

Drawbacks of Self-Micro Emulsifying Drug Delivery System (SMEDDS) Developed by Poorly Soluble Drugs

Reena Evans*

Department of Pharmaceutical Science, Hanyang University, Ansan, South Korea

Commentary

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***For Correspondence:**

Reena Evans, Department of Pharmaceutical Science, Hanyang University, Ansan, South Korea

E-mail: evanr11q@gmail.com

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ABOUT THE STUDY

Self-Micro Emulsifying Drug Delivery System (SMEDDS) formulation for the improvement of bioavailability has become an essential technique. SMEDDS formulations do have several drawbacks, such as *in vivo* drug precipitation, formulation handling problems, restricted lymphatic absorption, a lack of predictive *in vitro* testing, and unsaturated fatty acid oxidation. Their potential use is constrained by these drawbacks. A SMEDDS formulation typically consists of a medication, oil, a surfactant, and a co-surfactant.

The primary factors to take into account before developing SMEDDS formulation oils are lipophilicity and medication dosage.

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A drug's ideal properties include low dose, log P 2, and limited first pass metabolism. For the oils carbon-containing Medium Chain Triglycerides (MCT) 6 to 12 are carried directly from the portal blood to the systemic circulation. Long Chain Triglycerides (LCT) with more than 12 carbon atoms per chain is carried by the intestinal lymphatic system. When choosing a surfactant, the HLB value and surfactant concentration must be taken into account. Co-surfactants provide an adaptable interfacial film that allows them to take on the many curved shapes needed to create microemulsions over a wide range of composition. Alcohols of a medium chain length (C3–C8) are frequently used.

Draw backs of SMEDDS

In gastrointestinal fluid, diluted SMEDDS experience drug precipitation. The benefit provided by the lipid-based formulation technique is eliminated when the medication precipitates out of the system. Drug precipitation frequently lowers the amount of drug needed for immediate action in the aqueous phase, which results in a delayed or diminished efficacy. After the SMEDDS formulation is diluted with aqueous medium in the gastrointestinal tract, the medication must continue to be partitioned inside the oil/water emulsion droplets. Supersaturation, nucleation, and crystal formation are the fundamentally three processes that make up the complicated process of drug precipitation.

The majority of SMEDDS formulations on the market come in soft gelatin capsule form. Gelatin capsules do have few disadvantages, including the cost of production, Transmissible Spongiform Encephalopathy (TSE), and consumer preference and religion. Lipophilic medicines are known to precipitate as a result of migration of volatile co-solvents into the shells of soft or hard gelatin capsules used in self-microemulsifying formulations. These issues fuel the market's need for an alternative to soft gelatin capsules. These days, HPMC-made capsules are the preferred substitute for animal gelatin ones. Liquid SMEDDS have issues with handling, stability, and storage.

The use of lymphatics as a target offers two key benefits over traditional absorption by the portal circulation. First, oral medication concentration that reaches the systemic circulation is increased because transport by the intestinal lymph avoids pre-systemic hepatic processing. Second, it might be possible to administer drugs to lymphatic organs at specific sites. Normal requirements for lymphatic transport include high log P and high triglyceride solubility. The amount of a medicine that enters lymphatics varies depending on the drug.

Lack of superior predictive *in vitro* models for evaluating the formulations is yet another barrier to the development of SMEDDS. Traditional dissolve techniques are ineffective because these formulations may require fat digestion in the gut before the medicine is released.

Lipids used in the production of SEDDS and SMEDDS are oxidized and polymorphized. Unsaturated fatty acids and their derivatives found in lipid excipients are prone to oxidation. Lipid soluble antioxidants must be used in the formulation of the capsules. To minimize polymorphic alterations of the excipient matrix caused by thermo-softening lipid excipients, specific process control is needed during application.