation of a fine dispersion after dilution.

Zeta potential

The optimized F2 formulation exhibited a reported zeta potential of−25.5 mV. The project attributed the negative charge to the formulation system and noted that the non-ionic surfactant and co-surfactant themselves do not inherently provide strong ionic charge.

FTIR analysis

FTIR spectroscopy was used to investigate the chemical compatibility of Telmisartan with the formulation components. Characteristic absorption bands corresponding to the principal functional groups of Telmisartan were observed in the optimized formulation (Table 6). The project did not report the disappearance of the principal drug-related bands suggestive of a major chemical interaction.

The FTIR findings were interpreted in the project as supporting compatibility of Telmisartan with the selected formulation components.

In vitro dissolution study

The dissolution behavior of the optimized F2 formulation was compared with a marketed Telmisartan formulation (Figure 7). The study employed USP Type-II dissolution equipment using 0.1 N HCl as the dissolution medium at 37°C. Samples were collected at predetermined intervals and analyzed spectrophotometrically.

The optimized F2 formulation demonstrated a higher dissolution profile than the marketed formulation throughout the reported study period. At 120 min, F2 released 94.38% of the drug compared with 78.49% from the marketed formulation. At 150 min, the corresponding values were 97.34% and 82.37%, respectively (Table 7 & Figure 6). The improved dissolution can reasonably be associated with the lipidic formulation environment, spontaneous formation of a fine dispersion, and increased interfacial area following dilution.

DISCUSSION

The present investigation demonstrated the feasibility of developing a Telmisartan SMEDDS using oleic acid, Tween 80 and PEG 400 (Table 2). Solubility screening indicated that the selected components provided suitable solubilization characteristics for Telmisartan. The selection of the formulation components was therefore followed by phase-behavior studies to identify a composition capable of spontaneous formation of a clear microemulsion. The pseudo-ternary phase-diagram investigation demonstrated that the 1:1 Tween 80/PEG 400 Smix system provided a suitable microemulsion region (Figure 5). This finding supported selection of the 1:1 Smix ratio for further formulation development.

Among the ten formulations, F2 showed a combination of favorable characteristics. It contained the 1:1 Smix ratio and 1:5 oil-to-Smix ratio. F2 exhibited high drug content (Table 3), rapid self-emulsification, high transmittance, and absence of visible precipitation. The drug content of F2 was approximately 98% (Table 7), indicating efficient incorporation of Telmisartan into the formulation. The self-emulsification time of 1.31 min demonstrated rapid formation of the aqueous dispersion. The high transmittance value of 98.50% (Table 5), further indicated formation of a relatively clear dispersion. The reported cloud point of approximately

52°C was higher than physiological temperature, suggesting that the non-ionic surfactant-based formulation maintained acceptable clarity under physiological thermal conditions. The optimized formulation showed a droplet diameter of approximately 28.36 nm following dilution. Formation of such small droplets increases the effective interfacial area between the formulation and aqueous phase and can facilitate drug dissolution. Most importantly, the dissolution study demonstrated a clear improvement in the release of Telmisartan from F2 compared with the marketed formulation. The optimized SMEDDS released 94.38% of Telmisartan at 120 min compared with 78.49% from the marketed product. This finding supports the original objective of using a SMEDDS approach to enhance the dissolution performance of poorly water-soluble Telmisartan. The thermodynamic stability experiments further supported the physical robustness of the developed formulations during the investigated stress conditions. FTIR analysis did not reveal evidence of major incompatibility between Telmisartan and the selected formulation components. It should be noted that the present study primarily demonstrates enhancement of solubilization and *in vitro* dissolution. Improved dissolution should not automatically be interpreted as demonstrated improvement in oral bioavailability. Pharmacokinetic or *in vivo* bioavailability studies would be necessary to establish such an effect.

CONCLUSION

A Telmisartan-loaded SMEDDS was successfully developed using oleic acid as oil, Tween 80 as surfactant, and PEG 400 as co-surfactant. Among the investigated formulations, F2 containing a 1:1 Tween 80/PEG 400 Smix ratio and an oil-to-Smix ratio of 1:5 demonstrated favorable formulation characteristics. Compared with the marketed formulation, the optimized SMEDDS demonstrated markedly improved *in vitro* dissolution. The findings suggest that SMEDDS is a promising formulation strategy for improving the aqueous solubilization and dissolution performance of Telmisartan. Further work involving validated quantitative analytical methods, comprehensive stability studies, *in vitro* lipolysis, and pharmacokinetic evaluation would be useful to establish the potential of the optimized formulation for enhanced oral bioavailability.

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Source of Support: Nil. **Conflicts of Interest:** None declared.