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Self-Emulsifying Drug Delivery System: Transition from Liquid to Solid

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Abstract:

Self-emulsifying drug delivery systems (SEDDS) represent an innovative approach to improving the solubility and bioavailability of poorly water-soluble drugs, addressing significant challenges associated with oral drug delivery. This review highlights the advancements and applications of SEDDS, including their transition from liquid to solid forms, while addressing the formulation strategies, characterization techniques, and future prospects in pharmaceutical sciences. Characterization techniques such as droplet size analysis, dissolution studies, and solid-state evaluations are detailed. Additionally, emerging trends, including 3D printing, hybrid systems, and super saturable SEDDS (Su-SEDDS), are explored. Liquid SEDDS (L-SEDDS) enhance drug solubility and absorption by forming emulsions upon contact with gastrointestinal fluids. However, they suffer from stability and leakage issues. Transitioning to solid SEDDS (S-SEDDS) has resolved these limitations, offering enhanced stability, scalability, and patient compliance. Innovations such as personalized 3D-printed SEDDS, biologics delivery, and targeted systems demonstrate their potential for diverse therapeutic applications. Computational modeling and in silico approaches further accelerate formulation optimization. SEDDS have revolutionized drug delivery by improving bioavailability and enabling precise, patient-centric therapies.

Keywords: SEDDS, bioavailability enhancement, 3-D printing, drug solubility, optimization.

Introduction

The oral route is the most favored route of administration due to ease of administration and thus improved patient compliance. However, low oral bioavailability due to poor aqueous solubility or permeability or both is still the significant challenge encountered by a formulator during developing a pharmaceutical product for the successful achievement of the desired in vivo performance for better therapeutic outcomes. The introduction of high-throughput screening to the drug discovery process has led to numerous lipophilic and poorly water-soluble new chemical entities. The poor solubility of these new chemical moieties poses a major challenge to formulation scientists during the formulation development of the brand and generic products. Generally, drug absorption is mainly dependent on two factors: solubility

and permeability. In 1995, Amidon et al. introduced the Biopharmaceutics Classification System (BCS) that classified drugs into four categories based on these two factors. Among the four BCS classes. Class II and IV drugs show poor aqueous solubility and low bioavailability. Thus, improving the dissolution profile of drugs within the BCS Class II and IV is a major challenge for researchers during the oral delivery of these drugs.

Advantages

a) Enhanced solubility of poorly water-soluble drugs:

Significantly increase the surface area for drug dissolution.

b) Improved oral bioavailability:

By overcoming solubility/dissolution limitations, SEDDS often lead to higher absorption and better bioavailability especially of lipophilic drugs.

c) Reduced dose required:

Because more of the drug is absorbed, lower doses may achieve the same therapeutic effect, which can reduce cost, side-effects or toxicity. More consistent drug absorption /reduced variability.

Classification

a) Conventional SEDDS, SMEDDS, and SNEDDS

Self-emulsifying drug delivery systems (SEDDS) are categorized based on their droplet size, stability, and bioavailability. These systems also differ significantly in the types of oils, surfactants, and co-surfactants used, which influence their self-emulsification efficiency and overall performance. Conventional SEDDS primarily use long-chain triglycerides, while SMEDDS and SNEDDS incorporate medium- and short-chain triglycerides, enabling improved emulsification and absorption. Furthermore, SMEDDS and SNEDDS rely on high-HLB surfactants and specific co-surfactants to achieve superior stability and bioavailability.

b) Lipid Formulation Classification System (LFCS)

Lipid-based formulations are systematically classified under the Lipid Formulation Classification System (LFCS) to facilitate their selection and optimization based on drug characteristics and therapeutic goals. The LFCS categorizes formulations into four types (I–IV), with SEDDS primarily falling under Types II and III.

Method of Preparation

a) Solidification techniques for transforming liquid/semisolid:

Various solidification techniques are as listed below; 1) Capsule filling with liquid and semisolid self-emulsifying formulations: Capsule filling is the simplest and the most common technology for the encapsulation of liquid or semisolid SE formulations for the oral route.

For semisolid formulations, it is a four step process: A) Heating of the semisolid excipient to at least 20˚C above its melting point. B) Incorporation of the active substances (with stirring). C) Capsule filling with the molt cooling to room temperature. For liquid formulations, it involves a two-step process. D) Filling of the formulation into the capsules followed by sealing of the body and cap of the capsule, either by banding or by micro spray sealing.

b) Spray drying:

Essentially, this technique involves the preparation of a formulation by mixing lipids, surfactants, drug, solid carriers, and solubilization of the mixture before spray drying. The solubilized liquid formulation is then atomized into a spray of droplets. The droplets are introduced into a drying

chamber, where the volatile phase (e.g. the water contained in an emulsion) evaporprepared into tablet pattern and the drying chamber design are selected according to the drying characteristic the product and powder specification.

c) Adsorption to solid carriers: Free flowing powders may be obtained from liquid SE formulations by adsorption to solid carriers. The adsorption process is simple and just involves addition of the liquid on to carriers by mixing in a blender.

d) Melt granulation:

Melt extrusion is a solvent-free process that allows high drug loading (60%), as well as content uniformity. Extrusion is a procedure of product of uniform shape and density, by forcing it through a die under controlled temperature, product flow, and pressure conditions.

Challenges Of Self-Emulsifying Drug Delivery Systems

a) High surfactant concentration & toxicity risk

- SEDDS require 30–60% surfactants for rapid emulsification.
- High surfactant levels can cause GI irritation, diarrhea, or nausea.

b) Limited drug loading for hydrophilic drugs

- SEDDS are most suitable for lipophilic drugs (BCS class II/IV).
- Hydrophilic drugs show poor solubilization in lipid-surfactant systems.

c) Drug precipitation after dilution

- Upon dispersion in GI fluids, the solubilized drug may precipitate due to dilution, pH changes, or bile salt interaction.
- Leads to reduced bioavailability.

d) Stability & storage issues

- Liquid SEDDS can suffer from leakage, phase separation, and capsule incompatibility.
- Solidification techniques help but add cost & complexity.

Future Perspectives

a) Solid SEDDS (S-SEDDS) Development: Transforming liquid SEDDS into solid dosage forms (tablets, pellets, capsules) improves stability, handling, storage, and patient compliance.

Techniques: adsorption on carriers, spray-drying, melt granulation, extrusion.

b) Supersaturated SEDDS (S-SEDDS)

- Incorporation of precipitation inhibitors (e.g., polymers like HPMC, PVP) to prevent drug crystallization after dilution in GI fluids.
- Ensures higher and sustained drug concentrations for absorption.

c) Targeted & Site-Specific Delivery

- Modification of SEDDS with mucoadhesive polymers, ligands, or nanoparticles can allow targeting of specific tissues (e.g., lymphatic targeting, brain delivery).
- Useful in cancer therapy, CNS disorders, and immunotherapy.

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