INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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**Review Article**

# Solid SMEDDS: An Emerging Lipid-Based Drug Delivery Approach for Improving Solubility and Oral Bioavailability of Poorly Soluble Drugs

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ARTICLE INFO

Published: 05 Aug 2026

Keywords:
Solid Self-Microemulsifying Drug Delivery Systems (S-SMEDDS), Lipid-Based Drug Delivery, Oral Bioavailability Enhancement, Self-Emulsification, Poorly Water-Soluble Drugs

DOI:
10.5281/zenodo.21802255

## ABSTRACT

Solid self-microemulsifying drug delivery systems (S-SMEDDS) represent a transformative advancement in lipid-based drug delivery, designed to overcome the inherent limitations of liquid formulations while significantly enhancing the oral delivery of poorly water-soluble therapeutic agents. This report details the transition from liquid SMEDDS—isotropic mixtures of oils, surfactants, and co-surfactants—to robust solid-state dosage forms. The significance of S-SMEDDS lies in their ability to spontaneously form fine oil-in-water microemulsions upon contact with gastrointestinal fluids, facilitating drug absorption via specialized pathways such as the lymphatic system and effectively bypassing hepatic first-pass metabolism. By utilizing a diverse array of solidification techniques—including adsorption onto solid carriers, spray drying, electrospraying, extrusion-spheronization, and spherical crystallization—these systems provide enhanced chemical stability, improved ease of handling, and greater versatility in dosage form design, such as tablets, pellets, and chewable formulations. This comprehensive review encompasses the strategic selection of formulation components, the underlying mechanisms of self-emulsification and absorption, various solidification methodologies, rigorous characterisation parameters, and the broad applications of S-SMEDDS in modern pharmaceutical science, while also addressing current challenges and future trends like 3D printing and supersaturable systems.

## INTRODUCTION

The pharmaceutical industry faces a persistent challenge in the oral delivery of new chemical entities, as a vast majority of these molecules exhibit poor aqueous solubility. Lipid-based drug delivery systems (LBDDS) have emerged as a critical strategy to enhance the oral bioavailability of these poorly water-soluble drugs, which are typically categorized under BCS Classes II and IV (1,2). LBDDS leverage the natural physiological processes of lipid digestion and

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**Relevant conflicts of interest/financial disclosures**: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

absorption to maintain the drug in a solubilized state throughout the gastrointestinal (GI) transit, thereby overcoming the critical rate-limiting step of dissolution.

Among the various types of LBDDS, self-microemulsifying drug delivery systems (SMEDDS) are particularly prominent. SMEDDS are defined as isotropic mixtures of oils, surfactants, and co-surfactants that, upon mild agitation in an aqueous environment, spontaneously form stable oil-in-water (o/w) microemulsions with droplet sizes typically below 200 nm (1) .These systems offer several advantages, including the ability to present the drug in a fine dispersion that maximizes surface area and facilitates rapid absorption.

However, traditional liquid SMEDDS formulations possess inherent drawbacks that can limit their commercial and clinical utility. Primary among these is chemical instability, as the lipid and surfactant components may be prone to oxidation or hydrolysis over time. Furthermore, liquid SMEDDS are typically encapsulated in soft gelatin capsules, which can lead to issues such as drug precipitation, leakage, or capsule shell embrittlement due to interactions between the formulation and the shell material (1). The development of solid SMEDDS (S-SMEDDS) has been driven by the need to address these limitations. S-SMEDDS involve the incorporation of liquid lipid-based systems into solid matrices or carriers, resulting in free-flowing powders, granules, or pellets. This transition combines the solubilization benefits of lipid-based delivery with the superior stability, portability, and manufacturing ease associated with solid dosage forms (1,3).

## 2. Principle and Mechanism of SMEDDS Formulation

### 2.1 Spontaneous Self-Emulsification

The fundamental principle governing SMEDDS is the spontaneous formation of a microemulsion when the formulation comes into contact with the aqueous phase of the gastrointestinal tract (1). Unlike conventional emulsions that require high-energy input (such as homogenization), SMEDDS are thermodynamically stable systems where the free energy of formation is very low or negative. This spontaneous process is achieved through a precise balance of excipients that reduces the interfacial tension between the oil and water phases to a negligible level.

### 2.2 Mechanisms of Absorption Enhancement

S-SMEDDS enhance drug absorption through several interrelated mechanisms:

- **Nano-dispersion and Increased Surface Area:** Upon reconstitution in the gut, the formulation releases the drug within fine oil droplets. This micro- or nano-sized dispersion significantly increases the effective surface area for drug release and interaction with the intestinal mucosa (4)

- **Solubilization and Maintenance of Supersaturation:** The drug remains solubilized within the lipid core of the droplets. In some advanced "supersaturable" systems (S-SuSMEDDS), polymers are included as precipitation inhibitors to maintain a high concentration of the drug in the GI fluids, preventing it from reverting to its poorly soluble crystalline form (5,6)

- **Bypassing Hepatic First-Pass Metabolism:** One of the most significant advantages of lipid-based delivery is the stimulation of intestinal lymphatic transport. Large lipid droplets and chylomicrons

containing the drug are absorbed into the lymphatic vessels rather than the portal vein. This allows the drug to enter the systemic circulation via the thoracic duct, effectively bypassing the liver and increasing the systemic bioavailability of drugs that are prone to extensive first-pass metabolism (1)

- **Modulation of Membrane Permeability:** Certain surfactants (e.g., polysorbates and polyoxyl castor oils) used in SMEDDS can increase the fluidity of the intestinal cell membranes or inhibit efflux transporters such as P-glycoprotein (P-gp), thereby enhancing the transcellular and paracellular transport of the drug (5,7)

## 3. Selection of Components (Lipids, Surfactants, Co-surfactants)

The design of a successful S-SMEDDS requires the careful selection of components based on their ability to solubilize the drug and facilitate rapid self-emulsification.

### 3.1 Lipids (Oils)

Lipids are the primary solvent for the lipophilic drug and form the internal phase of the microemulsion. They are generally classified by their chain length and degree of esterification.

- **Triglycerides:** Natural oils such as castor oil, sesame oil, and soybean oil are often used (8,9). Synthetic derivatives like ethyl oleate are also common (10)

- **Modified Lipids:** Medium-chain triglycerides and partial glycerides (mono- and di-glycerides) are frequently preferred for their superior emulsifying properties and high solvent capacity. Examples include Labrafil M 1944 CS (11), Capmul MCM (12,13), Peceol (14), and monocaprylin glycerate (15)

### 3.2 Surfactants

Surfactants are critical for reducing interfacial tension and stabilizing the droplets against coalescence. Non-ionic surfactants with a high HLB (Hydrophilic-Lipophilic Balance) are typically chosen for their safety profile and efficiency in forming o/w emulsions

- **Polyoxyl Castor Oils:** Cremophor RH 40 (10,15) and Cremophor EL (12) are widely used due to their excellent emulsifying power and ability to enhance drug permeability.

- **Polysorbates:** Tween 80 (5,1416,17) and Tween 20 (13) are versatile surfactants commonly employed in these systems.

- **Other Surfactants:** Labrasol is often utilized for its ability to produce very small droplets and improve drug solubility (4,11)

### 3.3 Co-surfactants

Co-surfactants are used to refine the surfactant film at the oil-water interface, increasing its flexibility and allowing for the formation of smaller, more stable droplets.

- **Glycols and Ethers:** Transcutol P and Transcutol HP are highly effective co-surfactants frequently paired with lipids and surfactants to optimize microemulsion regions (4,5,10,16)

- **Polyethylene Glycols:** PEG 400 is often used to assist in drug solubilization and emulsion stabilization (12,18)

- **Alternative Co-surfactants:** Examples include tetraglycol (13) and 1,2-propylene glycol (8)

## 4. Formulation of Liquid SMEDDS and Conversion to Solid SMEDDS (S-SMEDDS)

### 4.1 Liquid SMEDDS Development and Optimization

The development of the liquid precursor involves rigorous solubility assessments followed by the construction of pseudo-ternary phase diagrams. These diagrams map the proportions of oil, surfactant, and co-surfactant that result in a transparent, isotropic microemulsion upon dilution. Optimization often utilizes experimental designs, such as central composite design or orthogonal optimization, to identify the formulation with the minimum droplet size and fastest emulsification time (10,14,19)

### 4.2 Solidification Techniques

The conversion of the optimized liquid SMEDDS into a solid form is achieved through several specialized methodologies:

- **Adsorption onto Solid Carriers**: This is the most straightforward technique, involving the addition of liquid SMEDDS to a high-surface-area solid carrier under mixing. The liquid is adsorbed into the pores or onto the surface of the carrier, resulting in a free-flowing powder (1).
- **Carriers**: Porous silica-based materials are the most common, including Neusilin US2 (17), Sylysia 350 (5,13) Aerosil 200 (13,16), and Syloid XDP (14) These carriers are selected for their high oil-adsorption capacity and their ability to facilitate rapid desorption and emulsification in the GI tract. Other hydrophilic carriers like maltodextrin (18) and dextran (4) have also been explored.
- **Spray Drying**: In this process, the liquid SMEDDS is mixed with a carrier solution and atomized into a hot drying gas. The solvent evaporates rapidly, leaving behind dry, solid particles (20). Spray drying can produce nano-sized microcapsules when using hydrophilic carriers like dextran (4). It has been successfully applied to produce uniform, scalable S-SMEDDS powders (4,11,19,21,22).
- **Electrospraying**: This technique uses electrical forces to atomize a solution containing the liquid SMEDDS and a polymer (such as PVP or PEO). The resulting spheres often exhibit a core-shell or matrix structure that effectively encapsulates the drug in an amorphous state and prevents crystallization during storage (12)
- **Extrusion and Spheronization**: This method is employed to produce uniform pellets. The liquid SMEDDS is blended with solid excipients (e.g., microcrystalline cellulose) and a binder to form a wet mass, which is then extruded and spheronized into spherical beads (10).
- **Spherical Crystallization**: A sophisticated technique where matrix-forming polymers like ethyl cellulose (EC) and enteric polymers like Eudragit S100 are used to create solid particles. This method can be tailored to achieve sustained-release profiles by using different ratios of polymers and solvents (8)
- Granulation and Tabletting: Liquid SMEDDS can be incorporated into granules through wet or dry granulation processes. These granules can then be blended with superdisintegrants (e.g., croscarmellose sodium) and lubricants for compression into tablets (5,9,15)

## 5. Characterization of S-SMEDDS

Rigorous characterization is essential to confirm that the solidification process has not negatively impacted the self-emulsifying properties or the stability of the drug.

### 5.1 Morphology and Particle Analysis

- **Microscopy: Scanning Electron Microscopy (**SEM) is used to examine the surface features of S-SMEDDS powders, granules, or pellets. It confirms whether the liquid phase has been successfully adsorbed or encapsulated and checks for the absence of drug crystals on the particle surface (8,14,16,23).

- **Transmission Electron Microscopy** (TEM) provides high-resolution images of the droplets formed upon reconstitution (14,15).

- **Particle Size and Zeta Potential**: Upon dilution in aqueous media, the droplet size distribution is measured using techniques like photon correlation spectroscopy (PCS). A narrow polydispersity index (PDI) and small droplet size (typically <50 nm for microemulsions) are indicative of an efficient system (15,16). Zeta potential measurements help predict the physical stability of the reconstituted emulsion, with higher absolute values indicating better resistance to droplet coalescence (14,16).

### 5.2 Solid-State Characterization

- **Thermal and X-ray Analysis: Differential Scanning Calorimetry** (DSC) and X-ray Diffraction (XRD) are critical for determining the physical state of the drug. S-SMEDDS aim to maintain the drug in an amorphous or molecularly dispersed state within the solid matrix. The absence of sharp endothermic peaks in DSC or characteristic diffraction peaks in XRD confirms the amorphous nature of the drug, which is a key driver for enhanced dissolution (4,23,12,14,19)

- **Fourier-Transform Infrared Spectroscopy** (FTIR): FTIR is used to investigate potential chemical interactions between the drug and the excipients, ensuring that the formulation components are compatible and the drug remains chemically stable (9,12).

### 5.3 Pharmaceutical Performance

- **In Vitro Dissolution Studies**: These studies evaluate the rate and extent of drug release in various simulated GI fluids. S-SMEDDS typically show rapid and nearly complete release (often >85-90% within 30-60 minutes), whereas the pure crystalline drug may show minimal release under the same conditions (9,14,17).

- **Reconstitution and Disintegration**: For tablets and capsules, the disintegration time and the time required for complete emulsification (reconstitution time) are measured. Rapid disintegration and emulsification are essential for achieving quick onset of action (5,16).

- **Micromeritic Properties**: The flowability of S-SMEDDS powders—measured by parameters like the angle of repose, Carr's index, and Hausner ratio—is crucial for ensuring uniform dosing during capsule filling or tabletting (14,16).

## 6. Applications of Solid SMEDDS in Pharmaceutical Science

S-SMEDDS have demonstrated broad applicability in improving the delivery of a wide range of lipophilic therapeutic agents.

### 6.1 Bioavailability Enhancement

The primary application of S-SMEDDS is the dramatic improvement of oral bioavailability. Various studies have reported:

- Relative Bioavailability Gains: Improvements ranging from 216% to 289% compared to conventional drug suspensions (10,13).
- High-Fold Increases: Some systems have achieved more than a 4-fold increase in systemic exposure (AUC) compared to the pure drug or traditional formulations (12,14).
- Superior Performance over Marketed Products: S-SMEDDS have been shown to outperform established commercial products, achieving higher Cmax and AUC values (9,15,24)

### 6.2 Development of Novel Dosage Forms

S-SMEDDS allow for the creation of sophisticated delivery platforms:

- **Gastroretentive Systems**: By combining S-SMEDDS with swelling and bioadhesive polymers like PEO and chitosan, tablets can be designed to remain in the stomach for extended periods. This approach is particularly useful for drugs with a narrow absorption window in the upper GI tract, providing sustained release and reduced blood concentration fluctuations (15).
- **Chewable and Disintegrating Tablets**: S-SMEDDS can be formulated into chewable tablets or orally disintegrating tablets (ODTs) to improve patient compliance, especially in pediatric or geriatric populations (9).
- **Enteric-Coated Systems**: Techniques like spherical crystallization allow for the development of enteric-coated solid particles that protect the drug from the acidic environment of the stomach and release it specifically in the intestine (8).

### 6.3 Dose Reduction and Improved Safety

By significantly increasing the efficiency of drug absorption, S-SMEDDS allow for the administration of lower total doses to achieve the same therapeutic effect. This dose reduction can minimize systemic toxicity and improve the overall safety profile of the treatment(19).

## 7. Challenges and Future Perspectives

### 7.1 Current Challenges

Despite their advantages, S-SMEDDS face several hurdles:

- **Stability of the Solid Matrix:** High concentrations of surfactants and lipids can sometimes compromise the physical integrity of the solid dosage form or lead to leakage of the liquid components during long-term storage (1).
- **Carrier Limitations:** There is often a trade-off between the oil-adsorption capacity of the carrier and its ability to release the self-emulsifying system rapidly. Some carriers may irreversibly trap a portion of the lipid formulation, reducing the effective dose (5).
- **Cost and Scalability:** Specialized solidification techniques like spray drying and electrospraying involve higher equipment costs and more complex processing compared to conventional tablet manufacturing (1).

### 7.2 Future Perspectives and Trends

- **3D Printing:** The emergence of 3D printing (additive manufacturing) in pharmaceutical sciences offers the possibility of creating customized S-SMEDDS with complex geometries and tailored release profiles, enabling personalized medicine (25).

- **Supersaturable Formulations (S-SuSMEDDS):** The integration of precipitation inhibitors into S-SMEDDS is a growing trend. These systems maintain the drug in a supersaturated state for a longer duration, further maximizing the absorption potential for extremely insoluble drugs (5,6,26)

- **Industrial Innovation:** Research is increasingly focused on the use of robust and inexpensive carriers like Neusilin and Fujicalin, which can simplify the scale-up process and reduce manufacturing costs, bringing these advanced delivery systems closer to widespread clinical use (1).

## CONCLUSION

Solid Self-Microemulsifying Drug Delivery Systems (S-SMEDDS) have emerged as a robust and versatile platform for overcoming the bioavailability challenges associated with poorly water-soluble therapeutic agents. By integrating the solubilization advantages of lipid-based formulations with the superior stability and manufacturing benefits of solid dosage forms, S-SMEDDS effectively bridge the gap between experimental pharmaceutical science and industrial application. The transition from liquid to solid state through techniques like adsorption, spray drying, and electrospraying preserves the spontaneous emulsification behavior of the system, ensuring rapid drug release and enhanced absorption through mechanisms such as nano-dispersion and intestinal lymphatic transport. Despite existing challenges regarding carrier capacity and scalability, ongoing innovations in 3D printing and the development of supersaturable systems promise further to refine the performance and clinical accessibility of S-SMEDDS. Ultimately, this delivery approach stands as a critical strategy in the oral delivery of BCS Class II and IV drugs, offering a path toward more effective and patient-centric pharmaceutical products.

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HOW TO CITE: Krishna Haridas, Neema George, Athmika Haika, Aswathy Mohan, Divyamol A K, Gayathri P M, Praveena V A, Shabnam Shibu Sekumeeran, Solid SMEDDS: An Emerging Lipid-Based Drug Delivery Approach for Improving Solubility and Oral Bioavailability of Poorly Soluble Drugs, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 8, 711-719. https://doi.org/10.5281/zenodo.21802255