Journal of Pharmaceutical Research and Integrated Medical Sciences (JPRIMS)
ISSN: 3049-1681 | Vol. 03, Issue-03, March-2026 | pp.-117-124

ORIGINALARTICLE https://aktpublication.com/index.php/jprims/index

Advances in Self-Emulsifying Drug Delivery Systems: Supersaturated, Solid, Hybrid, 3D Printed and Computationally Optimized Approaches

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Abstract:
Recent developments, including supersaturation SED Interprovincial Developmental Special Education Council (Su-SEDDS), solid SEDS (S-SEDDS), hybrid systems, 3D printing technologies, and computational modelling, have greatly improved their performance. Su-SEDDS enhance the rate of drug absorption by exerting supersaturation, and S-SEDDS improve stability and patient compliance. Hybrid systems and 3D Printing for targeted and Personalized Drug Delivery. Computational modelling is further used to optimise formulation design and to help predict in vivo behaviour. In the present review, all these innovations and their impact on today's drug delivery are fully discussed.

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Keywords: SEDDS; Super saturable SEDDs; Solid SEDDs; 3D Printing; Computational Modeling; Bioavailability Enhancement

Received: Jan. 14, 2026 **Revised: Jan. 22, 2026** **Accepted: Feb. 27, 2026** **Published: March. 25, 2026**

DOI: https://doi.org/10.64063/3049-1681.vol.3.issue3.8

https://aktpublication.com/index.php/jprims/issue/archive

I. INTRODUCTION

A considerable portion of newly developed drug molecules experience poor aqueous solubility and thus low oral bioavailability[1,2] and inconsistent therapeutic scenarios[11]. Lipid-based formulations and especially self-emulsifying drug delivery systems (SEDDS) have attracted significant interest for their potential for increased solubilization and absorption of drugs[1,11,12]. SEDDS are isotropic mixtures of oil(s), surfactant(s), and co-solvent(s) which form fine

emulsions in the gastrointestinal tract to enhance dissolution and drug permeability[13]. Despite their benefits, conventional SEDDs can be associated with precipitation of the drug when diluted and stability[14]. In order to counter these issues, various new approaches have been developed, including super saturable SEDDS (Su-SEDDS), solid SEDDS (S-SEDDS), hybrid delivery systems, 3D printing integration and computational modelling [15-17]. These innovations aim to improve drug loading, stability and targeted delivery and provide new opportunities for pharmaceutical formulation science[3,4].

II. Materials and Methods:

A considerable portion of newly developed drug molecules exhibit poor aqueous solubility, resulting in low oral bioavailability and inconsistent therapeutic outcomes11. Lipid-based formulations and especially self-emulsifying drug delivery systems (SEDDS) have attracted significant interest for their potential for increased solubilization and absorption of drugs[12]. SEDDS are isotropic mixtures of oil(s), surfactant(s), and co-solvent(s) which form fine emulsions in the gastrointestinal tract to enhance dissolution and drug permeability[13]. Despite their benefits, conventional SEDDs can be associated with precipitation of the drug when diluted and stability[14]. In order to counter these issues, various new approaches have been developed including super saturable SEDDS (Su-SEDDS), solid SEDDS (S-SEDDS), hybrid delivery systems, 3D printing integration and computational modeling[15-17]. These innovations aim to improve drug loading, stability, and targeted delivery, and to provide new opportunities for pharmaceutical formulation science.

III. Results:

Table 1. Comparison of advanced SEDDS approaches

Approach	Key Feature	Advantages	Limitations
Su-SEDDS	Supersaturation maintenance	Enhanced absorption	Precipitation risk
S-SEDDS	Solid dosage conversion	Stability, compliance	Processing complexity
Hybrid Systems	Multi-technology integration	Targeted delivery	Cost and scale-up
3D Printed SEDDS	Personalized dosing	Precision medicine	Regulatory barriers
Computational Modeling	Predictive optimization	Reduced development time	Technical expertise

Table 2. Common excipients used in advanced SEDDS

Category	Examples	Function
Oils	Caprylic/capric triglycerides	Drug solubilization
Surfactants	Tween 80, Cremophor EL	Emulsification
Polymers	HPMC, PVP	Precipitation inhibition

Solid carriers	Neusilin, Aerosil	Solidification

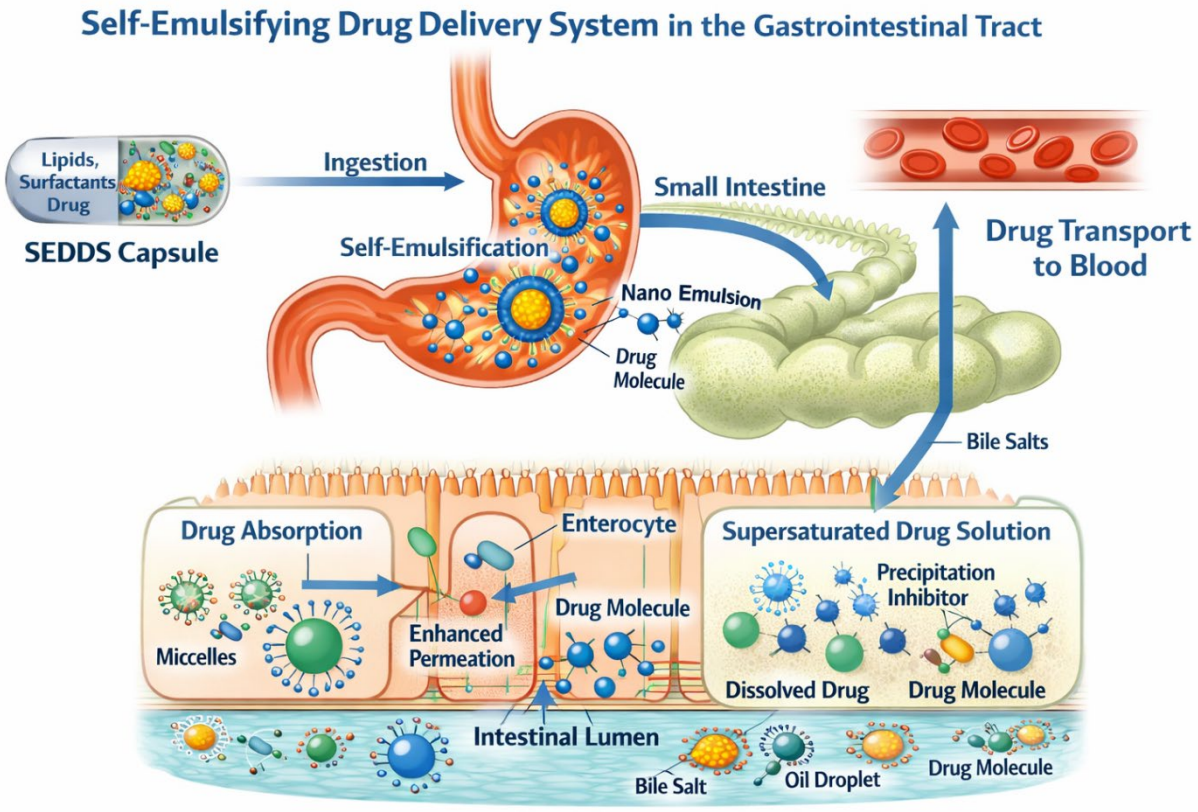
IV. Discussion:

The advancement of self-emulsifying drug delivery systems (SEDDS) has significantly improved the oral delivery of poorly water-soluble drugs by enhancing solubilization, dissolution, and bioavailability[1,12]. The comparative features of advanced approaches of SEDS are summarized in Table 1 while commonly used excipients and their role in functioning are shown in Table 2.

Super saturable SEDDS (Su-SEDDS)

Super saturable SEDDS have been developed specifically to create and maintain a metastable supersaturated state in the gastrointestinal tract, and thus increasing the thermodynamic activity of the drug and favouring absorption[5,18]. As depicted in Figure 1, the formulation forms an emulsion upon contact with gastric fluids alone producing fine droplets, which promote solubilization and permeation of drugs across the intestinal epithelium[13].

Figure 1: Schematic representation of self-emulsifying drug delivery system mechanism in gastrointestinal tract



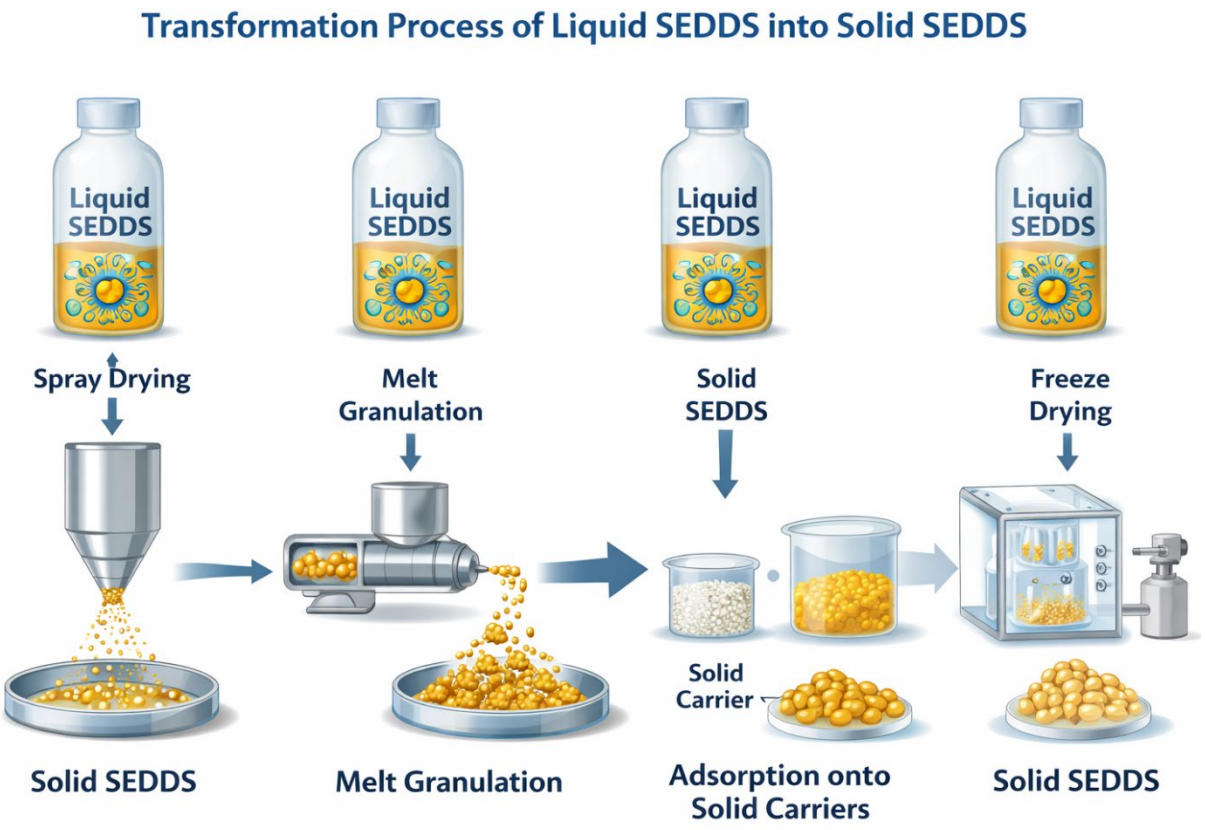
The addition of precipitation inhibitors such as hydroxypropyl methylcellulose and polyvinylpyrrolidone (Table 2) is important to keep supersaturation high and to prevent rapid drug crystallization[19]. Compared with conventional systems (Table 1), Su-SEDDS have better

absorption efficiency; however, thermodynamic instability as well as the tendency for drug precipitation are the main formulation issues of these systems[14].

Solid Self-Emulsifying Drug Delivery Systems (S-SEDDS)

The translation of liquid SEDDs to create solid dosage forms has become a practical approach for improving stability, portability and compliance by and for patients[6,20]. As shown in Figure 2, methods related to spray drying, melt granulation and adsorption on solid carriers allow a liquid formulation to be converted into a powder, granule or tablet form.

Figure 2: Transformation process of liquid SEDDS into solid SEDDS



As presented in Table 1, there are advantages of S-SEDDS, including an improved handling and lower leakage, but the complexity of the manufacturing process and possible changes in emulsification efficiency have to be carefully controlled[20].

Hybrid Systems

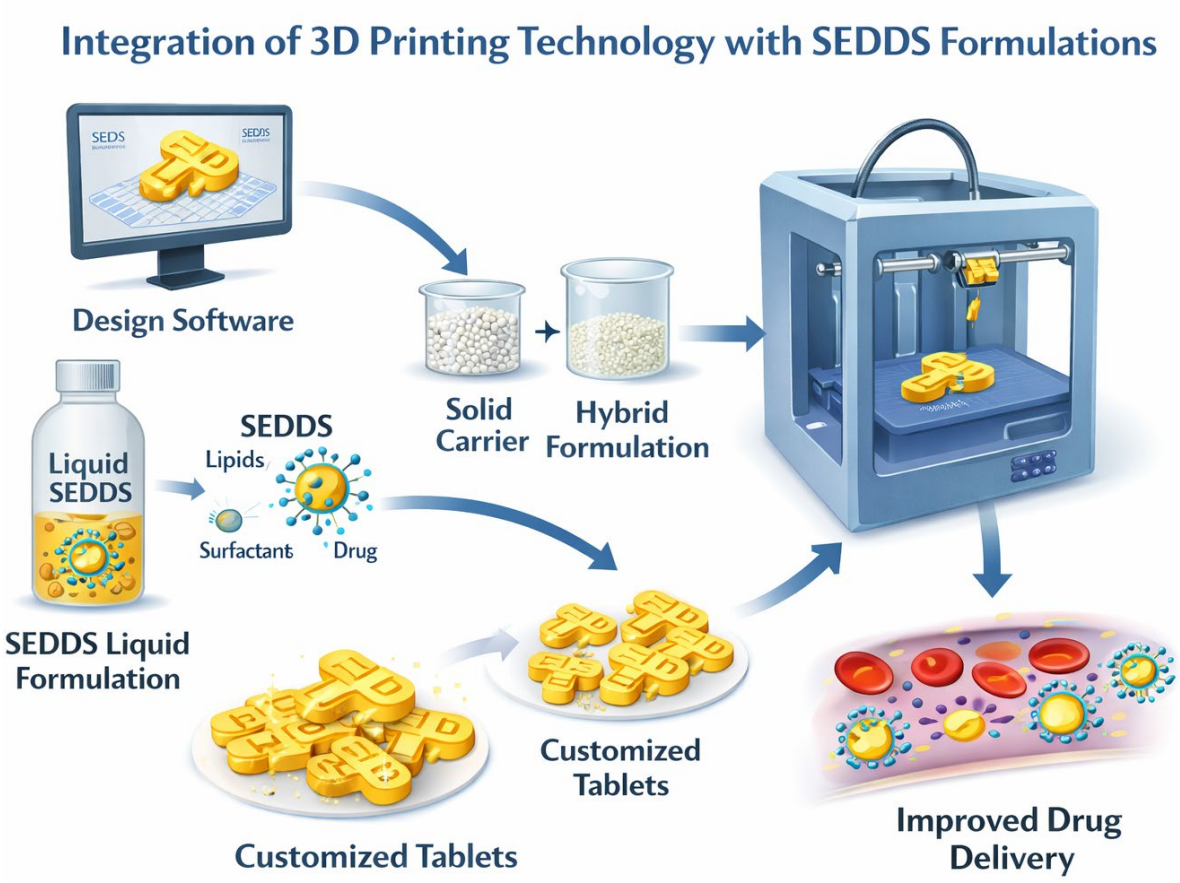
Hybrid SEDS is a combination of lipid-based SEDs with nanotechnology and polymer-based carriers to improve the improvement of drug delivery[22]. These systems overcome some of the shortcomings highlighted in Table 1, especially as they enable better targeting of drugs, reducing systemic toxicity and allowing controlled drug release profiles[23]. The combination of the functional excipients (Table 2) also increases the drug loading capacity and drug stability. Hybrid systems have been shown to have better pharmacokinetic characteristics and therapeutic

effects than conventional SEDDS16. Nevertheless, challenges in the areas of scalability, reproducibility, and cost-effectiveness are still major obstacles for industrial application[22].

3D Printing in SEDDS

The use of 3D printing technology for Formulation of SEDS marks a revolutionary step in personalized medicine[24] as shown in Figure 3.

Figure 3: Integration of 3D printing technology with SEDDS formulations



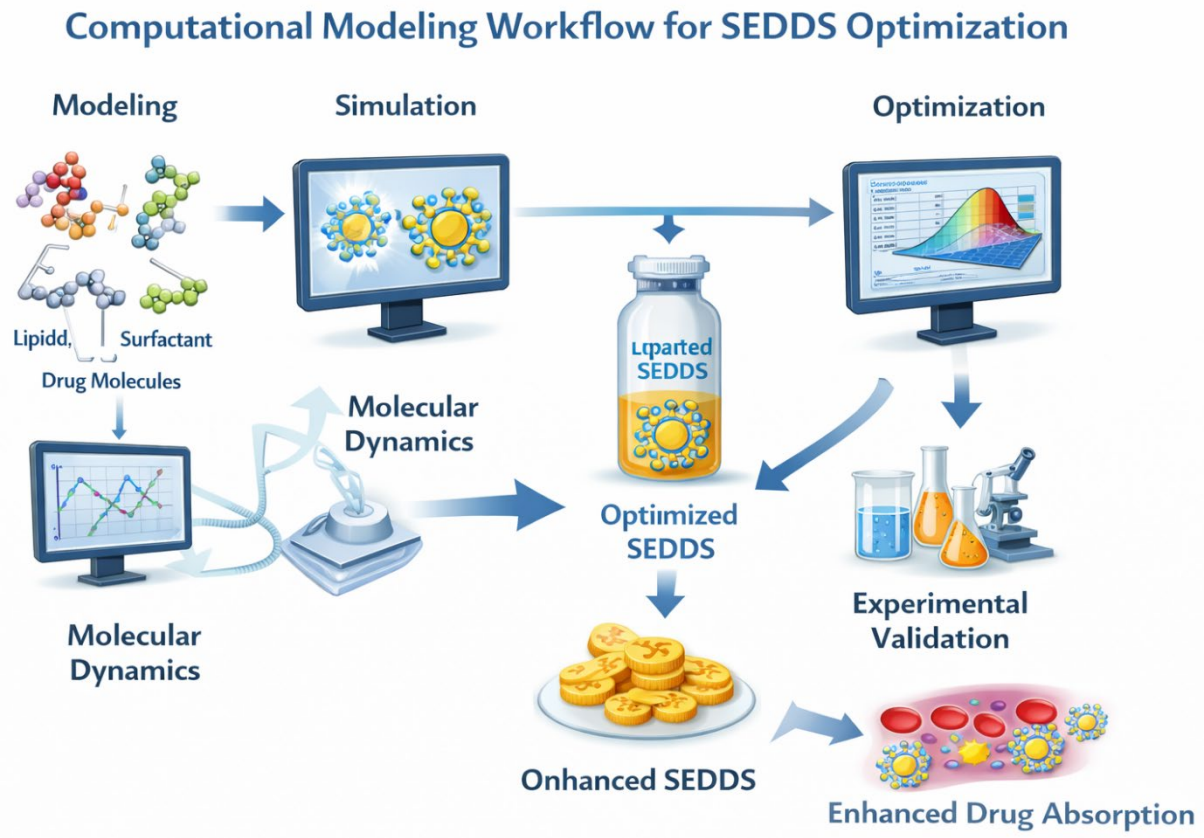
SEDDS can be processed into printable intermediates and can be manufactured into tailored dosage forms with specified control over the drug dose, drug geometry, and drug release kinetics[25]. This approach overcomes a number of restrictions of traditional systems (Table 1), and in particular allows for patient-specific therapy and flexible dosing regimens[7,8]. The choice of compatible excipients (Table 2) is key to guarantee printability and stability of formulations. Despite the potential, regulatory challenges and issues related to standardisation remain major obstacles to a large scale implementation[24].

Computational Modeling in SEDDS

Computational modeling has proven to be a potent way to rationally design and optimize SEDDs formulation[26]. The integration of the drug physicochemical properties, the choice of excipient (Table 2), and predictive simulations for the design of optimal systems are highlighted in the workflow as shown in Figure 4. These tools cover some of the major formulation challenges

listed in Table 1, such as the prediction of solubility, drop size and stability. Advanced techniques like molecular dynamics simulations and machine learning algorithms allow to gain more knowledge about molecular interactions[27] and formulation behaviour[9,10]. However, the credibility of these models depends on good experimental validation and good quality of input data[26].

Figure 4: computational modeling workflow for SEDDS optimization



Overall Perspective

Collectively, the available advanced SEDDS strategies such as supersaturation, solidification, hybridization, 3D printing and computational modeling provide a comprehensive framework to overcome the shortcomings of conventional lipid-based formulations[15,17]. The interplay between the components involved in the formulation (Table 2), system performance (Table 1) and technology (Figures 1-4) illustrate the multi-disciplinary character of current drug delivery research. Future efforts should then focus on improving the scalability, acceptance by the regulatory bodies, and in vivo predictability to enable the successful translation of these highly developed systems into the clinical setting[10].

V. Conflict of Interests

The authors declare no conflict of interest.

VI. Acknowledgements:

The authors acknowledge institutional support for conducting this review.

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