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Self-Emulsified Nanoparticles: Recent Advancements in Formulation, Characterization and Therapeutic Applications (2020–2025)

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Abstract: Self-emulsifying nanoparticle systems commonly classified as self-emulsifying drug delivery systems (SEDDS), self-microemulsifying drug delivery systems (SMEDDS) and self-nanoemulsifying drug delivery systems (SNEDDS) remain among the most clinically translatable lipid based nanocarrier platforms for overcoming poor aqueous solubility and limited oral bioavailability of drug candidates. Between 2020 and 2025, the field has progressed substantially beyond conventional liquid isotropic mixtures toward solidified, stimuli responsive, mucus penetrating and biologics compatible platforms. This review synthesizes recent literature on the composition, mechanism, classification and evaluation of self-emulsifying nanoparticles, with an emphasis on advances reported over the past five years, including Quality by Design (QbD) and *in- silico* guided formulation, solidification technologies such as hot melt extrusion and twin screw melt granulation, hydrophobic ion pairing and reverse micelle strategies for oral peptide and protein delivery, permeability modulating approaches for Biopharmaceutics Classification System (BCS) class III drugs, and applications in oncology, ocular delivery and functional foods.

Keywords: Self-nanoemulsifying drug delivery system, Oral bioavailability, Lipid based nanocarriers, Solid self-emulsifying systems, oral peptide delivery.

Introduction

An estimated 40% or more of new chemical entities in the pharmaceutical development pipeline, and up to 90% of molecules in discovery stage libraries, are poorly water soluble, presenting a persistent barrier to oral drug development [1]. Self-emulsifying nanoparticle systems address this challenge by presenting the drug pre dissolved within an isotropic blend of oil, surfactant and co-surfactant/co-solvent that spontaneously forms fine oil in water emulsion droplets upon exposure to gastrointestinal fluids under the mild agitation provided by peristalsis [1,2]. Depending on the resulting droplet size, these systems are conventionally described as SEDDS (100 nm–5 μm), SMEDDS (<100–200 nm, thermodynamically translucent microemulsions) or SNEDDS (droplets generally below 100–200 nm formed spontaneously without energy input, giving a kinetically stable nanoemulsion) [1,2]. Because the drug is already solubilized within the lipid vehicle prior to dilution, self-emulsifying nanoparticle systems bypass the dissolution step that normally rate limits absorption of Biopharmaceutics Classification System (BCS) class II and IV drugs, while the resulting nanodroplets increase interfacial surface area, promote micellar solubilization by bile salts, and can engage the intestinal lymphatic pathway to partially evade hepatic first pass metabolism [1,3]. Over the 2020–2025 period, research interest has broadened considerably beyond small molecule solubility enhancement toward robust solidification of liquid SNEDDS for improved stability and patient acceptability, systematic QbD and computationally guided formulation design, oral delivery of peptides, proteins and nucleic acids via hydrophobic ion pairing and reverse micelle engineering, permeability modulating strategies for hydrophilic BCS class III drugs and targeted applications in oncology, ophthalmology and functional foods [2-7]. This review consolidates these advances with an emphasis on primary literature published between 2020 and 2025.

Composition and Mechanism of Self-Emulsification

A typical self-emulsifying nanoparticle formulation contains an oil phase (natural, semi-synthetic or synthetic medium/long chain triglycerides or mixed mono-/di-/tri-glycerides), a non-ionic surfactant (commonly polysorbates, polyoxyl castor oils, or polyglycolyzed glycerides with HLB > 10), and a co-surfactant or co-solvent (short chain alcohols, propylene glycol, PEG-400 or Transcutol HP) that reduces interfacial tension sufficiently to allow spontaneous emulsification [1,8]. When such a preconcentrate contacts aqueous gastrointestinal fluid, water penetrates the interfacial film formed by the surfactant, and the free energy required for emulsification is very low or negative because of the substantial reduction in interfacial tension, allowing droplets to form spontaneously rather than through mechanical energy input [1]. Pouton's biopharmaceutical classification system stratifies these formulations into Type I (oils only), Type II (SEDDS; oils plus water insoluble surfactants), Type IIIA/B (SMEDDS/SNEDDS; increasing hydrophilic surfactant and co-solvent content) and Type IV (surfactant/co-solvent systems without oil), with Type III systems containing higher proportions of hydrophilic surfactants (HLB > 12) generally producing the smallest, most rapidly dispersing nanoemulsion droplets and the greatest oral absorption enhancement [9]. Recent dielectric spectroscopy and molecular level studies have further characterized the micro structural organization, water uptake behavior and percolation phenomena of SNEDDS preconcentrates, providing mechanistic insight into the self-emulsification process at the molecular scale [10].

Classification Overview

Table 1: Classification of self-emulsifying nanoparticle systems (adapted from Pouton's Lipid Formulation Classification System and recent literature) [1,9].

Type	Composition	Approx. droplet size	Dispersion behavior
Type I	Oils (triglycerides/mixed glycerides) only	>1 μm (coarse emulsion)	Requires digestion by lipases for dispersion
Type II (SEDDS)	Oils + water-insoluble (lipophilic) surfactants	100 nm–5 μm	Disperses without loss of solvent capacity; slightly turbid
Type IIIA/IIIB (SMEDDS/SNEDDS)	Oils + hydrophilic surfactants ± co-solvents	20–200 nm	Spontaneous, rapid dispersion; near-optically clear to translucent
Type IV	Surfactant/co-solvent mixtures, little/no oil	<100 nm (micellar)	Very rapid dispersion; highest risk of drug precipitation on dilution

Recent Advancements (2020–2025)

Solidification Technologies for Solid SNEDDS

A major translational limitation of liquid SNEDDS has historically been packaging in soft gelatin capsules, physical/chemical instability on storage, and drug leakage or precipitation. Between 2020 and 2025, several solidification strategies have matured considerably. Hot melt extrusion (HME) has been used as a single step, solvent free process to convert liquid SEDDS into solid oral dosage forms; Kallakunta *et al.* developed and optimized HME based solid SEDDS using response surface methodology, demonstrating a scalable, continuous manufacturing route amenable to good manufacturing practice [11]. Related twin screw melt granulation approaches have likewise been used to produce solid SEDDS for lipophilic drugs in a single processing step, improving flow and compressibility while retaining self emulsification performance [12]. Hot melt extrusion has also been applied to specific actives such as quetiapine fumarate, where a central composite design was used to optimize solid SNEDDS produced via HME [13]. Spray drying remains one of the most extensively used solidification techniques; a 2023 review specifically evaluated spray drying as an effective method for converting liquid SEDDS into free flowing solid intermediates suitable for downstream tableting or capsule filling [14]. Adsorption onto porous, high surface area carriers (e.g., silicates such as Neusilin), liquid solid compaction, and freeze drying continue to be used, particularly for oncology actives; for example, a solid SEDDS of cabazitaxel prepared by solvent evaporation combined with liquid solid compression technology achieved an absolute oral bioavailability of approximately 17–20%, roughly an order of magnitude greater than the cabazitaxel

solution [1]. Tablet based solid SNEDDS platforms have also been reported, including statistically optimized tablets containing pitavastatin loaded SNEDDS [9].

Quality by Design (QbD) and *In Silico* Guided Formulation Design

Systematic, risk based formulation development has become a defining feature of recent SNEDDS research. A 2025 narrative review synthesizing publications from 2020–2025 concluded that QbD frameworks anchored to a defined Quality Target Product Profile (QTPP) and integrated with Design of Experiments (DoE) to evaluate critical material and process attributes substantially improve the robustness and reproducibility of SNEDDS formulations, while *in silico* molecular modelling (e.g., molecular docking and dynamics simulations of drug excipients interactions) increasingly complements empirical screening of oils, surfactants and co-surfactants [7]. QbD driven optimization has been applied to a wide range of actives, including bedaquiline loaded SNEDDS for multidrug resistant tuberculosis, in which critical quality attributes such as globule size, polydispersity index and drug release were optimized using a central composite design, yielding a formulation with improved biopharmaceutical attributes and favorable *in vitro* safety in A549 cells [15]. QbD approaches have similarly been used for ocular SNEDDS formulations, including co-loaded resveratrol melatonin systems optimized by full factorial design of experiments for ocular administration [16].

Oral Delivery of Peptides, Proteins and Nucleic Acids

Perhaps the most rapidly expanding application area for self-emulsifying nanoparticle systems since 2020 is oral macromolecule delivery. Because native peptides and proteins are too hydrophilic to partition into the lipid phase of SEDDS, hydrophobic ion pairing (HIP) with oppositely charged surfactant counter ions is used to lipophilize the macromolecule sufficiently for incorporation, while protecting it from intestinal proteolysis and improving mucus permeation [17-18]. Building on this concept, Jorgensen *et al.* introduced SEDDS containing reverse micelles as an alternative to conventional HIP for incorporating peptide drugs such as polymyxin B, addressing the limitation that HIP efficiency depends on the number of ionizable groups on the peptide [19]. Zwitterionic surface engineering, using phospholipids such as dilauroyl phosphatidylcholine, has also been explored to confer mucus penetrating properties to self-assembled nanoparticles for oral peptide delivery. Clinically relevant examples include a mucoadhesive auto nanoemulsifying (SNEDDS) system evaluated for oral insulin administration, in which mucoadhesive excipients were combined with the self-emulsifying core to prolong intestinal residence time and improve insulin absorption [5], and nanoplatforms based on SNEDDS designed for co-delivery of siRNA together with anticancer drugs, illustrating extension of self-emulsifying nanocarriers beyond peptides to nucleic acid therapeutics [6]. Reviews covering the wider field emphasize that solid lipid nanoparticles, nanostructured lipid carriers and SEDDS are currently regarded as among the most promising lipid based platforms for improving the oral bioavailability of therapeutic peptides, primarily through protease protection and mucus permeation enhancement [17-18].

Permeability Modulating Approaches for BCS Class III Drugs

While SNEDDS were originally developed to enhance the solubility limited absorption of BCS class II/IV drugs, a growing body of 2024–2025 literature addresses their use as nanocarrier platforms for permeability modulating approaches (PMAs) applicable to BCS class III drugs, which are highly soluble but poorly permeable. A 2025 review catalogued strategies including ion pairing, phospholipid complexation and surfactant drug interactions that are embedded within the lipid phase of SNEDDS to transform hydrophilic BCS class III actives into nano dispersible, more permeable species, thereby combining the solubilization capacity of the SNEDDS ternary system with targeted permeability enhancement [2].

Oncology Applications

Self-nanoemulsifying platforms have been increasingly investigated for anticancer drug delivery, often combining solid-SNEDDS technology with co-delivery of a chemo sensitizer or natural adjuvant to achieve synergistic cytotoxicity while mitigating systemic toxicity. Representative examples include a solid SNEDDS co-loading docetaxel with the natural monoterpenoid carvacrol, which improved anticancer activity while conferring a safer toxicity profile relative to docetaxel alone, evaluated across *in vitro*, *ex vivo* and *in vivo* pharmacokinetic models [3]; a solid self-nanoemulsifying nanoplatform co-loading tamoxifen and resveratrol for breast cancer, exploiting resveratrol's P-glycoprotein inhibitory and antioxidant activity for synergistic effect; and a SNEDDS based approach for AC1497, a dual malate

dehydrogenase 1/2 inhibitor targeting cancer metabolism, in which the SNEDDS formulation markedly improved dissolution and oral bioavailability relative to the free drug [20]. Reviews specifically addressing herbal anticancer agents highlight SEDDS as a focused strategy for improving the oral bioavailability of poorly soluble phytochemicals used in colorectal cancer therapy [21].

Ocular, Mucosal and Other Non-Oral Routes

Self-nanoemulsifying systems have expanded beyond the oral route into ocular and mucosal delivery, exploiting their small droplet size and capacity to enhance corneal/conjunctival permeation. Zingale *et al.* formulated co-loaded resveratrol melatonin SNEDDS for ocular administration using design of experiments optimization, targeting antioxidant protection of ocular tissue [16], while QbD based SNEDDS have also been developed for ocular delivery of flurbiprofen, aiming to improve precorneal residence time and anti-inflammatory efficacy relative to conventional eye drops. These developments illustrate a broadening of self-emulsifying nanoparticle technology from a purely oral bioavailability tool toward a general purpose nanocarrier platform for poorly soluble actives across multiple mucosal routes.

Functional Food and Nutraceutical Applications

SNEDDS have also attracted interest in functional food formulation for delivery of lipophilic nutraceuticals such as curcumin and resveratrol. A thermodynamic and molecular perspective on SNEDDS specifically discusses their potential applications in functional foods, given the generally recognized safety of pharmaceutical grade oils and surfactants used in these systems and their capacity to improve the oral absorption of dietary polyphenols. Curcumin loaded self-nano/micro emulsifying systems have demonstrated enhanced antioxidant and anti-inflammatory effects relative to unformulated curcumin [22], and resveratrol self micro/nanoemulsifying systems have shown improved intestinal permeability and oral bioavailability in preclinical models, supporting their translational potential in nutraceutical and functional food contexts [23-24].

Characterization of Self-Emulsifying Nanoparticle Systems

Robust physicochemical characterization underpins both formulation optimization and regulatory acceptance of self-emulsifying nanoparticle systems. Commonly reported evaluation parameters, drawn from the 2020–2025 literature discussed above, are summarized in Table 2.

Table 2: Representative characterization techniques and critical quality attributes reported for SNEDDS/SEDDS in recent literature [3, 7, 10, 13, 15, and 16]

Parameter	Typical method	Purpose
Droplet/globule size & PDI	Dynamic light scattering (DLS)	Confirms nano-range dispersion and homogeneity after aqueous dilution
Zeta potential	Electrophoretic light scattering	Indicates colloidal stability of the dispersed droplets
Self-emulsification time / efficiency	Visual/turbidimetric dispersion test (USP dissolution apparatus)	Assesses spontaneity and completeness of emulsification
Thermodynamic stability	Heating–cooling cycles, freeze thaw, centrifugation	Screens for phase separation, creaming or cracking
Phase behavior	Pseudo-ternary phase diagrams	Identifies self-emulsifying region for oil:surfactant:co-surfactant ratios
Solid-state properties	DSC, PXRD	Confirms amorphization/molecular dispersion of drug in solid SNEDDS
Morphology	TEM, SEM, cryo-TEM	Visualizes droplet/particle shape and surface characteristics
Dielectric/microstructural behavior	Dielectric spectroscopy	Probes water-uptake and percolation phenomena during emulsification
In vitro release / dissolution	Dialysis bag, USP paddle/basket apparatus	Evaluates drug release kinetics from liquid or solid SNEDDS
Permeability	Caco-2 monolayers, single-pass intestinal perfusion (SPIP), ex vivo everted gut sac	Predicts intestinal absorption and permeability enhancement

Pharmacokinetics	In vivo oral bioavailability studies (AUC, Cmax, Tmax)	Confirms translational benefit relative to free drug/solution
Stability	ICH long-term/accelerated storage studies	Establishes shelf-life of liquid or solidified formulations

Representative Self-Emulsifying Nanoparticle Formulations (2020–2025)

Table 3: Selected self-emulsifying nanoparticle formulations reported between 2020 and 2025, illustrating diversity of actives, technologies and therapeutic goals.

Active/cargo	Platform / technology	Key reported outcome	References
Clofazimine	SNEDDS (liquid)	Improved oral absorption via extensive lymphatic transport	[4]
Quetiapine fumarate	Solid SNEDDS via hot-melt extrusion, CCD-optimized	Improved solid-state stability and processability	[13]
Insulin	Mucoadhesive auto-nanoemulsifying (SNEDDS)	Prolonged intestinal residence, improved oral insulin absorption	[5]
Resveratrol + melatonin	Ocular SNEDDS (DoE-optimized)	Enhanced ocular antioxidant delivery	[16]
siRNA + anticancer drug	SNEDDS nanoplatform (co-delivery)	Combined nucleic-acid/small-molecule oral transport	[6]
Docetaxel + carvacrol	Solid SNEDDS (co-loaded)	Synergistic anticancer activity, safer toxicity profile	[3]
Bedaquiline	QbD-optimized SNEDDS	Improved biopharmaceutical attributes for MDR-TB therapy	[15]
Pitavastatin	SNEDDS-loaded tablets	Statistically validated tablet performance	[9]
Erlotinib	Solid S-SNEDDS	Enhanced stability and oral bioavailability	[8]
Quercetin	Supersaturable SEDDS	Improved drug loading and oral bioavailability	[23]
Polymyxin B (model peptide)	SEDDS containing reverse micelles	Alternative to HIP for peptide incorporation	[19]
AC1497 (anticancer candidate)	SNEDDS	Markedly enhanced dissolution and bioavailability	[20]
Curcumin	Self-nano/microemulsifying systems	Enhanced antioxidant and anti-inflammatory effect	[22]
Resveratrol	Self-microemulsifying system	Enhanced intestinal permeability (SPIP studies)	[24]

Translational Challenges and Future Perspectives

Despite substantial formulation progress, several challenges continue to limit the clinical translation of self-emulsifying nanoparticle systems:

- Drug loading capacity remains limited for high dose or highly hydrophilic actives, constraining applicability to potent, low dose molecules or requiring hydrophobic ion pairing strategies for macromolecules [17-19].
- *In vitro in vivo* correlation remains imperfect, since standard dissolution testing does not fully replicate the dynamic digestion, bile salt mixed micelle formation and lymphatic uptake processes that occur *in vivo* [1-2].
- Long term physical and chemical stability of liquid preconcentrates (oxidation of unsaturated lipids, capsule shell interactions, drug precipitation on storage) continues to motivate solidification research [11, 12, and 14].
- Excipient safety and gastrointestinal tolerability of high surfactant loads, particularly for chronic oral dosing, requires further evaluation, alongside regulatory clarity on novel excipient combinations [1, 7].

- Scale-up and manufacturability of continuous solidification technologies (hot melt extrusion, twin screw melt granulation, spray drying) require further process validation for regulatory filings [11, 12, 14].

Looking forward, the convergence of Quality by Design frameworks with *in silico* molecular modelling and machine learning assisted excipients screening is expected to accelerate rational SNEDDS design and reduce empirical trial and error optimization [7]. Continued expansion into oral macromolecule delivery supported by advances in hydrophobic ion-pairing, reverse micelle engineering and mucus penetrating surface modification together with growing application in oncology, ophthalmology and functional foods, suggests that self-emulsifying nanoparticle platforms will remain an active and clinically relevant area of pharmaceutical nanotechnology research through the remainder of the decade [2, 6, 16, 19].

Conclusion

Self-emulsifying nanoparticle systems have evolved considerably over 2020–2025, moving from largely empirical, liquid-only oral bioavailability enhancers toward systematically optimized, solidified, and increasingly biologics compatible nanocarrier platforms. Advances in solidification technology, Quality by Design and *in silico* guided formulation, hydrophobic ion pairing and reverse micelle strategies for peptide/protein delivery, permeability modulation for BCS class III drugs, and targeted oncology and ocular applications collectively illustrate the versatility of this platform. Continued interdisciplinary work spanning formulation science, computational modelling and translational pharmacokinetics will be required to fully realize the clinical potential of self-emulsifying nanoparticle systems.

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