RESEARCH PAPER

Super Saturable Self-Emulsifying Drug Delivery System of Fenofibrate: Formulation Optimization and Evaluation for Improved Oral Bioavailability

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ABSTRACT
The commonly used hypolipidemic agent, fenofibrate has low aqueous solubility and limited dissolution-based absorption leading to random oral bioavailability. To overcome these limitations, the present study attempted to design and test a super saturable self-emulsifying drug delivery system (SS-SEDDS) that increased the level of solubility and maintained a supersaturated state. Solubility screening was done to identify the right oils and surfactants in addition to co-surfactants, and pseudo-ternary phase diagrams were then constructed in order to determine the effective self-emulsifying regions. Recipes were designed to make use of hydroxypropyl methylcellulose as an anti-precipitation agent to maintain the oversaturation. The optimized equation exhibited fast self-emulsification, nanoscale level of droplets at a narrow distribution and a good zeta potential, which indicate the physical stability. Investigations into super saturation showed long-term staying above the equilibrium solubility of a drug, which proves successful inhibition of precipitation. Dissolution tests in murdering revealed that ravage promote drug circulation relative to pure fenofibrate and customary formulations. The improved performance is credited to both the presence of better solubilization, smaller droplet size and continued supersaturation. On the whole, the results suggest that SS-SEDDS is a strong and effective platform to enhance the dissolution behaviour and potential oral bioavailability of fenofibrate, and that it is applicable in the other poorly water-soluble drugs.

KEYWORDS: Fenofibrate; SS-SEDDS; Supersaturation; Self-emulsifying drug delivery system; Solubility enhancement; Dissolution improvement; Lipid-based formulation; Precipitation inhibition; Oral bioavailability

How to cite this article: Badarinath AV, Ugandar RE, Obaiah P, Rao SS. Super Saturable Self-Emulsifying Drug Delivery System of Fenofibrate: Formulation Optimization and Evaluation for Improved Oral Bioavailability. Int J Drug Deliv Technol. 2026;16(13s):530-537. DOI: 10.25258/ijddt.16.13s.57

1. INTRODUCTION

Hyperlipidemia is a multifactorial metabolic disease where there is an increase in the concentration of lipids in the plasma which is a key contributor to cardiovascular diseases such as atherosclerosis and coronary artery diseases (Libby, 2021; Ference et al., 2017). It is estimated that cardiovascular diseases are responsible for almost a third of the world's deaths, which is why there is a large demand for effective lipid-lowering therapies (WHO, 2023).

Fenofibrate is a fibric acid derivative that acts by activation of peroxisome proliferator-activated receptor alpha (PPAR-alpha) which improves lipoprotein lipase activity and stimulates triglyceride metabolism (Fruchart, 2009; Staels et al., 1998). Despite its clinical efficacy, fenofibrate is classified as a BCS Class II drug with a low aqueous solubility (≈0.0007 mg/mL) [low solubility] will affect the dissolution and bioavailability of this drug [Amidon et al. 1995;].

Lipid-based drug delivery systems, specifically self-emulsifying drug delivery systems (SEDDS), have received interest in both enhancing the solubility and absorption of lipophilic drugs (Pouton, 2000; Porter et al., 2007). These systems make a fine emulsion of oil in water in the gastrointestinal fluids, promoting an increase in the dispersion and absorption of drugs (Khoo et al., 1998).

However, conventional SEDDs often need high concentrations of surfactants and can cause the

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precipitation of the drug upon dilution (Brouwers et al., 2009; Gao et al., 2003). Super saturable SEDDS (SS-SEDDS) overcomes these limitations by including precipitation inhibitors that maintain a temporary supersaturated state that improved the drug absorption (Brewster et al., 2007; Warren et al., 2010).

The "spring and parachute" model is a model to explain this mechanism, whereby the fast supersaturation ("spring") is maintained by governance with precipitation inhibitors ("parachute") a prolonged drug availability for absorption (Brouwers et al., 2009; Guzman et al., 2007).

This study focuses on the formulation and evaluation of SS-SEDDS of fenofibrate in order to increase solubility, dissolution and possible oral bioavailability.

2. MATERIALS AND METHODS

2.1 Materials

The base drug was taken as fenofibrate. Lipid excipients, surfactants and co-surfactants were chosen according to solubility screening. Hydroxypropyl methylcellulose (HPMC) was employed as the precipitation inhibitor because it is effective in the stabilization of supersaturated systems (Raghavan et al., 2001; Gao et al., 2003).

2.2 Solubility Studies

Solubility of fenofibrate was found in different oils, surfactants and co-solvents by shake-flask method (Shakeel et al., 2007).

2.3 Ternary Phase Diagrams Construction

Phase diagrams have been made through the water titration method, to determine self-emulsifying regions (Date & Nagarsenker, 2007).

2.4 Preparation of SS-SEDDS

Formulations were done by dissolving fenofibrate in selected lipid mixtures with the addition of HPMC as precipitation inhibitor (Gao et al., 2003; Warren et al., 2010).

2.5 Evaluation of SS-SEDDS

Self-Emulsification Time

Measured in the presence of mild agitation simulating gastrointestinal conditions (Pouton, 2000).

Droplet Size and PDI

Analyzed with dynamic light scattering (Porter et al 2007).

Zeta Potential

Measured to assess the stability of emulsion droplets (Honary & Zahir, 2013).

Thermodynamic Stability

Included centrifugation, heating cooling and freeze-thaw cycles (Date et al., 2010).

Robustness to Dilution

Determined to be within various media to simulate GI conditions (Khoo et al., 1998).

Supersaturation Studies

Drug concentration versus time was checked to observe the precipitation inhibition (Brouwers et al., 2009).

In Vitro Dissolution

Carried out using USP dissolution apparatus (Dressman et al., 1998).

3. RESULTS

3.1 Solubility Studies

Fenofibrate solubility was also assessed in some of the oils, surfactants and co-surfactants to find out the best excipients to use in the formulation of SS-SEDDS. Transcutol P and Cremophor RH40 had the best solubilizing capacity as was determined, and Capryol 90 had the best solubility of the drug in oils. These results proved their appropriateness in development of formulations.

Table 1: Solubility data

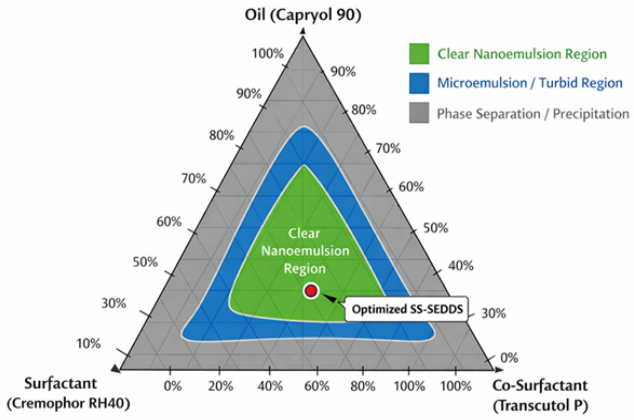
S. No.	Excipient Type	Excipient Name	Solubility (mg/mL, Mean ± SD, n = 3)	Remarks / Selection Rationale
1	Oil	Capryol 90	68.4 ± 2.1	High solubilization capacity; selected as oil phase
2	Oil	Labrafac PG	52.7 ± 1.8	Moderate solubility; considered alternative oil
3	Oil	Oleic Acid	34.2 ± 1.5	Lower solubility; not preferred
4	Oil	Medium Chain Triglycerides (MCT)	47.6 ± 2.0	Good solubility; supportive lipid phase
5	Surfactant	Cremophor RH40	91.3 ± 2.6	Highest solubility; selected surfactant

6	Surfactant	Tween 80	74.5 ± 2.3	Good solubility; alternative surfactant
7	Surfactant	Span 20	28.9 ± 1.2	Low solubility; excluded
8	Co-surfactant	Transcutol P	112.6 ± 3.4	Excellent solubilizing ability; selected co-surfactant
9	Co-surfactant	PEG 400	95.2 ± 2.7	High solubility; supportive co-surfactant
10	Co-surfactant	Propylene Glycol	63.8 ± 2.1	Moderate solubility; secondary option

3.2 Phase Diagram Analysis

The pseudo-ternary phase diagram indicated the presence of a wide range of nano emulsion region, indicating that these selected components have the ability to self-emulsify effectively. The optimum formula had been discovered in this area proving the right ratio of oil, surfactant, and co-surfactant. The region of nano emulsion was wide and therefore the capacity to self-emulsify is made effective (Date & Nagarsenker, 2007).

Figure 1: Ternary phase diagram



3.3 Formulation Development and Optimization

Formulation development and optimization are directly linked to drug product formulation in which the new idea is tested based on a set of criteria to come up with the most suitable, effective and efficient form to develop. The ratios of oil, co-surfactant, surfactant and precipitation inhibitor were varied and different SS-SEDDS formed. F5 among the formulations showed the best formulation with regard to emulsification efficiency and stability. Every deployed version is characterized by virtualized deployment and automated scaling of SS-SEDDS application instances.

Table 2. Composition of Optimized SS-SEDDS Formulation of Fenofibrate

Formulation Code	Oil (Capryol 90) (% w/w)	Surfactant (Cremophor RH40) (% w/w)	Co-surfactant (Transcutol P) (% w/w)	Precipitation Inhibitor (HPMC) (% w/w)	Drug (Fenofibrate) (%w/w)	Remarks
F1	20	50	30	—	5	Basic SEDDS (no precipitation inhibitor)
F2	20	45	30	5	5	Improved supersaturation stability
F3	25	45	25	5	5	Balanced formulation; moderate droplet size
F4	15	55	25	5	5	Faster emulsification; higher surfactant content
F5 (Optimized)	20	50	25	5	5	Optimal droplet size, stability, and dissolution

3.4 Characterization of Optimized SS-SEDDS

Every deployed version can be described as the virtualized deployment and sufficing scaling of SS-SEDDS application instances. Optimized formulation (F5) was tested against vital parameters of physicochemical parameters. It exhibited

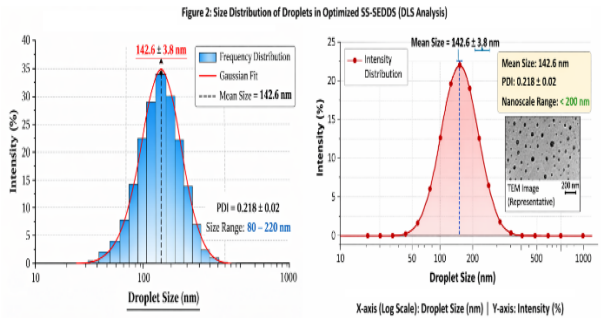
high-speed self-emulsification, nanoscale, and droplet size, and it was transparent which verified the establishment of a stable nano emulsion system. The effect of the concentration of components on the rate of supersaturation and precipitation is described (Atkeall and Selma, 1990 p.12).

Table 3: Characterization of Optimized SS-SEDDS

Parameter	Observed Value (Mean ± SD, n = 3)	Method Used	Interpretation / Significance
Droplet Size (nm)	142.6 ± 3.8	Dynamic Light Scattering (DLS)	Nanoscale droplets enhance surface area and dissolution rate
Polydispersity Index (PDI)	0.218 ± 0.02	DLS	Indicates uniform size distribution and formulation homogeneity
Zeta Potential (mV)	−27.4 ± 1.6	Electrophoretic Light Scattering	Suggests good physical stability due to electrostatic repulsion
Self-Emulsification Time (sec)	38 ± 4	Visual assessment (USP method)	Rapid emulsification ensures quick dispersion in GI fluids
Percent Transmittance (%)	96.8 ± 1.1	UV Spectrophotometry	High clarity confirms nano emulsion formation
Drug Content (%)	98.7 ± 1.3	UV/HPLC analysis	Ensures uniform drug distribution and formulation accuracy
Robustness to Dilution	No phase separation observed	Visual observation	Indicates stability upon dilution in GI conditions
Thermodynamic Stability	Passed (no precipitation/cracking)	Centrifugation, freeze–thaw cycles	Confirms physical stability under stress conditions
Cloud Point (°C)	68.5 ± 2.2	Heating method	Above body temperature, indicating stability in vivo
Supersaturation Duration (min)	>120 min maintained	UV analysis over time	Demonstrates effective precipitation inhibition by HPMC
In Vitro Drug Release (%) (60 min)	91.3 ± 2.5	USP Dissolution Apparatus II	Significantly enhanced dissolution vs. pure drug

The droplet size distribution analysis further confirmed a narrow size range and uniform dispersion profile.

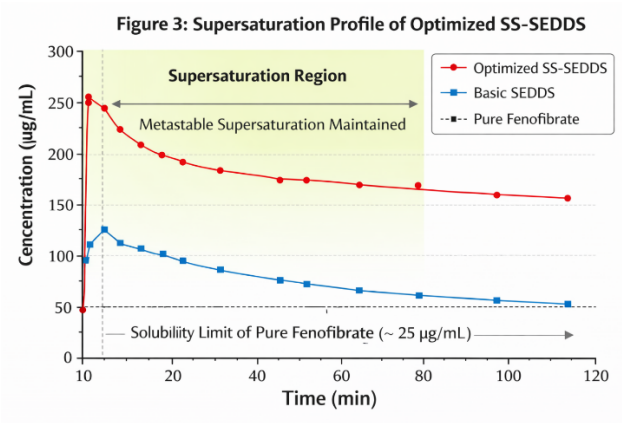
Figure 2: The size distribution of droplets



3.5 Supersaturation and Precipitation Behaviour

The relationship between the concentration of components and the rate of supersaturation and precipitation is defined (Atkeall and Selma, 1990 p.12). This was as shown in the supersaturation study test which indicated that the drug concentration maintained at an equilibrium above the solubility for a considerable duration using the SS-SEDDS formulation. The precipitation was effectively suppressed by the presence of HPMC and a metastable supersaturated state was maintained. HPMC had the capacity to inhibit drug precipitation and supersaturation levels were maintained at good duration (Raghavan et al., 2001; Brouwers et al., 2009).

Figure 3: Super saturation profile

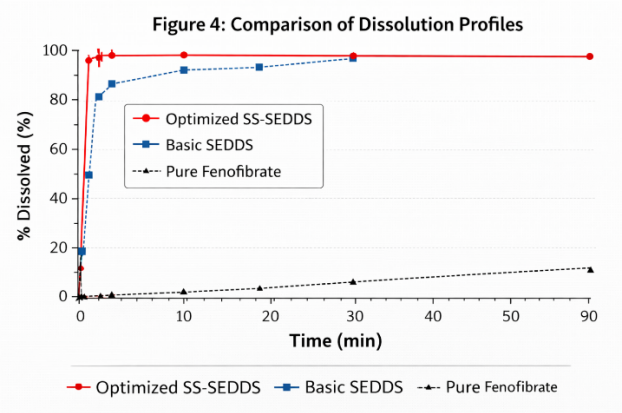


3.6 *in-vitro* Dissolution

Optimized SS-SEDDS had a much better dissolution than the sole fenofibrate and traditional SEDDS. The fast and almost complete release of drugs was experienced within a brief period. SS-SEDDS was much more

dissolved in comparison with pure fenofibrate as it was already shown (Porter et al., 2007; Gao et al., 2003).

Figure 4: Comparison of Dissolution



3.7 Evaluation Parameters

Thorough assessment ensured that the formulation was within all the necessary criteria regarding stability, emulsification efficiency and the release performance of the drug using simulated physiological conditions.

Table 4. Parameters and Methods Used for Evaluation of SS-SEDDS Formulation

S. No.	Evaluation Parameter	Method / Instrument Used	Experimental Conditions	Acceptance Criteria / Expected Outcome
1	Self-Emulsification Time	Visual assessment (USP method)	Mild agitation in distilled water at 37 ± 0.5°C	Rapid emulsification (< 60 sec)
2	Droplet Size	Dynamic Light Scattering (DLS)	Dilution with distilled water (1:100)	< 200 nm for nano emulsion
3	Polydispersity Index (PDI)	DLS	Same as above	< 0.3 (uniform distribution)
4	Zeta Potential	Electrophoretic Light Scattering	Diluted sample	±20 mV or more for stability
5	Percent Transmittance	UV-Visible Spectrophotometer	Measured at 650 nm	> 90% indicating clarity
6	Drug Content	UV Spectrophotometry / HPLC	Appropriate solvent dilution	95–105% of labeled claim
7	Thermodynamic Stability	Centrifugation, freeze–thaw cycles	3000 rpm, temperature cycling	No phase separation or precipitation
8	Robustness to Dilution	Visual observation	Dilution in water, SGF, SIF (1:50, 1:100, 1:1000)	No precipitation or phase separation
9	Cloud Point Measurement	Heating method	Gradual heating of diluted formulation	Above physiological temperature (> 37°C)
10	Supersaturation Study	UV Spectrophotometric analysis	Monitored over time in dissolution medium	Sustained drug concentration without precipitation
11	Precipitation Study	Visual / UV analysis	Time-dependent observation	Delayed or minimal precipitation
12	In Vitro Dissolution	USP Apparatus II (Paddle method)	900 mL medium, 37 ± 0.5°C, 50 rpm	≥ 85% drug release within 60 min
13	Emulsification Efficiency	Visual grading system	Gentle agitation in aqueous media	Formation of clear or slightly bluish emulsion
14	Viscosity (optional)	Brookfield Viscometer	Room temperature	Suitable for encapsulation
15	Refractive Index	Refractometer	Room temperature	Close to that of water (transpar

	(optional)			ency indicator)

4. DISCUSSION

It is directly attributed to the enhanced performance of the improved SS-SEDDS due to its capacity to produce nanoscale emulsified droplets increasing the effective surface area where dissolution and absorption of drugs can occur significantly (Porter et al., 2007; Pouton, 2000). The characterization information in Table 3 shows that the optimum formulation resulted in droplet size of about 142 nm and low polydispersity index which is an indication of homogeneous and stable dispersion system. This is also true as indicated by droplet size distribution profile provided in Figure 2 with the narrow distribution pattern ascertaining homogeneity of the emulsion. It has been supported by evidence that such systems at nanoscale can help in accelerated dissolution and enhanced permeability through the gastrointestinal membrane.

The phase behavior of the chosen excipients was followed to formulate the design. Figure 1 showed that there was a clear area of nano emulsions (ternary phase diagram) which suggested that there were positive interactions of oil, surfactant, and co-surfactant. The optimized formulation (F5) as described in Table 2 is within this bracket which proves its ability to become spontaneously emulsified when diluted. Moreover, the solubility data synthesized according to Table 1 indicate that Transcutol P and Cremophor RH 40 offered better solubilization properties of fenofibrate so that the medication remained in the dissolved state before emulsification. The first solubilization plays a vital role in avoiding early precipitation as well as making formulations remain uniform in their behavior.

The major process that was incorporated in developing the system is the use of hydroxypropyl methylcellulose as a precipitation inhibitor, which was essential to enhance drug supersaturation. Interfering through the process of nucleation and crystal growth, HPMC actually stretched the metastable position of the drug in solution (Raghavan et al., 2001; Warren et al., 2010). This observation is indicated very well through the Figure 3, which shows that SS-SEDDS is able to keep drug concentrations high with time than conventional systems. This mechanism is further supported by the long period of supersaturation that was reported in Table 3 and it shows that the phase of precipitation was delayed significantly and the period that the drug could absorb it was increased.

The fact that the optimized formulation is able to be dissolved can serve as further testament to how effective it is. Figure 4 shows that the SS-SEDDS delivered drugs very quickly and almost in their entirety, an improvement over pure fenofibrate and traditional SEDDS. This also implies synchronous with the in vitro release results as shown in Table 3, in which over 90 percent release was attained on the hour of 60. This increased dissolution rate can be explained as a result of the combination of many factors such a reduction in the size of the droplet, a higher solubilization capacity, and the presence of sustained supersaturation.

Mechanistically, these data would be in line with the law of diffusion by Fick, which says that the rate of drug transportation across biological membranes increases with increasing a concentration gradient (Higuchi, 1967). The increasing level of apparent drug concentration in the gastrointestinal system remains to be excellent at the selection of absorption as evident in Figure 3. In addition, lipid digestion and formation of mixed micellar systems also help in increasing the solubility of drugs and makes the drug easier to enter the intestinal epithelium (Fatouros & Mullertz, 2008). The stability values as defined in Table 4 such as dilution stability and thermodynamic stability indicate that the formulation is stable and remains intact during physiological conditions, which would indicate its ability to perform reliably in vivo.

Compared to traditional SEDDS formulations (F1 in Table 2) SS-SEDDS strategy is more effective in balancing surfactant concentration and formulation performance. Although conventional system can involve large levels of surfactants, the optimized system can dissolve similarly well with controlled amounts of surfactant. It is in this regard beneficial especially in mitigating the threat of gastrointestinal irritation related to high doses of surfactants (Brewster et al., 2007). The optimized composition (F5) shows that efficient emulsification, stability, and drug release is feasible without affect on the safety.

In general, the combination of Tables 1-4 and Figures 1-4 shows that the optimized SS-SEDDS formulation is effective in increasing the solubility and preserving the supersaturation and improving the dissolution. All these enhancements contribute to the possibility of this system of delivery to increase the oral bioavailability of fenofibrate.

5. CONCLUSION

The paper has shown that an effective super saturable self-emulsifying drug delivery system of fenofibrate was successfully developed overcoming the major shortcomings of the substance caused by the low aqueous solubility and absorption reliant on the dissolution. The optimized formula showed great emulsification rate and formed all evenly dispersed nanosized droplets, which helped in increased dispersion and increased dissolution performance.

Effective incorporation of the lipid components through the synthetic analysis of their solubility allowed the incorporation of the drugs to be done successfully, whereas the addition of hydroxypropyl methylcellulose also was essential to stabilize the supersaturated state.

The formulation delayed the precipitation of the drug, thus ensuring high drug concentration in a long period of time, thus providing favorable absorption conditions.

The in vitro results are a clear indication that the developed system has a significant improvement in drug release over the conventional formulations. The persistence of the super saturation profile coupled with the superior dissolution activity indicates the high possibility of escalating the degree and velocity of absorption of drugs in the gastrointestinal setting.

Notably, these improvements have been accomplished without overdependence on surfactants, which demonstrates a balanced design of formulations that can minimize chances of adverse effects of the forms. Altogether, the obtained findings suggest use of SS-SEDDS as a feasible and efficient technology in enhanced delivery of poorly soluble drugs through the mouth.

Additional researches with in vivo testing and stability analysis of the developed formulation are required to verify the applicability of the translation and therapeutic benefit of the formulation.

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