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Self-Emulsifying and Solid Self-Emulsifying Drug Delivery Systems: Emerging Strategies for Solubility and Lymphatic Transport Enhancement

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Abstract: *The oral delivery of hydrophobic and poorly water-soluble drugs remains a major challenge in pharmaceutical development due to limited aqueous solubility, poor dissolution behavior, variable gastrointestinal absorption, and low bioavailability. Self-emulsifying drug delivery systems (SEDDS) have emerged as promising lipid-based formulations capable of overcoming these limitations by spontaneously forming fine oil-in-water emulsions upon contact with gastrointestinal fluids. Through enhanced solubilization, improved dissolution, increased intestinal permeability, and facilitation of lymphatic transport, SEDDS significantly improve the oral absorption of lipophilic therapeutic agents, particularly those belonging to Biopharmaceutical Classification System (BCS) Class II and IV.*

This review provides a comprehensive overview of the fundamental principles, formulation components, self-emulsification mechanisms, and biopharmaceutical advantages of SEDDS. Particular emphasis is placed on their role in enhancing drug solubility and promoting intestinal lymphatic transport, thereby reducing hepatic first-pass metabolism and improving systemic drug availability. The review further discusses the evolution of conventional liquid SEDDS into Solid Self-Emulsifying Drug Delivery Systems (S-SEDDS), which offer superior physicochemical stability, improved patient compliance, controlled drug release potential, and greater industrial feasibility. Various solidification approaches, including adsorption onto solid carriers, spray drying, freeze drying, and hot-melt extrusion, are critically examined along with key characterization techniques used for evaluating formulation performance.

Recent advances in self-emulsifying technologies, therapeutic applications, formulation challenges, and future opportunities for targeted and personalized oral drug delivery are also highlighted. Overall, SEDDS and S-SEDDS represent versatile and effective strategies for addressing solubility-limited drug absorption and advancing the development of next-generation oral delivery systems for hydrophobic therapeutics.

Keywords: Self-Emulsifying Drug Delivery System (SEDDS); Solid Self-Emulsifying Drug Delivery System (S-SEDDS); Lipid-Based Drug Delivery; Hydrophobic Drugs; Oral Bioavailability; Solubility Enhancement; Lymphatic Transport; BCS Class II Drugs; BCS Class IV Drugs; Drug Solubilization; Lipid Formulations; Oral Drug Delivery

I. INTRODUCTION

The oral route remains the most preferred method of drug administration because of its convenience, patient compliance, cost-effectiveness, and suitability for long-term therapy. However, the successful oral delivery of many therapeutic agents is often limited by poor aqueous solubility and inadequate gastrointestinal absorption. It is estimated

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that a substantial proportion of newly developed drug candidates exhibit low water solubility, resulting in poor dissolution rates, variable absorption profiles, and reduced oral bioavailability (Gursoy & Benita, 2004). These challenges are particularly evident in drugs belonging to the Biopharmaceutical Classification System (BCS) Class II and Class IV categories, where solubility represents a major barrier to effective drug delivery (Kohli et al., 2010).

To address these limitations, lipid-based drug delivery systems have gained significant attention in pharmaceutical research. Among these approaches, Self-Emulsifying Drug Delivery Systems (SEDDS) have emerged as a promising strategy for improving the oral delivery of hydrophobic and lipophilic drugs. SEDDS are isotropic mixtures of oils, surfactants, and co-surfactants or co-solvents that spontaneously form fine oil-in-water emulsions when exposed to gastrointestinal fluids under gentle agitation generated by gastric and intestinal motility (Gursoy & Benita, 2004). The formation of small emulsion droplets significantly increases the interfacial surface area available for drug release, thereby enhancing drug solubilization and dissolution within the gastrointestinal tract (Ujhelyi et al., 2018).

The enhanced performance of SEDDS is attributed not only to improved solubility but also to their ability to facilitate intestinal permeability and promote lymphatic drug transport. Lipid digestion products generated in the intestine interact with bile salts and phospholipids to form mixed micellar systems capable of maintaining poorly soluble drugs in a solubilized state. Furthermore, highly lipophilic drugs incorporated into lipid-based formulations may enter the systemic circulation through intestinal lymphatic pathways, thereby partially bypassing hepatic first-pass metabolism and increasing overall bioavailability (Chatterjee et al., 2016). This mechanism has made SEDDS particularly attractive for compounds exhibiting extensive presystemic metabolism and poor oral absorption.

Despite their advantages, conventional liquid SEDDS are associated with several limitations, including formulation instability, drug precipitation upon dilution, leakage from capsule shells, limited dosage-form flexibility, and challenges related to large-scale manufacturing (Maji et al., 2021). To overcome these drawbacks, Solid Self-Emulsifying Drug Delivery Systems (S-SEDDS) have been developed by converting liquid formulations into solid dosage forms using techniques such as adsorption onto solid carriers, spray drying, freeze drying, and hot-melt extrusion. These systems combine the solubilization benefits of lipid-based formulations with the improved stability, portability, patient acceptability, and manufacturing convenience of solid dosage forms (Maji et al., 2021).

In recent years, growing interest in advanced lipid-based technologies has accelerated research into both SEDDS and S-SEDDS as versatile platforms for enhancing oral drug delivery. Therefore, this review aims to provide a comprehensive overview of the formulation principles, mechanisms of solubility enhancement, lymphatic transport pathways, solidification technologies, characterization methods, therapeutic applications, current challenges, and future prospects of self-emulsifying and solid self-emulsifying drug delivery systems in modern pharmaceutical development.

II. BIOPHARMACEUTICAL CONSIDERATIONS OF HYDROPHOBIC DRUGS

The successful oral delivery of therapeutic agents depends largely on their ability to dissolve in gastrointestinal fluids and permeate biological membranes. Hydrophobic drugs, which constitute a significant proportion of newly discovered chemical entities, frequently exhibit poor aqueous solubility and variable absorption characteristics, resulting in suboptimal oral bioavailability (Amidon et al., 1995). These limitations represent a major challenge in pharmaceutical formulation development and have stimulated extensive research into advanced drug delivery systems, including Self-Emulsifying Drug Delivery Systems (SEDDS) and Solid Self-Emulsifying Drug Delivery Systems (S-SEDDS).

Drug solubility and permeability are the two most important physicochemical properties influencing oral absorption. For a drug to reach systemic circulation, it must first dissolve in gastrointestinal fluids before permeating the intestinal epithelium. Hydrophobic drugs generally possess high lipophilicity and low aqueous solubility, which slows dissolution and limits the amount of drug available for absorption. In many cases, the dissolution process becomes the rate-limiting step in oral drug absorption, leading to poor and variable therapeutic outcomes (Dressman et al., 1998). Factors such as particle size, crystal form, molecular structure, pKa, partition coefficient, and gastrointestinal conditions further influence dissolution behavior and absorption efficiency.

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The Biopharmaceutical Classification System (BCS) provides a scientific framework for understanding the relationship between solubility, permeability, and oral drug absorption (Amidon et al., 1995). According to the BCS, drugs are categorized into four classes. Class I drugs exhibit high solubility and high permeability, while Class III drugs possess high solubility but low permeability. In contrast, Class II drugs are characterized by low solubility and high permeability, whereas Class IV drugs demonstrate both low solubility and low permeability. The majority of formulation challenges are associated with BCS Class II and Class IV compounds because insufficient dissolution in gastrointestinal fluids restricts the amount of drug available for absorption. Consequently, strategies that enhance solubility and maintain drugs in a dissolved state are essential for improving bioavailability.

The interplay between solubility and permeability is particularly important in hydrophobic drug delivery. Although many lipophilic drugs readily diffuse across biological membranes because of their high membrane affinity, their poor dissolution in aqueous gastrointestinal environments often prevents adequate absorption (Porter et al., 2007). Therefore, enhancing solubilization without compromising membrane transport is a critical objective in oral formulation design. Lipid-based delivery systems have demonstrated significant potential in achieving this balance by maintaining drugs in a solubilized form while facilitating transport across the intestinal membrane.

Another important biopharmaceutical consideration is presystemic or first-pass metabolism. After absorption from the gastrointestinal tract, many drugs are transported through the portal circulation to the liver, where extensive metabolic degradation may occur before the drug reaches systemic circulation. This phenomenon substantially reduces bioavailability and therapeutic efficacy (Porter et al., 2007). Lipid-based formulations such as SEDDS can partially overcome this limitation by promoting intestinal lymphatic transport. Highly lipophilic compounds incorporated into lipid droplets may associate with chylomicrons and enter the lymphatic system, thereby bypassing hepatic first-pass metabolism and enhancing systemic drug exposure (Gursoy & Benita, 2004).

Understanding these biopharmaceutical challenges is essential for the rational design of SEDDS and S-SEDDS. By addressing poor solubility, dissolution limitations, permeability barriers, and first-pass metabolism, these lipid-based systems provide an effective platform for improving the oral delivery of hydrophobic therapeutic agents.

III. FUNDAMENTALS OF SELF-EMULSIFYING DRUG DELIVERY SYSTEMS (SEDDS)

Self-Emulsifying Drug Delivery Systems (SEDDS) are isotropic mixtures of oils, surfactants, and, in some cases, co-surfactants or co-solvents that spontaneously form fine oil-in-water emulsions upon dilution in gastrointestinal fluids under gentle agitation provided by gastrointestinal motility (Gursoy & Benita, 2004). These lipid-based formulations were developed to overcome the poor aqueous solubility and limited oral bioavailability of hydrophobic drugs. By maintaining drugs in a solubilized state throughout the gastrointestinal tract, SEDDS improve dissolution, absorption, and systemic exposure, making them an effective strategy for oral delivery of lipophilic therapeutic agents (Kohli et al., 2010).

SEDDS are commonly classified according to the size of the emulsion droplets formed after aqueous dilution. Conventional SEDDS generally produce emulsions with droplet sizes greater than 200 nm, whereas Self-Microemulsifying Drug Delivery Systems (SMEDDS) generate transparent or translucent microemulsions with droplet sizes typically ranging between 100 and 250 nm. Self-Nanoemulsifying Drug Delivery Systems (SNEDDS) represent a further advancement and form nanoemulsions with droplet sizes generally below 100 nm, resulting in larger surface area, enhanced dissolution, and improved drug absorption (Salawi, 2022). The distinction among these systems is important because droplet size significantly influences drug release characteristics, stability, and bioavailability.

The performance of SEDDS depends largely on the careful selection of formulation components. Oils constitute the primary solvent phase and facilitate drug solubilization while also contributing to lymphatic transport. Long-chain triglycerides and medium-chain triglycerides are frequently employed because of their favorable digestion and absorption characteristics (Porter et al., 2007). Surfactants are essential for reducing interfacial tension between oil and water phases, thereby enabling spontaneous emulsification. Nonionic surfactants such as polysorbates, Cremophor® derivatives, and polyethylene glycol esters are widely used due to their relatively low toxicity and good emulsification

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efficiency (Gursoy & Benita, 2004). Co-surfactants and co-solvents, including propylene glycol, ethanol, and polyethylene glycol, are incorporated to improve drug loading capacity, increase interfacial fluidity, and facilitate the formation of stable emulsions (Kohli et al., 2010).

The mechanism of self-emulsification is based on the spontaneous formation of an emulsion when the formulation comes into contact with an aqueous medium. Upon dilution, water penetrates the oil–surfactant interface, causing disruption of the interfacial film and generation of fine droplets. The process occurs because the free energy required to create the new interface is minimized by the presence of surfactants, making emulsification thermodynamically favorable or only minimally energy-dependent (Gursoy & Benita, 2004). Unlike conventional emulsions, which require substantial external energy for preparation, SEDDS utilize the intrinsic physicochemical properties of their components to achieve rapid dispersion.

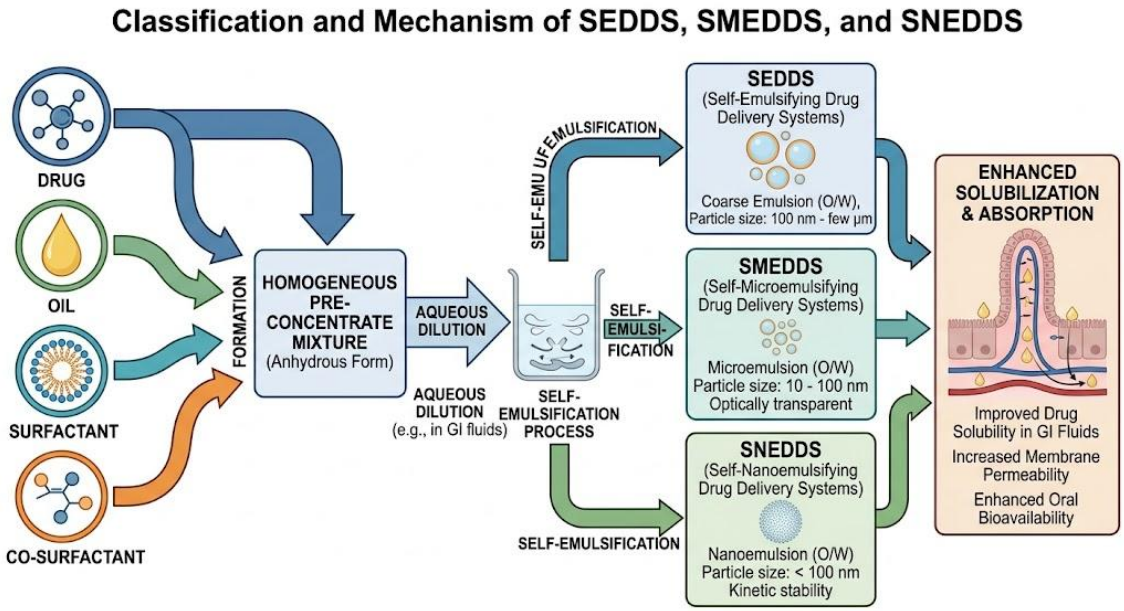

Figure 1: Classification and Mechanism of SEDDS, SMEDDS, and SNEDDS

From a thermodynamic perspective, self-emulsification occurs when the entropy gained through dispersion exceeds the energy required to increase the interfacial surface area. The low interfacial tension generated by optimized surfactant systems facilitates the formation of stable droplets and prevents coalescence (Ujhelyi et al., 2018). Kinetic factors such as droplet size distribution, emulsification rate, and formulation composition also influence the stability and performance of the resulting emulsion. Consequently, understanding both thermodynamic and kinetic principles is essential for the rational design and optimization of effective SEDDS formulations.

IV. SOLUBILITY ENHANCEMENT MECHANISMS IN SEDDS

Poor aqueous solubility remains one of the most significant barriers to the successful oral delivery of hydrophobic drugs. Self-Emulsifying Drug Delivery Systems (SEDDS) address this challenge through multiple complementary mechanisms that enhance drug solubilization, maintain supersaturation, improve dissolution kinetics, and ultimately increase oral bioavailability. Unlike conventional formulations, SEDDS retain lipophilic drugs in a dissolved state before administration and facilitate the formation of fine emulsified systems upon contact with gastrointestinal fluids, thereby overcoming dissolution-limited absorption (Gursoy & Benita, 2004).

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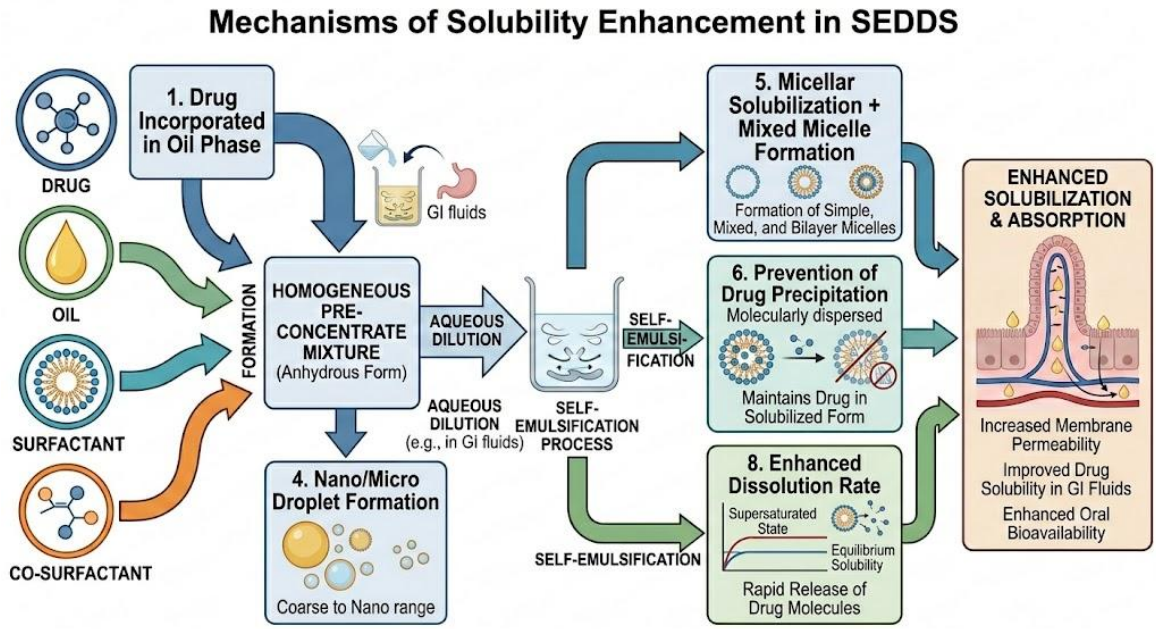

Figure 2: Mechanisms of Solubility Enhancement in SEDDS

One of the primary mechanisms responsible for enhanced solubility in SEDDS is micellar solubilization. Upon dispersion in the gastrointestinal tract, the oil phase, surfactants, and digestive products interact with endogenous bile salts and phospholipids to form mixed micellar structures. These colloidal assemblies provide hydrophobic domains capable of incorporating poorly water-soluble drugs and maintaining them in a solubilized state within the intestinal lumen (Porter et al., 2007). The continuous partitioning of drug molecules into these micelles prevents premature precipitation and increases the concentration gradient required for intestinal absorption.

Another important mechanism involves drug dispersion and nano-droplet formation. Following aqueous dilution, SEDDS spontaneously generate emulsified droplets ranging from the micro- to nanometer scale, depending on the formulation type. The formation of these fine droplets dramatically increases the interfacial surface area available for drug release and diffusion. According to the Noyes–Whitney dissolution principle, increased surface area enhances the dissolution rate of poorly soluble compounds, enabling more rapid drug availability at the absorption site (Kohli et al., 2010). In advanced systems such as Self-Nanoemulsifying Drug Delivery Systems (SNEDDS), nano-sized droplets provide an even greater surface area, resulting in superior dissolution performance and absorption efficiency.

A major challenge associated with poorly soluble drugs is drug precipitation following dilution. When lipophilic compounds are released from lipid-based systems, changes in solvent composition during digestion may reduce drug solubility and promote crystallization. SEDDS are specifically designed to minimize this risk through the use of optimized lipid–surfactant combinations that maintain drug molecules in a metastable dissolved state (Chatterjee et al., 2016). Furthermore, formulation excipients can delay nucleation and crystal growth, thereby prolonging the residence time of dissolved drug within the gastrointestinal environment.

The concept of supersaturation and controlled drug release behavior has gained considerable attention in recent years. Supersaturated systems generate drug concentrations that temporarily exceed equilibrium solubility, creating a strong thermodynamic driving force for absorption. However, maintaining supersaturation is challenging because spontaneous precipitation can rapidly occur. Modern supersaturable SEDDS (Su-SEDDS) incorporate precipitation inhibitors such as hydroxypropyl methylcellulose (HPMC), polyvinylpyrrolidone (PVP), and Soluplus®, which stabilize the supersaturated state and extend the absorption window (Gao et al., 2003; Xu & Dai, 2013). This strategy enables enhanced drug exposure while reducing the need for excessive surfactant concentrations.

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Collectively, these mechanisms contribute to significant improvements in dissolution and oral bioavailability. By increasing drug solubilization, maintaining supersaturation, reducing precipitation, and facilitating efficient intestinal transport, SEDDS improve the absorption of many BCS Class II and IV compounds (Porter et al., 2007). Numerous studies have demonstrated that lipid-based self-emulsifying formulations achieve higher plasma drug concentrations and greater systemic exposure than conventional dosage forms. Consequently, SEDDS have become one of the most effective approaches for overcoming solubility-limited oral drug delivery and enhancing the therapeutic performance of hydrophobic pharmaceuticals.

V. LYMPHATIC TRANSPORT ENHANCEMENT BY SEDDS

One of the most significant advantages of Self-Emulsifying Drug Delivery Systems (SEDDS) is their ability to promote intestinal lymphatic transport of highly lipophilic drugs. In addition to improving solubility and dissolution, SEDDS facilitate an alternative absorption pathway that can substantially increase systemic drug exposure by reducing presystemic hepatic metabolism. This mechanism is particularly beneficial for drugs exhibiting poor oral bioavailability due to extensive first-pass metabolism and limited gastrointestinal absorption (Porter et al., 2007).

The intestinal lymphatic system plays a crucial role in the absorption and transport of dietary lipids. Following oral administration, lipids are digested in the small intestine by pancreatic lipases to form free fatty acids and monoglycerides. These digestion products interact with bile salts and phospholipids to generate mixed micelles that facilitate uptake into enterocytes. Within intestinal epithelial cells, absorbed lipids undergo re-esterification to form triglycerides, which are subsequently incorporated into lipoprotein particles known as chylomicrons (Trevaskis et al., 2015). These chylomicrons are secreted into intestinal lymphatic vessels rather than directly entering the portal blood circulation, thereby providing an alternative pathway for systemic drug delivery.

The lipid components of SEDDS play a central role in stimulating this lymphatic uptake process. Long-chain triglycerides and long-chain fatty acids are particularly effective because they promote chylomicron synthesis and secretion within enterocytes (Porter et al., 2007). When a highly lipophilic drug is dissolved within the lipid phase of a SEDDS formulation, it can partition into these newly formed lipoprotein structures during intestinal processing. As a result, the drug becomes associated with chylomicrons and is transported through the mesenteric lymphatic system. The extent of lymphatic transport generally increases with drug lipophilicity, especially for compounds exhibiting high partition coefficients and significant solubility in triglyceride-rich environments (Charman & Stella, 1991).

A key mechanism underlying lymphatic delivery is chylomicron-mediated drug transport. After formation in enterocytes, chylomicrons enter intestinal lacteals and travel through the lymphatic network before eventually draining into the systemic circulation via the thoracic duct. Because chylomicrons are too large to readily enter blood capillaries, they preferentially utilize the lymphatic route (Trevaskis et al., 2015). Drugs associated with these lipoproteins are therefore transported directly into the bloodstream while avoiding immediate passage through the liver. This process enables higher concentrations of intact drug to reach systemic circulation compared with conventional oral formulations.

The ability of SEDDS to bypass hepatic first-pass metabolism is of particular therapeutic importance. Many drugs undergo extensive enzymatic degradation in the liver following absorption through the portal vein, significantly reducing bioavailability. By directing drug transport through the lymphatic system, SEDDS decrease hepatic exposure during the initial absorption phase and improve the fraction of drug reaching systemic circulation unchanged (Gursoy & Benita, 2004). This effect has been reported for several highly lipophilic compounds, resulting in enhanced pharmacokinetic performance and improved therapeutic outcomes.

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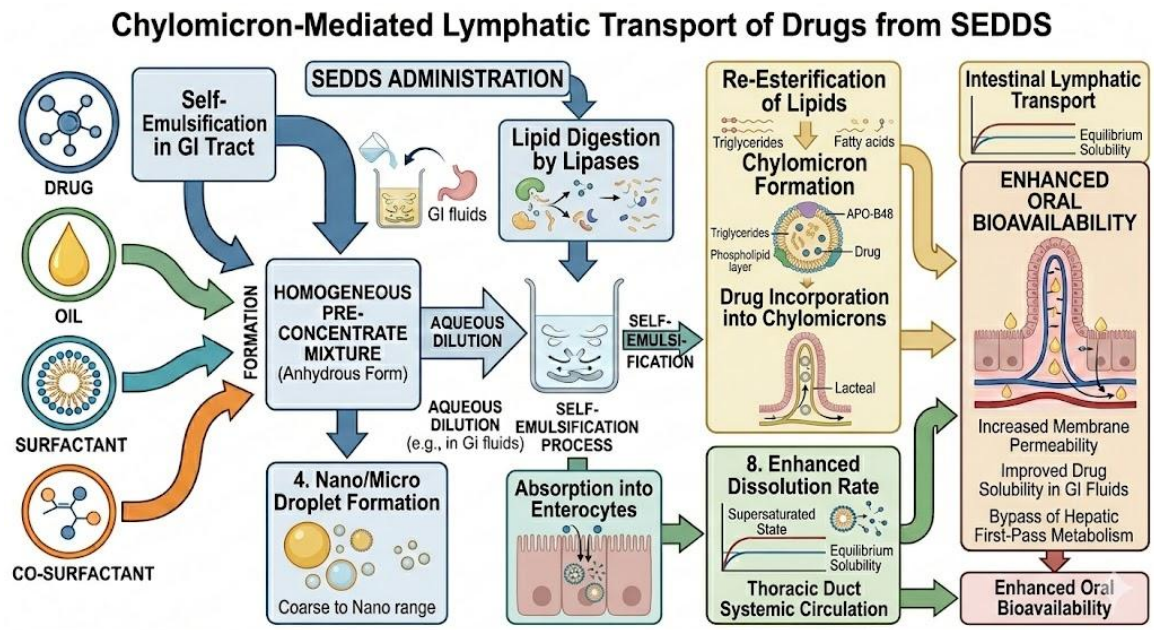

Figure 3: Chylomicron-Mediated Lymphatic Transport of Drugs from SEDDS

The therapeutic implications of lymphatic drug delivery are substantial. Enhanced lymphatic transport can improve bioavailability, reduce dose requirements, decrease interpatient variability, and increase the effectiveness of drugs with extensive first-pass metabolism (Porter et al., 2007). Furthermore, lymphatic targeting may be advantageous for the treatment of diseases involving the lymphatic system, including certain cancers, infectious diseases, and immune-related disorders. Consequently, the ability of SEDDS to stimulate lymphatic transport represents one of their most valuable attributes and a major factor contributing to their success as advanced lipid-based oral drug delivery systems.

VI. FORMULATION DESIGN AND OPTIMIZATION OF SEDDS

The successful development of Self-Emulsifying Drug Delivery Systems (SEDDS) requires systematic formulation design and optimization to achieve efficient self-emulsification, high drug-loading capacity, physicochemical stability, and enhanced oral bioavailability. Since the performance of SEDDS depends on complex interactions among oils, surfactants, co-surfactants, and drug molecules, careful selection and optimization of formulation components are essential for obtaining robust and reproducible delivery systems (Kohli et al., 2010).

The first step in SEDDS formulation involves the selection of lipid excipients, which serve as the primary drug-solubilizing medium. The choice of oil significantly influences drug loading, emulsification efficiency, digestion behavior, and lymphatic transport potential. Medium-chain triglycerides (MCTs) are widely used because of their superior solvent capacity and rapid emulsification characteristics, whereas long-chain triglycerides (LCTs) are often preferred when enhanced lymphatic transport is desired (Porter et al., 2007). Solubility screening studies are typically performed to identify oils capable of dissolving the maximum amount of drug while maintaining formulation stability.

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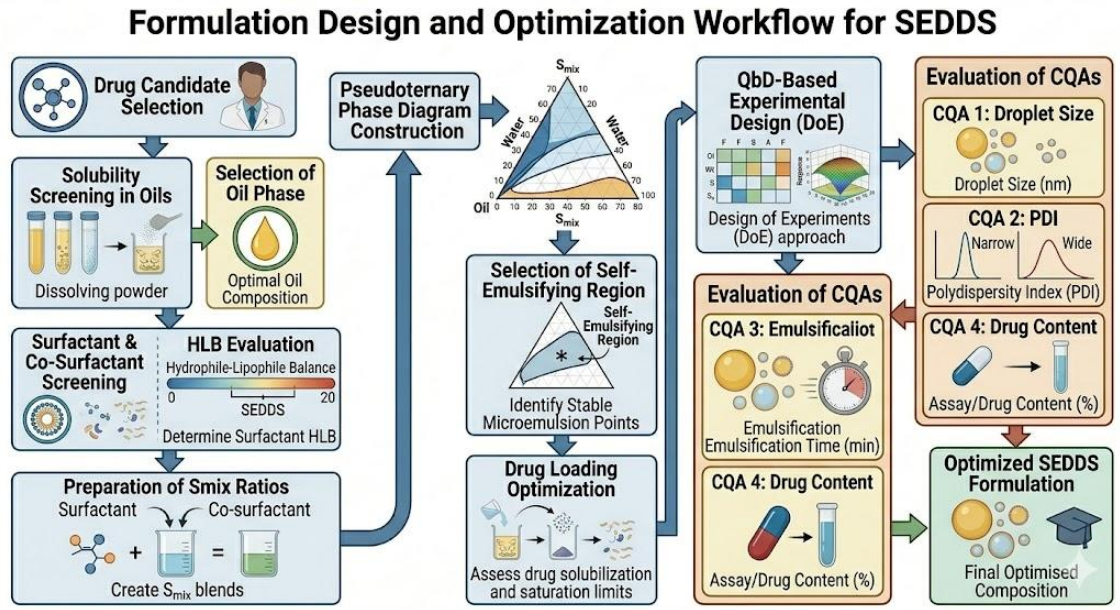

Figure 4: Formulation Design and Optimization Workflow for SEDDS

Surfactant selection represents another critical aspect of formulation development. Surfactants reduce interfacial tension between oil and aqueous phases and facilitate spontaneous emulsion formation upon dilution. Nonionic surfactants are generally preferred because of their lower toxicity and better gastrointestinal compatibility. The hydrophilic–lipophilic balance (HLB) value is an important parameter in surfactant selection, with surfactants possessing HLB values above 12 generally promoting the formation of oil-in-water emulsions suitable for oral delivery (Gursoy & Benita, 2004). Co-surfactants such as polyethylene glycol, propylene glycol, and Transcutol® are frequently incorporated to improve interfacial flexibility, enhance drug solubilization, and facilitate rapid emulsification.

The pseudoternary phase diagram approach is widely employed during formulation optimization. These phase diagrams provide a graphical representation of the emulsification behavior of oil, surfactant/co-surfactant mixture (Smix), and aqueous phases. By systematically varying component ratios, researchers can identify self-emulsifying regions capable of producing stable emulsions with desirable droplet sizes and transparency (Date &Nagarsenker, 2007). Phase diagram studies therefore serve as valuable tools for determining optimal formulation compositions and minimizing experimental variability.

Another important consideration is drug loading capacity, which refers to the amount of drug that can be incorporated into the formulation without precipitation. High drug loading is desirable to reduce dosage volume and improve patient compliance. However, excessive drug concentrations may destabilize the system or lead to precipitation following dilution. Therefore, equilibrium solubility studies are routinely conducted to establish appropriate drug concentrations and ensure long-term formulation stability (Kohli et al., 2010).

In recent years, Quality-by-Design (QbD) principles have been increasingly applied to SEDDS development. QbD emphasizes a systematic understanding of formulation variables and process parameters that influence product quality. Critical Quality Attributes (CQAs) such as droplet size, emulsification time, drug content, and dissolution performance are identified, while Design of Experiments (DoE) methodologies are used to evaluate the impact of formulation variables on these attributes (Singh et al., 2009). This approach enhances formulation robustness, reduces development time, and facilitates regulatory compliance.

Several critical formulation parameters ultimately determine SEDDS performance, including oil-to-surfactant ratio, surfactant concentration, droplet size distribution, zeta potential, drug solubility, and emulsification efficiency. Optimization of these parameters is necessary to ensure rapid self-emulsification, prevention of drug precipitation, and

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consistent bioavailability enhancement (Porter et al., 2007). Consequently, rational formulation design supported by systematic optimization strategies remains fundamental to the successful development of effective SEDDS for oral delivery of hydrophobic drugs.

VII. SOLID SELF-EMULSIFYING DRUG DELIVERY SYSTEMS (S-SEDDS)

Self-Emulsifying Drug Delivery Systems (SEDDS) have demonstrated remarkable potential in enhancing the oral bioavailability of poorly water-soluble drugs through improved solubilization and lymphatic transport. Despite these advantages, conventional liquid SEDDS are associated with several practical limitations, including leakage from soft or hard gelatin capsules, incompatibility with capsule shell materials, precipitation during storage, limited physical stability, and challenges in handling, transportation, and large-scale manufacturing (Pouton, 2006). To address these shortcomings, researchers have developed Solid Self-Emulsifying Drug Delivery Systems (S-SEDDS), which combine the biopharmaceutical advantages of liquid SEDDS with the stability and convenience of solid dosage forms.

The concept of S-SEDDS involves transforming liquid or semi-solid self-emulsifying formulations into solid pharmaceutical systems without compromising their self-emulsification properties. Upon contact with aqueous gastrointestinal fluids, S-SEDDS rapidly reconstitute into fine emulsions or nanoemulsions similar to their liquid counterparts, thereby preserving the drug solubilization and absorption-enhancing capabilities of the original formulation (Maji et al., 2021). This transformation is achieved through various solidification techniques such as adsorption onto porous carriers, spray drying, freeze drying, hot-melt extrusion, fluid-bed coating, and melt granulation. The rationale behind this approach is to overcome the formulation and stability issues associated with liquid systems while retaining their therapeutic effectiveness.

Compared with conventional liquid SEDDS, S-SEDDS offer several significant advantages. One of the primary benefits is improved physical and chemical stability. The conversion of liquid formulations into solid dosage forms reduces the risk of phase separation, leakage, and degradation during storage (Ito et al., 2019). In addition, S-SEDDS exhibit greater patient acceptability because they can be formulated as tablets, capsules, pellets, granules, powders, or orally disintegrating dosage forms. Their solid nature also facilitates accurate dosing, easier packaging, improved portability, and enhanced compliance. Furthermore, solid systems generally demonstrate superior manufacturing flexibility and compatibility with established pharmaceutical production processes (Tang et al., 2008).

The composition of S-SEDDS includes the same essential components found in liquid SEDDS, namely oils, surfactants, co-surfactants, and the incorporated drug. However, additional solid carriers are required to convert the liquid formulation into a free-flowing powder or solid matrix. Commonly used carriers include porous materials such as colloidal silicon dioxide, magnesium aluminometasilicate, microcrystalline cellulose, and various inorganic adsorbents that possess high surface area and excellent liquid adsorption capacity (Tang et al., 2008). These carriers enable efficient incorporation of liquid self-emulsifying formulations while maintaining rapid emulsification upon reconstitution. The selection of suitable carriers is critical because carrier properties influence powder flowability, compressibility, drug loading capacity, and self-emulsification efficiency.

The growing interest in S-SEDDS reflects their considerable industrial significance and commercial potential. The pharmaceutical industry increasingly favors solid dosage forms because of their ease of scale-up, lower production costs, longer shelf life, and greater patient acceptance. S-SEDDS provide a practical solution for translating lipid-based formulations from laboratory development to commercial manufacturing. Moreover, their compatibility with modern formulation technologies and Quality-by-Design (QbD) approaches supports regulatory compliance and product reproducibility (Maji et al., 2021). As the number of poorly water-soluble drug candidates continues to increase, S-SEDDS are expected to play an increasingly important role in overcoming solubility-limited oral drug delivery challenges and advancing the development of next-generation lipid-based therapeutic systems.

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VIII. CHARACTERIZATION AND EVALUATION OF SEDDS AND S-SEDDS

Comprehensive characterization and evaluation are essential for ensuring the quality, stability, and performance of Self-Emulsifying Drug Delivery Systems (SEDDS) and Solid Self-Emulsifying Drug Delivery Systems (S-SEDDS). Since the therapeutic efficacy of these lipid-based formulations is closely linked to their emulsification behavior, droplet characteristics, drug-loading efficiency, and stability, a range of physicochemical and biopharmaceutical evaluation techniques are employed during formulation development (Ujhelyi et al., 2018).

One of the primary assessments is self-emulsification efficiency, which evaluates the ability of the formulation to spontaneously form emulsions upon dilution in aqueous media. The test is typically performed using dissolution apparatus under gentle agitation, simulating gastrointestinal conditions. Emulsification time, visual appearance, transparency, and phase separation behavior are monitored to determine formulation performance. Rapid emulsification and the formation of homogeneous dispersions indicate efficient self-emulsifying properties (Kohli et al., 2010).

Droplet size and polydispersity index (PDI) are among the most critical quality attributes of SEDDS. Dynamic light scattering (DLS) techniques are commonly used to measure droplet size after aqueous dilution. Smaller droplet sizes provide larger interfacial surface areas, facilitating improved drug release, dissolution, and absorption. The PDI indicates the uniformity of droplet distribution within the formulation. Lower PDI values generally reflect a narrow size distribution and improved physical stability, whereas higher values indicate heterogeneity and potential instability (Date et al., 2010).

Zeta potential analysis is conducted to assess the surface charge and colloidal stability of emulsified droplets. Zeta potential reflects the degree of electrostatic repulsion between dispersed particles and serves as an indicator of emulsion stability. Although many SEDDS formulations utilize nonionic surfactants and therefore exhibit relatively low surface charge, zeta potential measurements remain valuable for predicting aggregation tendencies and storage stability (Ujhelyi et al., 2018).

Morphological characterization provides information regarding droplet shape, surface characteristics, and structural organization. Advanced imaging techniques such as transmission electron microscopy (TEM), scanning electron microscopy (SEM), and atomic force microscopy (AFM) are frequently employed for this purpose. In S-SEDDS, SEM is particularly useful for examining particle morphology, carrier surface properties, and the distribution of self-emulsifying formulations within solid matrices (Tang et al., 2008).

Another important evaluation parameter is drug content and encapsulation efficiency. Accurate quantification of drug loading ensures dose uniformity and formulation reproducibility. Drug content is typically determined using high-performance liquid chromatography (HPLC), ultraviolet spectroscopy, or related analytical methods. Encapsulation efficiency indicates the proportion of drug successfully incorporated into the formulation and reflects the solubilization capacity of the selected excipients (Date et al., 2010).

In vitro dissolution studies are widely employed to evaluate drug release behavior. These studies compare the dissolution performance of SEDDS or S-SEDDS with conventional dosage forms under simulated gastrointestinal conditions. Enhanced dissolution rates generally correlate with improved solubilization and increased bioavailability potential (Kohli et al., 2010). However, in vitro data alone may not fully predict in vivo performance, necessitating further pharmacokinetic evaluation.

Consequently, in vivo bioavailability assessment represents a critical stage in formulation development. Pharmacokinetic studies are conducted to determine parameters such as maximum plasma concentration (Cmax), time to reach peak concentration (Tmax), area under the concentration–time curve (AUC), and relative bioavailability. Numerous studies have demonstrated superior oral absorption and enhanced systemic exposure for drugs formulated as SEDDS and S-SEDDS compared with conventional formulations (Porter et al., 2007).

Finally, stability studies are performed to evaluate the long-term integrity of formulations under different storage conditions. Parameters such as droplet size, emulsification efficiency, drug content, precipitation tendency, and physical appearance are monitored according to regulatory guidelines. Stability assessment is particularly important for

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S-SEDDS because their commercial success depends on maintaining self-emulsification performance throughout storage and distribution (Maji et al., 2021).

IX. THERAPEUTIC APPLICATIONS OF SEDDS AND S-SEDDS

Self-Emulsifying Drug Delivery Systems (SEDDS) and Solid Self-Emulsifying Drug Delivery Systems (S-SEDDS) have found extensive applications in improving the oral delivery of poorly water-soluble therapeutic agents across diverse disease areas. Their ability to enhance drug solubilization, dissolution, intestinal absorption, and lymphatic transport has made them valuable platforms for overcoming bioavailability limitations associated with hydrophobic drugs.

In oncology, SEDDS have been widely investigated for the oral delivery of anticancer agents such as paclitaxel, docetaxel, and curcumin, where poor aqueous solubility and extensive first-pass metabolism often limit therapeutic effectiveness. Improved drug solubilization and lymphatic uptake contribute to enhanced systemic exposure and therapeutic outcomes. Similarly, antiviral drugs including ritonavir and saquinavir have been formulated using self-emulsifying systems to improve oral absorption and pharmacokinetic performance.

The application of SEDDS has also expanded to antidiabetic therapies. Lipophilic drugs such as glibenclamide and repaglinide have demonstrated improved dissolution and bioavailability when incorporated into self-emulsifying formulations. Likewise, anti-inflammatory agents including ibuprofen, celecoxib, and meloxicam have shown enhanced oral absorption and more consistent plasma drug concentrations through SEDDS-based delivery approaches.

Natural bioactive compounds and nutraceuticals represent another important application area. Phytoconstituents such as curcumin, resveratrol, coenzyme Q10, and various lipid-soluble vitamins often exhibit poor aqueous solubility and limited bioavailability. SEDDS and S-SEDDS effectively improve their gastrointestinal absorption and systemic availability. Furthermore, ongoing research is exploring the use of self-emulsifying systems for peptide and protein delivery, where lipid-based formulations may enhance intestinal permeability and protect sensitive biomolecules from degradation.

Overall, the broad therapeutic applicability of SEDDS and S-SEDDS highlights their significance as versatile lipid-based platforms for improving the oral delivery and clinical performance of hydrophobic therapeutics.

Table 1: The major therapeutic applications of SEDDS and S-SEDDS

Therapeutic Category	Example Drugs/Compounds	Major Benefit of SEDDS/S-SEDDS
Anticancer Agents	Paclitaxel, Docetaxel, Curcumin	Enhanced solubility and bioavailability
Antiviral Drugs	Ritonavir, Saquinavir	Improved oral absorption
Antidiabetic Drugs	Glibenclamide, Repaglinide	Increased dissolution and systemic exposure
Anti-inflammatory Drugs	Ibuprofen, Celecoxib, Meloxicam	Enhanced absorption and therapeutic efficacy
Nutraceuticals	Curcumin, Resveratrol, Coenzyme Q10	Improved gastrointestinal uptake
Peptides & Proteins	Insulin (investigational), peptide therapeutics	Potential enhancement of intestinal permeability

X. RECENT ADVANCES AND EMERGING TRENDS

Recent years have witnessed significant advancements in Self-Emulsifying Drug Delivery Systems (SEDDS) and Solid Self-Emulsifying Drug Delivery Systems (S-SEDDS), driven by the increasing need to improve the oral delivery of poorly water-soluble drugs. Among the most notable developments is the emergence of Supersaturable Self-Emulsifying Drug Delivery Systems (Su-SEDDS), which are designed to generate and maintain a supersaturated drug

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state following gastrointestinal dilution. By incorporating precipitation inhibitors, these systems enhance drug absorption while minimizing the requirement for high surfactant concentrations, thereby improving formulation safety and efficiency.

Another important advancement is the development of Self-Nanoemulsifying Drug Delivery Systems (SNEDDS), which produce nano-sized droplets with exceptionally large surface areas. The resulting improvement in drug dissolution and absorption has expanded the applicability of self-emulsifying technologies for highly hydrophobic compounds. In parallel, researchers are exploring targeted and mucoadhesive SEDDS, which utilize functional excipients and surface-modification strategies to prolong gastrointestinal residence time and enhance site-specific drug absorption.

The integration of SEDDS with advanced lipid-based nanocarriers has further broadened their therapeutic potential. Hybrid systems combining self-emulsifying formulations with nanoparticles, nanostructured lipid carriers, and polymeric matrices are being investigated to achieve controlled drug release, enhanced stability, and improved bioavailability. Additionally, the growing adoption of Quality-by-Design (QbD) principles and advanced formulation analytics has enabled more systematic optimization of self-emulsifying systems.

Emerging technologies such as artificial intelligence (AI) and machine learning are also beginning to influence formulation development by facilitating excipient selection, formulation prediction, and process optimization. Collectively, these advances are transforming SEDDS and S-SEDDS into increasingly sophisticated platforms capable of supporting next-generation and personalized oral drug delivery strategies.

XI. CHALLENGES AND REGULATORY PERSPECTIVES

Despite the considerable success of Self-Emulsifying Drug Delivery Systems (SEDDS) and Solid Self-Emulsifying Drug Delivery Systems (S-SEDDS) in enhancing the oral delivery of poorly water-soluble drugs, several formulation, manufacturing, and regulatory challenges continue to limit their widespread application. One of the primary concerns is the selection of suitable excipients capable of providing efficient self-emulsification while maintaining long-term physicochemical stability. Variations in oil composition, surfactant concentration, and environmental conditions may influence droplet size, drug precipitation behavior, and formulation performance during storage and administration.

Another significant challenge relates to the use of high concentrations of surfactants. Although surfactants are essential for spontaneous emulsification, excessive amounts may cause gastrointestinal irritation, alter membrane integrity, and raise safety concerns, particularly during chronic therapy. Furthermore, predicting the in vivo behavior of SEDDS remains complex because lipid digestion, bile salt interactions, food effects, and physiological variability can significantly influence drug absorption and bioavailability.

For S-SEDDS, additional challenges include maintaining self-emulsification efficiency following solidification, ensuring uniform drug distribution within solid carriers, and achieving scalable manufacturing processes. Variability in solidification techniques may affect formulation reproducibility and product performance, requiring careful process optimization and quality control.

From a regulatory perspective, lipid-based formulations present unique evaluation requirements due to their complex composition and dynamic behavior within the gastrointestinal environment. Regulatory agencies emphasize comprehensive characterization of formulation components, excipient safety, stability profiles, dissolution performance, and in vivo bioavailability. The implementation of Quality-by-Design (QbD) principles, risk-based assessment strategies, and robust analytical methodologies has become increasingly important for regulatory approval. Addressing these scientific and regulatory challenges will be essential for facilitating the successful translation of SEDDS and S-SEDDS from research laboratories to commercially viable pharmaceutical products.

XII. FUTURE PERSPECTIVES

The future of Self-Emulsifying Drug Delivery Systems (SEDDS) and Solid Self-Emulsifying Drug Delivery Systems (S-SEDDS) is closely linked to the growing demand for advanced oral delivery technologies capable of addressing the

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challenges associated with poorly water-soluble drugs. As an increasing proportion of newly developed drug candidates exhibit low aqueous solubility, self-emulsifying systems are expected to play an increasingly important role in enhancing oral bioavailability and therapeutic performance.

Future research is likely to focus on the development of advanced lipid-based platforms with improved drug-loading capacity, greater formulation stability, and enhanced control over drug release behavior. The integration of SEDDS with nanotechnology-based systems, including nanostructured lipid carriers, polymer–lipid hybrid systems, and multifunctional nanocarriers, offers promising opportunities for achieving targeted and site-specific drug delivery. Such hybrid approaches may further improve absorption efficiency while minimizing variability in drug exposure.

Another important area of advancement involves the optimization of lymphatic drug transport. A deeper understanding of lipid digestion, chylomicron formation, and intestinal absorption mechanisms may facilitate the rational design of formulations capable of maximizing lymphatic uptake and reducing first-pass metabolism. These developments could be particularly beneficial for highly lipophilic drugs, biologics, and compounds with poor pharmacokinetic profiles.

The application of artificial intelligence, machine learning, and computational modeling is also expected to transform formulation development by enabling predictive excipient selection, optimization of formulation variables, and accelerated product development. In addition, the adoption of Quality-by-Design (QbD) principles and advanced analytical technologies will support more robust and reproducible formulations.

Overall, continued innovations in lipid science, formulation engineering, and digital technologies are expected to expand the capabilities of SEDDS and S-SEDDS, strengthening their role as versatile platforms for next-generation oral drug delivery and facilitating their translation into clinically successful pharmaceutical products.

XIII. CONCLUSION

The oral delivery of hydrophobic and poorly water-soluble drugs continues to represent a significant challenge in pharmaceutical development due to limitations associated with poor dissolution, low gastrointestinal absorption, and extensive first-pass metabolism. Self-Emulsifying Drug Delivery Systems (SEDDS) have emerged as an effective lipid-based strategy for overcoming these barriers by enhancing drug solubilization, promoting rapid emulsification, improving dissolution behavior, and facilitating intestinal absorption. In addition to increasing drug solubility, SEDDS offer the unique advantage of enhancing lymphatic transport, thereby reducing hepatic first-pass metabolism and improving systemic bioavailability of highly lipophilic therapeutic agents.

This review has highlighted the fundamental principles of SEDDS, including their formulation components, self-emulsification mechanisms, solubility enhancement pathways, and role in lymphatic drug delivery. Particular emphasis has been placed on the evolution of conventional liquid SEDDS into Solid Self-Emulsifying Drug Delivery Systems (S-SEDDS), which successfully combine the biopharmaceutical benefits of lipid-based formulations with the stability, convenience, and manufacturing advantages of solid dosage forms. Advances in solidification technologies, formulation optimization strategies, and characterization methodologies have further expanded the applicability of S-SEDDS for a wide range of therapeutic compounds.

The growing integration of supersaturable systems, nanoemulsifying technologies, hybrid lipid-based carriers, and data-driven formulation approaches has accelerated the development of next-generation self-emulsifying platforms. Despite existing challenges related to excipient selection, formulation stability, scale-up, and regulatory evaluation, continuous progress in lipid science and pharmaceutical engineering is strengthening the translational potential of these systems.

Overall, SEDDS and S-SEDDS represent versatile and highly promising drug delivery platforms capable of addressing solubility-limited absorption and enhancing oral bioavailability. Their ability to improve therapeutic performance, support lymphatic targeting, and accommodate emerging pharmaceutical technologies positions them as key contributors to the future of advanced oral drug delivery and patient-centered therapeutics.

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