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Review Paper

# A Systematic Review On: Design, Development and Evaluation of SMEDDS for Solubility Enhancement

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## ABSTRACT

The oral administration route remains the most favored approach for delivering therapeutic agents across a wide spectrum of medical disorders, serving as the cornerstone strategy in contemporary dosage form design. However, the development of effective oral formulations is frequently impeded by deficient and inconsistent bioavailability, a direct consequence of inadequate aqueous solubility. Notably, more than 40% of potential active pharmaceutical ingredients display poor water solubility profiles. To mitigate these limitations, diverse methodologies have been implemented, focusing on modifying drug solubility characteristics or ensuring the molecule remains in a solubilized liquid state throughout gastrointestinal transit.This growing recognition stems from their straightforward manufacturing methodologies, high physical stability, and compatibility with soft gelatin capsule filling. Upon entering the gastrointestinal tract, these formulations spontaneously generate a drug-loaded microemulsion featuring an expansive surface area. Ultimately, the self-microemulsifying architecture represents a highly efficient vehicle for augmenting the solubility of hydrophobic therapeutic entities, successfully facilitating the transport of water-insoluble molecules across biological membranes by pre-solubilizing them within a lipidic matrix.

## INTRODUCTION

This comprehensive review evaluates the features of Self-Microemulsifying Drug Delivery Systems (SMEDDS), which represent a sophisticated paradigm shift in pharmaceutical processing technology.These systems are highly regarded for their capacity to maximize drug solubility, optimize bioavailability, and elevate overall therapeutic outcomes, thereby generating profound interest across academic research sectors and the pharmaceutical industry. The subsequent sections explore the fundamental concepts, structural advantages, and technical challenges associated with SMEDDS, emphasizing their capacity to redefine conventional drug delivery methodologies[1].Among the various options

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available for administering therapeutics, oral delivery stands out as the most patient-compliant and convenient route. A primary determinant governing the clinical efficacy of an orally administered drug is its solubility profile, as it must undergo complete dissolution within the gastrointestinal tract to permit subsequent systemic absorption. Remarkably, although approximately 40% of lipophilic therapeutic agents are designed for oral administration, their underlying hydrophobic nature presents a formidable formulation obstacle. A substantial proportion of modern discovery compounds, particularly those categorized under BCS Class II, exhibit high lipophilicity coupled with poor aqueous solubility, with over half of newly identified drug candidates falling into this specific category[2]. Although these techniques can successfully accelerate dissolution rates and enhance systemic absorption, they suffer from limited universal applicability. For instance, salt formation is completely ineffective for neutral molecules, and salts derived from weak bases or acids are prone to precipitation and aggregation within the gastrointestinal environment. Furthermore, reducing particle size often introduces powder handling complications and does not reliably guarantee improved surface wettability[3].

Their documented capability to optimize the absorption profiles of poorly soluble therapeutic agents has positioned them as a primary focal point of current pharmaceutical research. Nevertheless, despite these formulation advancements, an unacceptable number of candidate molecules fail to transition into commercial products due to unresolved solubility deficiencies. Consequently, excessive dosing is frequently mandated to achieve therapeutic systemic concentrations, which can cause unwanted toxicity, compromise patient safety, reduce physical comfort, and undermine long-term medication adherence[4].

## MECHANISM OF SELF EMULSIFICATION

The characteristic low energy threshold typical of conventional emulsification processes relates directly to the energy required to generate a new interface separating the immiscible oil and water domains, a relationship mathematically defined by the following thermodynamic expression:

$$\Delta G = \Sigma N \pi r^2 \sigma$$

Structural stabilization of the resulting emulsion is maintained by surface-active agents that form a protective mechanical or steric barrier around the dispersed droplets, effectively reducing the interfacial energy. For self-microemulsifying systems, the energetic barrier opposing dispersion is minimized to a negligible, ultra-low, or even negative value, implying that the microemulsification process proceeds spontaneously without requiring external mechanical or thermal inputs[6].

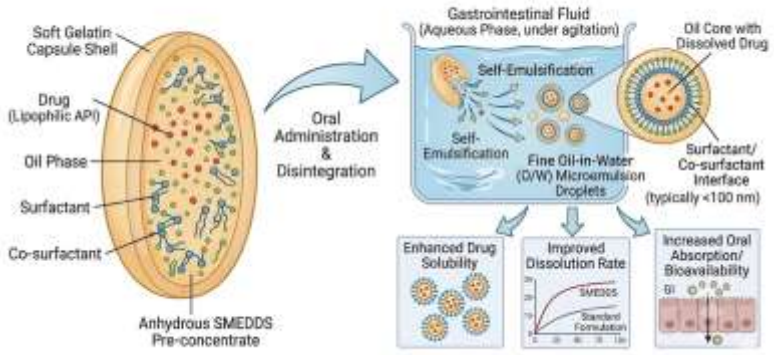


**Fig: Mechanism Of Self Emulsification**

## NEED OF SMEDD

The conventional oral delivery of hydrophobic compounds typically requires pre-dissolving the active substance into an appropriate liquid vehicle, followed by encapsulation into capsule shells. When the drug is stabilized within a lipidic carrier core, its vulnerability to recrystallization upon exposure to gastric and intestinal fluids is notably lowered, as the therapeutic molecule remains safely sequestered within the interior of the dispersed lipid droplets[7].

An alternative technique involves creating solid molecular solutions utilizing water-soluble polymers to enhance overall drug solubility. Representative polymeric carriers frequently selected for this purpose include polyvinylpyrrolidone (PVP) and polyethylene glycol (PEG 6000), both of which assist in maintaining the drug in an amorphous, dissolved state. Nonetheless, a persistent limitation of this strategy is the thermodynamic tendency of the drug to revert to its low-energy crystalline state, leading to phase separation and crystal growth inside the polymer matrix[8].

Beyond simply optimizing dissolution performance, SMEDDS can shield sensitive drug molecules from degrading gastric environments, thereby maximizing intact systemic absorption into the bloodstream[9].

## ADVANTAGES:

- These formulations can be stored with relative ease because they exist as thermodynamically stable isotropic systems.
- They minimize the potential for localized mucosal irritation by reducing direct contact with the gastrointestinal lining.
- The manufacturing methodologies are straightforward and highly amenable to industrial scale-up.
- They can successfully deliver therapeutic peptides that are otherwise prone to rapid enzymatic degradation by intestinal proteases.
- Integrating specialized polymers into the SMEDDS structure enables sustained-release delivery profiles.
- They ensure more reproducible and consistent plasma-concentration time profiles during drug absorption.
- Therapeutic agents can be targeted to specific absorption windows within the gastrointestinal tract, optimizing overall drug safety profiles[10].

## DISADVANTAGES:

- Traditional dissolution testing setups fail to provide relevant data because these specialized lipid frameworks rely heavily on in vivo lipolysis and enzymatic digestion before drug release can occur.
- Consequently, existing in vitro lipolysis models require further technical refinement and regulatory validation before their full analytical utility can be established.
- Additional drawbacks include potential chemical instability of the active ingredients and the requirement for high surfactant concentrations (typically 30–60%), which can induce gastrointestinal irritation.
- This precipitation tendency can be worsened upon aqueous dilution due to the rapid migration of the hydrophilic solvent phase into the bulk medium.
- Lastly, managing formulations with multiple excipient components increases the complexity of analytical validation protocols[11].

## APPLICATIONS OF SMEDDS:

Representative applications of SMEDDS technology include:

**Enhancement of Solubility and Bioavailability:** By accelerating the underlying dissolution velocity and enhancing thermodynamic solubility, the systemic bioavailability of BCS Class II therapeutic agents is markedly elevated.

**Prevention of Drug Biodegradation:** A vast number of active components undergo rapid degradation in physiological fluids due to local variations in gastrointestinal pH. For instance, exposure to acidic gastric conditions can prompt hydrolytic or enzymatic breakdown. By generating a protective physical barrier between the drug and the hostile external environment via liquid crystalline phases, SMEDDS excipients effectively prevent chemical degradation.

**Independence from Lipid Digestion Interferences:** This specialized delivery platform remains largely unimpacted by active lipolysis processes. Pancreatic lipases and endogenous bile salts do not break down the carrier, but instead assist the self-emulsification behavior of the core components.

**High Payload Dissolution:** The clever selection of formulation excipients yields exceptionally high drug solubilization capacity, facilitating superior dosing efficiency[12].

**BIOPHARMACEUTICAL ASPECTS:**

The subsequent release of the therapeutic agent from this microemulsion occurs via molecular partitioning from the oil droplets into the surrounding intestinal fluid. The generation of nanometer-sized droplets provides a massive interfacial surface area, which directly accelerates this partitioning process.

The structural components of SMEDDS actively participate in optimizing the drug's in vivo behavior. The lipid and oil components modify the metabolic fate and pharmacokinetic profile of the dosage form by enhancing dissolution rates and promoting lymphatic transport pathways. Furthermore, because the drug is encapsulated inside oil droplets, it remains protected against chemical and enzymatic degradation pathways. Concurrently, the incorporated surfactants enhance membrane permeability by temporarily disrupting the structural organization of the intestinal epithelial lipid bilayer[13].

**SELECTION OF DRUG FOR SMEDDS:**

Active molecules with poor water solubility inherently display restrictive dissolution profiles, which limits their intestinal absorption and compromises their overall bioavailability[1415].

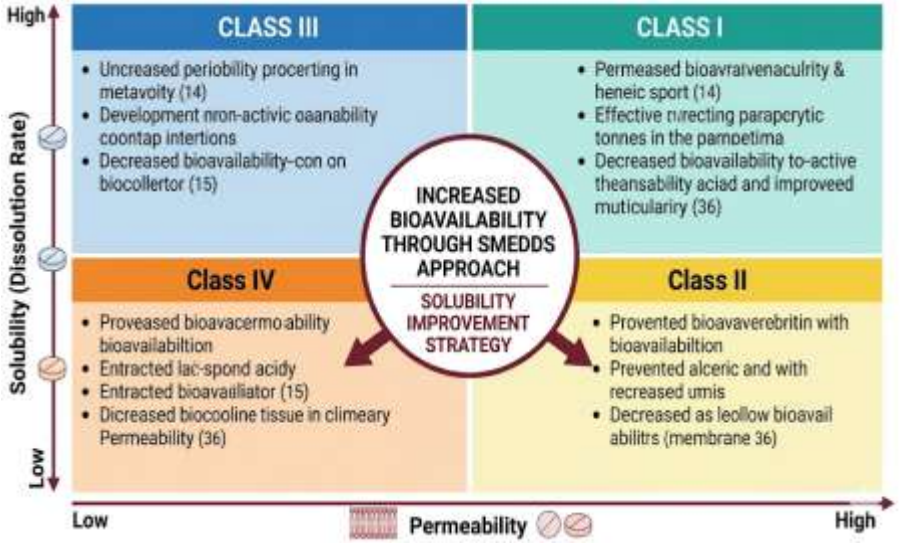


**Fig: Biopharmaceutical Classification System (BCS) Summary Chart**

## FACTORS AFFECTING SMEDDS FORMULATION:

Ideally, the candidate drug molecule should display high solubility in each individual component of the formulation matrix.
Maximizing drug solubility within the lipid phase is critical to ensuring a high drug payload while maintaining the targeted bioavailability profile.
Every selected excipient must possess chemical compatibility with the active drug and the other matrix components to avoid negative drug-excipient interactions.
Utilizing a lipid base with a higher polarity profile generally results in an accelerated drug release kinetics profile.
Minimizing the internal droplet size expands the effective surface area, leading to superior systemic absorption profiles[16].

## COMPONENTS OF SMEDDS:

### Oil:

The lipid component represents the most critical formulation element, as it dissolves the lipophilic active ingredient and enhances its absorption across the intestinal mucosa within the zone of emulsification40. Both natural edible oils and synthetic lipids are widely considered during SMEDDS development. However, because raw natural vegetable oils are frequently susceptible to microbial rancidification and chemical breakdown in the acidic gastric environment, hydrolyzed vegetable oils are often selected instead. These modified lipids offer robust emulsification profiles and exhibit excellent compatibility with a broad range of regulatory-approved oral surfactants[17].

### Surfactant:

Surfactants, or surface-active agents, align themselves at the water-air or oil-water interface, effectively reducing the surface tension of the aqueous phase. Structurally, a surfactant molecule possesses two distinct segments with contrasting solvent affinities: a hydrophilic region that lowers surface tension in polar solvents like water, and a lipophilic section that reduces tension in nonpolar environments. The selection of surfactants for SMEDDS is limited because only a restricted number of surface-active agents are approved for oral administration. These molecules are generally categorized into four primary classes based on the electrical charge of their head group[18].

**• Anionic Surfactants:**

These possess a negatively charged hydrophilic head group, such as carboxyl ($RCOO^-$), sulfonate ($RSO_3^-$), or sulfate ($RO\text{-}SO_3^-$) domains, which exhibit a strong affinity for water and facilitate aqueous mixing. Representative examples include potassium laurate and sodium lauryl sulfate, which are widely utilized.

**• Cationic Surfactants:**

These surfactants possess a hydrophilic moiety bearing an overall positive charge. Among this class, quaternary ammonium halide compounds are widely recognized representatives. Owing to their intrinsic antimicrobial activity, these agents are extensively incorporated into formulations intended for disinfection and personal care applications, including disinfectants, textile-conditioning products, and hair-conditioning preparations.

**• Nonionic Surfactants:** These agents carry no net electrical charge on their hydrophilic head group, yet achieve excellent water solubility due to the presence of highly polar regions, such as hydroxyl or polyoxymethylene ($-OCH_2CH_2O-$) chains. Sorbitan esters (Spans) and polysorbates (Tweens) represent two widely cited examples.

**• Amphoteric (Zwitterionic) Surfactants:**

Also referred to as ampholytic surfactants, these structures contain both positive and negative charges simultaneously within the same molecule,

as seen in sulfobetaines. They are structurally mild, highly compatible with other surfactant classes, and routinely used in personal care formulations[19].

**Co-surfactant:**

In general, optimizing a SMEDDS formulation requires using more than 30% w/w of a primary surfactant. To safely reduce this high surfactant requirement, co-surfactants are incorporated into the system. Working in tandem with the primary surfactant, the co-surfactant helps lower the interfacial tension to an ultra-low, transient value. At this stage, the interface expands rapidly, facilitating the formation of finely dispersed droplets that adsorb additional surfactant and co-surfactant molecules until the bulk concentration stabilizes and the interfacial tension returns to a positive value[20].

**Other Excipients:**

Various pH modifiers, flavoring agents, and antioxidants are routinely added to improve the chemical stability and patient compliance of SMEDDS formulations. During processing and storage, the generation of free radicals (such as ROO•, RO•, and •OH) can damage the active drug and cause toxicity. Furthermore, lipid excipients are prone to auto-oxidation, which forms peroxide ions, while shifts in pH can accelerate lipid hydrolysis[21].

## EVALUATION OF SMEDDS

**Droplet Size Analysis:**

This parameter is also verified via photon correlation spectroscopy (PCS), which monitors light scattering fluctuations driven by the random Brownian motion of the droplets. Additionally, structural morphology and droplet dimensions can be evaluated using transmission electron microscopy (TEM)[22].

**Drug Content Material:**

From this primary stock solution, a 1 mL aliquot is removed and diluted to 10 mL using a clean solvent phase that does not contain blank microemulsion components. The final drug concentration is subsequently calculated at the specific analytical maximum absorbance wavelength (λmax) of the target molecule[23].

**Phase Behavior Study:**

Maintaining a constant drug payload across all test batches, the viable microemulsion domain is mapped from these diagrams, allowing the selection of optimized formulation ratios required to ensure long-term thermodynamic stability[24].

## FORMULATION APPROACH:

**Solubility Study of the Drug:**

Solubility profiling of the active therapeutic agent is conducted across a panel of various edible lipid vehicles. An excess quantity of the drug (ranging from 300 to 500 mg) is introduced into a vial containing 2 g of the selected oil phase, which is then tightly sealed. The filtrate is diluted with chloroform and quantified spectrophotometrically against a pure chloroform blank. All solubility assessments are performed in triplicate to ensure reproducibility[25].

**Screening of Surfactants:**

From a pool of regulatory-approved oral surfactants, initial screening is conducted to evaluate their relative emulsification efficiency. Equal proportions of the chosen oil phase and the test surfactant are combined. To ensure complete homogeneity, the mixture is heated to 40 °C and agitated with a mechanical stirrer for a set period. Distilled water is then added to evaluate the formation of a clear, uniform mixture across the different surfactant candidates[26].

**Screening of Co-surfactants:**

Several orally acceptable co-surfactants are evaluated to determine their emulsification capacity and compatibility with the pre-selected primary surfactant The self-emulsification efficiency of these ternary blends is then evaluated following the same protocols used for initial surfactant screening[27].

**Drug-Excipient Compatibility:**

Fourier-transform infrared (FTIR) spectra are recorded for the pure active drug, a physical blend of the drug and lipid excipients, and the complete multi-component SMEDDS formulation. Any shifts or disappearances of characteristic spectral bands in the formulation mixtures are evaluated against the baseline spectrum of the pure drug to determine excipient compatibility[28].

**Formulation and Optimization:**

An accurately weighed quantity of the active drug is introduced into a glass vial, followed by the addition of the oil, surfactant, and co-surfactant phases in ratios determined from the optimized microemulsion region of the phase diagrams[29].

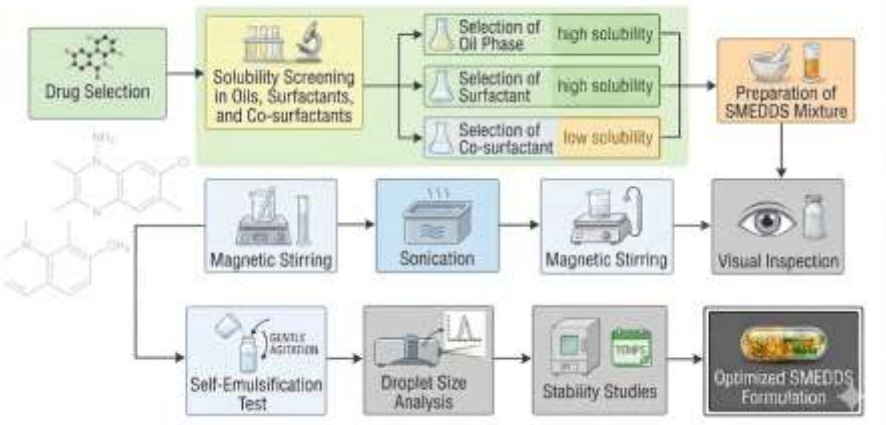


**Fig: Formulation Process Of Smedds**

**DRAWBACK OF SMEDDS:**

1. To address this limitation, in vitro lipolysis models designed to mimic the digestive environment of the duodenum have been developed.
2. The substantial surfactant concentration required in these self-emulsifying platforms (ranging from 30 to 60%) can trigger localized gastrointestinal tract irritation[30].

## FUTURE PERSPECTIVE SMEDDS:

SMEDDS technology represents an effective strategy for overcoming the solubility limitations of therapeutic compounds that display poor dissolution profiles in gastrointestinal fluids. The precise role of intestinal lipids in governing the solubilization cascade of these lipid-based vehicles can be better understood by combining in vitro dispersion protocols with advanced digestion methodologies. These in situ self-emulsifying frameworks exhibit high thermodynamic stability and can be manufactured as emulsion pre-concentrates.

Nevertheless, extensive research remains necessary before a wider array of SMEDDS-based products can be successfully launched on the commercial market[31].

## CONCLUSION

This formulation approach holds value across various BCS categories. The organized

microemulsion pre-concentrate ensures rapid dispersion, accelerated dissolution kinetics, and high systemic bioavailability by pre-solubilizing the drug within lipidic excipients, thereby bypassing the traditional solid-state disintegration step.

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