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Formulation and Evaluation of Liquid and Solid Self-Nanoemulsifying Drug Delivery System (SNEDDS) of Telmisartan for Enhanced Oral Bioavailability

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KEYWORDS

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Abstract

Telmisartan is a Biopharmaceutical Classification System (BCS) class II drug exhibiting poor aqueous solubility and variable oral bioavailability. The present investigation aimed to develop and evaluate liquid and solid self-nanoemulsifying drug delivery systems (SNEDDS) of Telmisartan to enhance its solubility and dissolution profile. Solubility studies were performed to screen suitable oils, surfactants and co-surfactants. Cinnamon oil exhibited maximum drug solubility (25 mg/ml). Pseudo-ternary phase diagrams were constructed to identify nanoemulsion regions. Liquid SNEDDS formulations were prepared and evaluated for droplet size, zeta potential, self-emulsification time and robustness to dilution. Optimized formulations (FT11, FT12 and FT13) showed droplet size range of 181–273 nm with acceptable polydispersity index and zeta potential values. The optimized liquid SNEDDS was converted into solid SNEDDS using adsorbents and compressed into tablets. Micromeritic studies indicated good flow properties. In vitro dissolution studies demonstrated improved drug release compared to conventional marketed formulation, with FT12 showing approximately 1.4-fold enhancement in bioavailability. The study concludes that solid SNEDDS formulation of Telmisartan is a promising strategy for enhancing dissolution and oral bioavailability of poorly soluble drugs.

INTRODUCTION

Poor aqueous solubility is a major limitation in oral drug delivery, as nearly 40% of newly developed drug molecules exhibit low solubility and dissolution rate, resulting in poor oral bioavailability (Desai et al., 2012). Oral administration remains the most preferred route due to patient compliance and convenience; however, dissolution rate-limited absorption remains a critical issue for BCS class II drugs (Pathak and Raghuvanshi, 2015). Telmisartan is an angiotensin II receptor blocker used in hypertension management and belongs to BCS class II with poor aqueous solubility (Robertis et al., 2015). Several approaches such as nanoparticles, lipid-based formulations and self-emulsifying systems have been explored to overcome solubility-related limitations (Shafiq et al., 2007).

Self-Nanoemulsifying Drug Delivery Systems (SNEDDS) are isotropic mixtures of oil, surfactant and co-surfactant that

spontaneously form nanoemulsions upon dilution in gastrointestinal fluids under mild agitation (Shen and Zhong, 2006). These systems enhance dissolution rate, increase interfacial surface area and improve drug absorption (Hiral et al., 2013). Solid SNEDDS offer additional advantages such as improved stability, ease of handling and better patient acceptability compared to liquid systems (Tang et al., 2008).

Several studies have demonstrated improved oral bioavailability of poorly soluble drugs using SNEDDS approach (Wang et al., 2010; Kang et al., 2004). Therefore, the present study was undertaken to develop liquid and solid SNEDDS of Telmisartan and evaluate their physicochemical characteristics and dissolution performance.

MATERIALS AND METHODS

Materials

Telmisartan was obtained as a gifted sample. Cinnamon oil, PEG 400, Pluronic F127, Span 60, microcrystalline cellulose, lactose, magnesium stearate, talc and dicalcium phosphate were procured from approved suppliers.

Preformulation Studies

Melting point was determined by capillary method. Solubility studies were performed in various solvents. λmax was determined by scanning drug solution (200–400 nm) using UV spectrophotometer and was found at 296 nm. Calibration curve was prepared in methanol (1–10 µg/ml), showing regression coefficient (r^2) of 0.991.

Screening of Excipients

Solubility of Telmisartan in various oils, surfactants and co-surfactants was determined by vial shake method. Cinnamon oil showed highest solubility.

Preparation of SNEDDS

Drug was mixed with selected oil, surfactant and co-surfactant and sonicated at 40°C for 15 minutes. Formulations FT1–FT13 were prepared in varying ratios.

Evaluation of Liquid SNEDDS

- Visual assessment
- Self-emulsification time
- Droplet size and zeta potential (Malvern Zetasizer)
- Robustness to dilution
- Drug content

Conversion to Solid SNEDDS

Optimized liquid SNEDDS was adsorbed onto Avicel PH 101 to obtain free flowing powder and compressed into tablets using 13 mm punch.

Micromeritic Evaluation

Bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose were determined.

In Vitro Dissolution Study

Dissolution studies were performed using USP apparatus II at 37±0.5°C and samples analyzed spectrophotometrically at 296 nm.

RESULTS & DISCUSSION

FT/IR data of Telmisartan

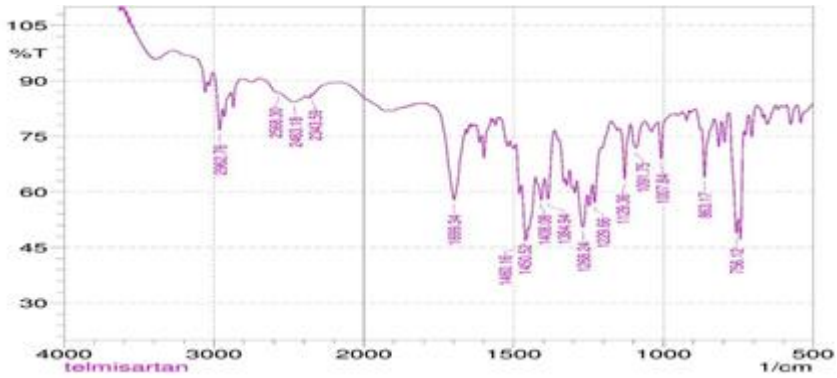

Figure 1: FT-IR data of Telmisartan

Particle size of FT11

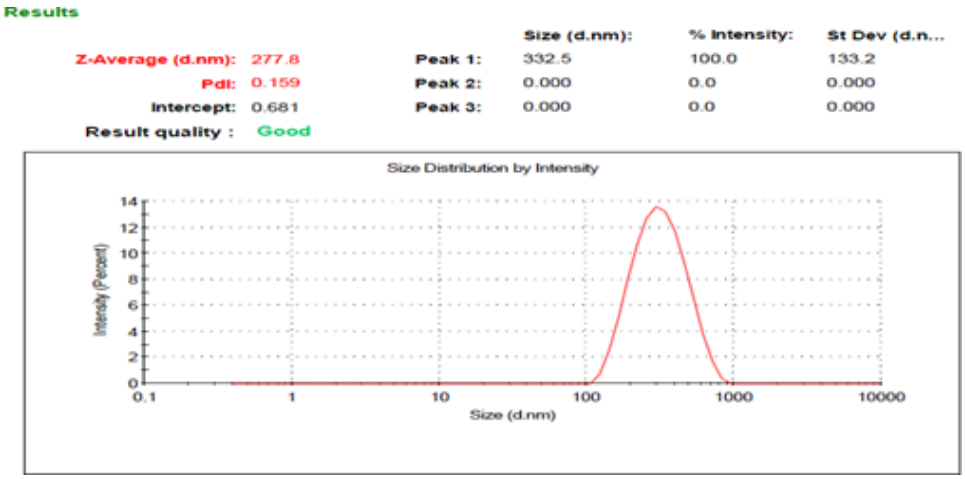

Figure 2: particle size of FT11

Particle size of FT12:

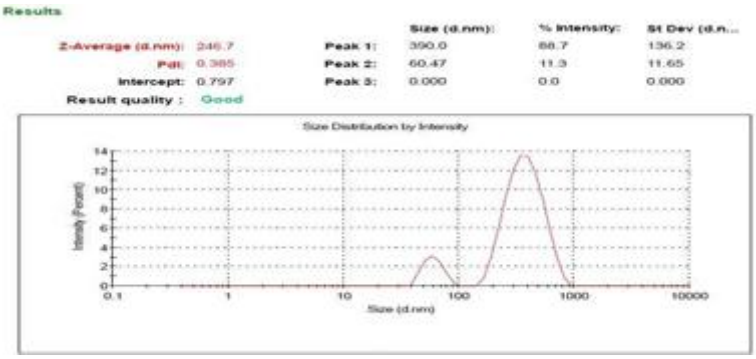

Figure 3: particle size of FT 12

Particle size of FT13:

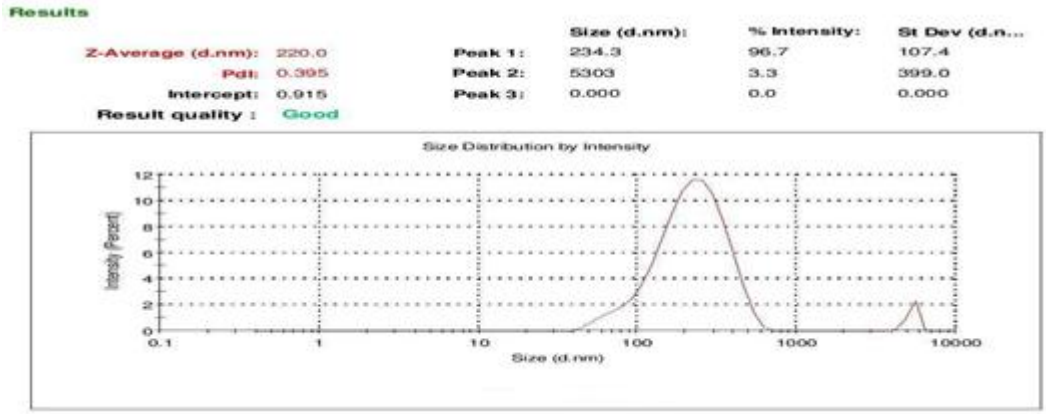

Figure 4: Particle size of FT13

MORPHOLIGICAL STUDIES
SCANNING ELECTRON MICROSCOPY

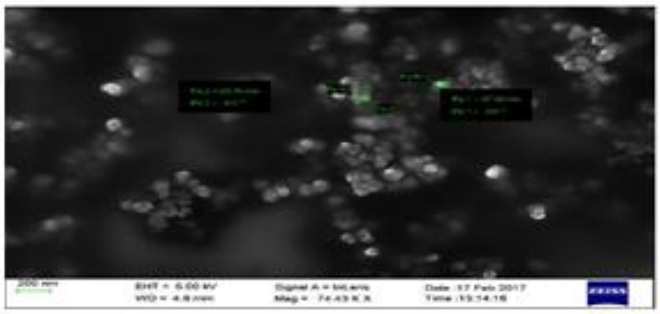

Figure 5: SEM image of FT11

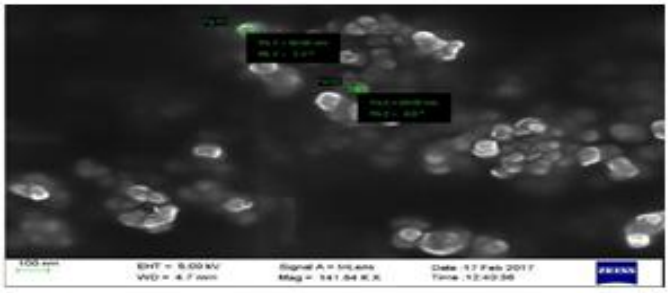

Figure 6: SEM image of FT12

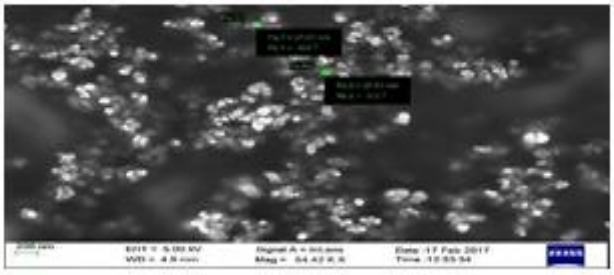

Figure 7: SEM image of FT13

Dissolution study

Dissolution data of FT11 Telmisartan SNE tablet

Table 1: Dissolution data of FT11 telmisartan SNE tablet

Time (minutes)	Absorbance (nm)	Concentration (µg/ml)	Amount of drug release (mg)	Percentage of drug release (%)
5	0.66	0.5	4.5	22.5
10	0.79	0.6	5.4	27
15	0.134	1	9	45
30	0.162	1.2	10.8	54
45	0.182	1.4	12.6	73

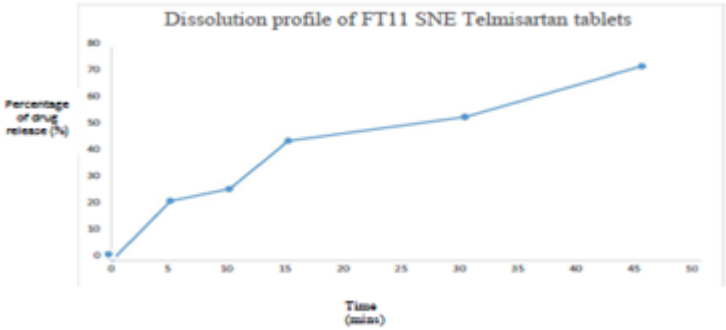

Figure 8: Dissolution profile of FT11 SNE Telmisartan tablet

Dissolution data of FT12 Telmisartan SNE tablet

Table 2: Dissolution data of FT12 Telmisartan SNE tablets

Time (minutes)	Absorbance (nm)	Concentration (µg/ml)	Amount of drug release (mg)	Percentage of drug release (%)
5	0.93	0.7	6.3	31.5
10	0.107	0.9	8.1	40.5
15	0.159	1.2	10.8	54
30	0.184	1.4	12.6	63
45	0.257	1.6	14.4	76

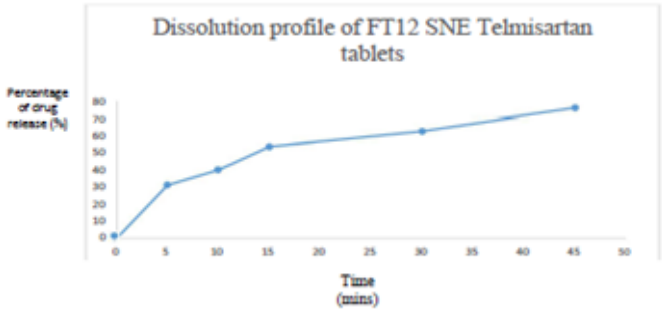

Figure 9: Dissolution study of FT12 SNE Telmisartan tablets

Dissolution data of FT13 Telmisartan SNE tablet

Table 4: Dissolution data of FT13 Telmisartan SNE tablet

Time (minutes)	Absorbance (nm)	Concentration (µg/ml)	Amount of drug release(mg)	Percentage of drug release (%)
5	0.070	0.6	5.4	27
10	0.128	1	9	45
15	0.133	1.1	9.9	49.5
30	0.164	1.4	12.6	63
45	0.211	1.6	14.4	72

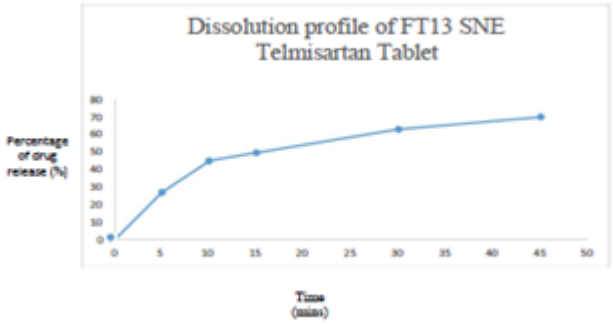

Figure 10: Dissolution profile of FT13 SNE Telmisartan tablets

Dissolution data of Telmisartan tablet- market formulation

Table 5: Dissolution data of Telmisartan tablet- marketed formulation

Time (minutes)	Absorbance (nm)	Concentration (µg/ml)	Amount of drug release(mg)	Percentage of drug release (%)
5	0.022	0.1	0.9	4.5
10	0.049	0.3	2.7	13.5
15	0.098	0.7	6.3	31
30	0.110	0.9	8.1	40.5
45	0.174	1..3	11.7	58.5

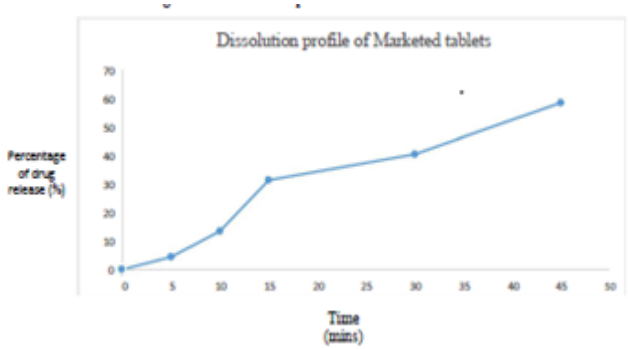

Figure 11: Dissolution profile of Telmisartan marketed tablets

DISCUSSION

Solubility screening revealed cinnamon oil as the most suitable oil phase due to highest drug solubility. Pseudo-ternary phase diagrams confirmed nanoemulsion region with surfactant concentration above 50% and oil below 30%. Optimized formulations (FT11–FT13) exhibited droplet size between 181–273 nm with acceptable PDI and negative zeta potential indicating good stability. Self-emulsification time ranged between 77–94 seconds indicating rapid emulsification.

Conversion to solid SNEDDS improved handling and stability. Micromeritic properties showed Carr's index below 15% and Hausner's ratio around 1.1 indicating good flowability.

Dissolution studies demonstrated significant improvement in drug release compared to conventional formulation. FT12 exhibited approximately 1.4-fold enhancement in bioavailability. These findings confirm that SNEDDS enhances dissolution by reducing droplet size, increasing surface area and maintaining drug in solubilized state.

CONCLUSION

Liquid and solid SNEDDS of Telmisartan were successfully formulated and evaluated. Optimized formulation demonstrated nano-sized droplets, good stability and rapid self-emulsification. Solid SNEDDS tablets showed improved micromeritic properties and enhanced dissolution profile compared to marketed formulation. Thus, SNEDDS represents a promising approach for improving oral bioavailability of poorly water-soluble drugs such as Telmisartan.

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CONFLICT OF INTERESTS

The authors declare no conflict-of-interest

ETHICS APPROVAL

Not applicable

FUNDING

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AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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