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SNEDDS FOR OMILEORATE THE DISSOLUTION OF BCS CLASS II DRUGS

Akkala Govardhan*[1], Gottemukkula Lakshmi Devi[1], Kavali Pavan Yadav[1], Kasula Arun Goud[1], Kavali Bhavana[1]

[1*]Department of Pharmaceutics, Zapthi Jankampally, Nagireddy Pet, Kamareddy, Telangana, India.

ABSTRACT

The significance of self-nanoemulsifying drug delivery systems (SNEDDS) in enhancing the solubility and bioavailability of hydrophobic drugs, which are often challenging to deliver effectively. SNEDDS, comprising oil, surfactant, co-surfactant and drugs, spontaneously form nanoemulsions upon dilution with water. This review highlights the basics, including composition, preparation, and characterization, as well as potential effects associated with oral delivery. It emphasizes SNEDDS' role in overcoming the limitations of poorly water-soluble drugs, presenting them as a proven method for enhancing solubility and bioavailability. The article also discusses the stability and formulation techniques of SNEDDS, including solidification for improved stability and controlled release options. Additionally, it underscores the advantages of SNEDDS, such as ease of large-scale production and patient compliance, while also addressing potential drawbacks. Finally, the abstract outlines the wide-ranging applications of SNEDDS, spanning various routes of administration beyond oral delivery, including parenteral, ophthalmic, intranasal and cosmetic applications. Overall, the abstract provides a comprehensive overview of SNEDDS, covering its mechanism, formulation excipients, recent advancements and biopharmaceutical aspects, while also highlighting its potential in enhancing the bioavailability of various drug classes.

KEYWORDS

SNEDDS, Solubility, Bioavailability, Dissolution and Nano-emulsion S.

Author for Correspondence:
Akkala Govardhan,
Department of Pharmaceutics,
Zapthi Tankampally, Nagireddy Pet,
Kamareddy, Telangana, India.
Email: govardhannani0613@gmail.com

INTRODUCTION

Oral route is the most convenient and preferable route for drug delivery system due to its safety, comfort, high patient compliance. However more than 40 percent of drugs delivered by oral route have limited therauptic effect due to poor solubility, low permeability and delayed onset of action. Due

to this many medicines have difficulties being developed as oral dosage forms1.

Based on solubility, dissolution and permeability the biopharmaceutical classification system [BCS] is evaluated. Based on these properties, the biopharmaceutical classification system (BCS) classifies the drugs into four categories: Class I. High solubility-high permeability; Class II. Low solubility-high permeability; Class III. High solubility-low permeability; Class IV. Low solubility low permeability. Since many of the drugs belong to BCS II and IV having low solubility and low permeability. These problems are addressed by using conventional and novel techniques[2].

S.No	Conventional Techniques	Novel Techniques
1	Salt formation	Lipid based formulation [SNEDDS/SMEDDS]
2	Use of co solvent	Solid, lipid nanoparticles [SLN]
3	Use of soluble prodrug	Nanostructured lipid carriers [NLC]
4	complexation	Inorganic nanocarriers

Among these lipid-based drug delivery systems, such as nanoemulsions have successfully demonstrated the potential to increase the solubility of drugs that are not highly water soluble They have developed an approach to increase drug bioavailability by prolonging the time so the drugs remains in the stomach, altering the biophysical barrier, enhancing drug solubilization and reducing drug metabolism. Having less toxicity, promoting lymphatic transport[3].

To date, the majority of research have concentrated on lipid-based formulations for enhancing the solubility and permeability of BCS II and class IV medicines when administered orally. The current review concentrates on mechanism, preparation methods, composition of SNEDDS and factors affecting the formulation of SNEDDS and its applications[4].

Self-emulsifying drug delivery systems (SEDDS)

These are lipid-based systems made up of uniform mixtures of oils, surfactants and co-solvents. Preconcentrates are were these are typically known as, and they are anhydrous. The SEDDS has spontaneously self-emulsified to create microemulsions or nanoemulsions with an average particle sizeof 200 nm or less under mild agitation in an aqueous phase[5].

TYPES OF SEDDS

Based on droplet size SEDDS are categorized into two types A) self-micro emulsifying drug delivery systems (SMEDDS) B] self-nano emulsifying drug delivery systems (SNEDDS). SEDDS is the term used to describe all types of self-emulsifying systems that contain a combination of oils, surfactants and co-solvents (or) co-surfactants. When the SMEDDS combination interacts with the aqueous environment in GIT, it produces a micro emulsion with the help of the mild agitation provided by the stomach and intestines' ability to digest. SNEDDS also describes systems that produce nano emulsions when distributed in aqueous fluids[6].

S.No	SNEDDS	SMEDDS
1	It is self-micro emulsifying drug delivery system	It is self nano Micro emulsifying drug delivery system
2	It is turbid in nature	It is transparent in nature
3	Large amount of energy is required for preparation as compared to nano emulsion	Less amount of energy is required for preparation as compared to nano emulsion
4	Droplet size is 100_300nm	Droplet size is less than 100nm
5	It is thermodynamically stable	It is thermodynamically and kinetically stable
6	It is optimized by ternary phase daigram	It is optimized by pseudoternary phase daigram

MECHANISM OF ACTION OF SNEDDS

Self-nanoemulsifying drug delivery systems (SNEDDS) are nanoemulsion preconcentrates or an anhydrous form of nanoemulsions.

↓

Preconcentrates are mixture of oil, surfactant, co-surfactant and drug.

↓

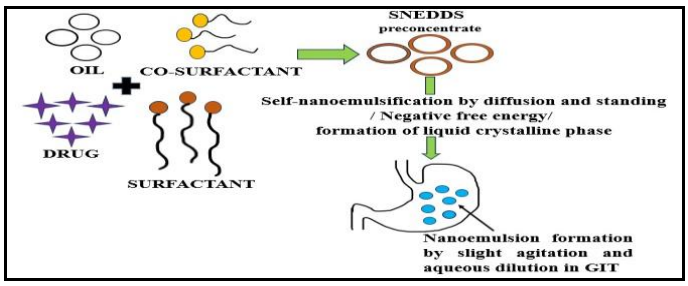
Upon introduction into the aqueous phase followed by gentle agitation with gastric motility the o/w nanoemulsions are formed.

↓

The fine droplets of drug dissolved in oilphase produces enhanced interfacial surface areafor dispersion to gastro intestinal fluid.

↓

The increased in interfacial surface area leads to increase in solubilization and permeability and also SNEDDS can bypass the first pass metabolism therefore fast onset of action will be achieved[7].



Mechanism of action of SNEDDS

ADVANTAGES OF SNEDDS

SNEDDS enhance the drug's bioavailability, which lowers the frequency of doses.

SNEDDS prevent the medication from the adverse GI tract environment.

SNEDDS improve the rate and extent of absorption

Drug partitioning among oil and water is made easier by SNEDDS, which increase the surface interfacial area.

SNEDDS made it easier for drugs to be distributed more widely throughout the GI tract and stomach, which reduced the irritation that comes from the drugs' prolonged contact with the gut walls.

SNEDDS manage controlled drug delivery profile[8].

DISADVANTAGES OF SNEDDS

Although traditional dissolving methods need digestion before dissolution, they cannot be used with supernatant-level dissolved solids (SNEDDS).

The *in vitro* models of SNEDDS need further research and validation for strength evaluation.

The *in vitro-in vivo* correlations of SNEDDS must be studied further.

Possibility of drug leakage and precipitation.

Higher amounts of surfactant used for formulation (30- 60%).

Higher production cost[9].

PREPARATION METHODS OF SNEDDS

The excipient, polymers, emulsifier and active medicinal ingredient are all components of the SNEDDS manufacturing process. Self-nano-emulsifying drug delivery systems can be prepared using a variety of techniques, however they are generally divided into two categories:

High-energy-emulsification

Low-energy-emulsification

The high-energy-emulsification method includes higher pressurized-homogenization (HPH), Ultra sonication and Micro-fluidization. The low-energy method includes Phase-inversion, Spontaneous emulsification[10].

High Energy Emulsification Method

High Energy Approach

When adopting a high energy technique, a nano emulsion forms based on the mixture's components, which include a surfactant, a co-surfactant, cosolvents and another functional chemical. Energy is employed to prepare the mixture. To produce a nanoemulsion, the emulsion is mechanically treated.

Micro fluidization

It is an important tool for identifying and producing Nanoemulsion. In the field of micro fluidization, a device called a "Micro Fluidizer" is used. This specific type of component is employed in a highpressure positive displacement pump (500-300 PSI) that drives the product through the interaction chamber. High-pressure positive displacement

pumps utilize micro channels, which are tiny channels droplets.

Very small submicron particles were created when the product was forced through microchannels and impinged on the impingement area. The inline homogenizer combines and produces two solutions with a mixture of aqueous and oil phase systems, resulting in a coarse emulsion. The coarse emulsion is processed in a micro fluidizer and then subjected to additional processing to produce a homogeneous, specific and stable nano emulsion.

Sonication Method

This technique is essential for measuring droplet size and for reducing droplet size in a typical emulsion utilizing a sonication mechanism. The energy-range is given through sonotrodes known to be Sonicator-probe. It can prevent the return of shattered excited volts by holding back the piezoelectric quartz precious stone that spreads out and tightens them. A mechanical throb is produced and captives are enrolled as the Sonicator's end tip makes contact with the liquid medium. The closure of liquid vapour cavities by the formation of crystals. Thus, ultrasounds canister straight produces an emulsion[11].

Low-energy-emulsification

Phase inversion emulsification method

This sort of technique is essential to produce nano- and microemulsions. The strategy is particularly dependent on the reaction to temperature. This method results in numerous physical changes, including physicochemical alterations, particle size and *in vivo-in vitro* drug release rate. Changing the system's temperature is frequently used to produce the non-ionic surfactant. The resulting in a transition from o/w nano emulsion was produced at low temperature and w/o Nanoemulsion was formed at higher temperature.

Continuous emulsification

In this system of emulsification is always formed. Whereas the hydrophilic-surfactant phase and miscible surfactant infill with grease and lipophilic-surfactant phase serve as the foundation for a uniform and standardized organic resolution. Under continuous enticing stirring, the organic point was injected into the aqueous stage, and string Oil-in-Water was created. As it disintegrated under concentrated pressure, the aqueous stage was unconcerned[12].

COMPOSITION OF SNEDDS FORMULATION

During the preparation of the SNEDDS, the following components are involved and should be taken into consideration**.**

Drugs

SNEDDs are frequently developed for medications with lower water solubility. In the majority of cases, BCS class II and class IV medications are frequently used in the production of SNEDDs. The performance of SNEDDS is significantly influenced by the physicochemical characteristics of the drug, including log P, pKa, molecular weight, presence of ionizable groups and quantity. Drugs with high melting points and log P values of less than 2 are not optimal for SNEDDS Lipophilic medications with log P values more than 5 are an ensuring choice for SNEDDS. Examples include Itraconazole, nifedipine, vitamin E, simvastatin, danazol, ketoconazole, mefanimicacid, carbamazepine, glibenclamide, cyclosporine-A, amphotericin B, furosemide, acetazolamide, ritonavir, paclitaxel etc.

Oils

The oil phase is essential for the production of SNEDDS because its physicochemical characteristics, such as its molecular volume, polarity, and viscosity, have a significant impact on the spontaneity of the nano emulsification process, droplet size, drug solubility and biological fate of nano emulsions. The oil phase's physicochemical properties, such as its molecular volume, polarity and viscosity, significantly affect the spontaneity of the nano emulsification process, droplet size, drug solubility and biological fate of nano emulsions. This makes the oil phase significant in the production of SNEDDS. The lipophilicity of the oil and concentration of the oily phase in SNEDDS have an inverse correlation with the nano emulsion size. In contrast to medium-chain tri-, di- and

mono-glycerides**,** long-chain triglycerides have shown a stronger capacity to improve lymphatic transport of medications (which in turn is in responsible for preventing first-pass metabolism of drugs). Whereas, medium-chain mono- and di-glycerides have greater permeation-enhancing characteristics and a higher tendency to solubilize hydrophobic drugs. Therefore, it will be challenging for a single oily component to provide the ideal properties for nano emulsification and drug administration. In certain cases, employing a mixture of oils also can be used to meet optimum properties of the oily phase. In general, a combination of oils is used to generate nanoemulsions and microemulsions, which are both produced using similar methods in order to have a high solubility for the added medicine.

In some cases, a mixture of fixed oil and medium-chain triglycerides is employed to maintain a good balance between drug loading and emulsification. Recently, SNEDDS with the calcium channel blocker lacidipine, which has a poor oral bioavailability, have been created by using a combination of oils. s(based on a three-component system: the oil phase X1 (a mixture of Labrafil®/Capmul®, 2:1, w/w), the surfactant X2 (a mixture of Cremophor®/Tween® 80, 1:1, w/w) and the co-surfactant X3

(Transcutol®)) and the authors reported high solubility of the drug in the selected components[13].

Surfactants

Surfactants are amphiphilic compounds with polar (water-soluble) and non-polar (water-insoluble) groups. They are commonly referred to as surface-active agents. It has the capacity to reduce interfacial tension and develop interfacial space. Surfactant characteristics including cloud point, viscosity, and affinity for the oily phase, as well as hydrophilic lipophilic balance (in oil), have a substantial impact on the nanoemulsification process, the self-nanoemulsification region, and consequently nanoemulsion droplet size.

Anionic surfactants

Potassium laurate, sodium lauryl sulphate

Cationic surfactant

Quaternary ammonium halide

Nonionic surfactants

Polysorbate (tweens), Sorbitan esters (Spans)

Co-surfactants/Co stabilizers

Glycofurol, Phospholipids, Propylene glycol, PEG, monoethyl ether, ethanol, triacetin.

Co-surfactants

It performs a similar role as the surfactant unit. In order to strengthen the effectiveness of the surfactant to improve the water solubility of poorly water-soluble drugs, co-surfactant was introduced alongside the surfactant unit or in combination with the surfactant unit. The primary objective of cosurfactants in SNEDDS is to reduce the oil-water interface, increase surface area, and facilitate the spontaneous generation of nanoemulsions. Co-surfactants having HLB values between 10 and 14 are utilized in SNEDDS. Medium-chain alcohols, such as hexanol, pentanol, and octanol, are hydrophilic co-surfactants that reduce the oil-water contact, facilitating the impulsive production of microemulsions[14].

Co-solvents

Typically, a high concentration of surfactant is necessary for an effective self-emulsifying formulation. As a result, co-solvents such ethanol, propylene glycol and polyethylene glycol are essential in order to facilitate in the dissolving of large amounts of hydrophilic surfactant. These co-solvents sometimes serve as co-surfactants in the microemulsion system. On the other hand, alcohol and other flammable cosolvents have the drawback of evaporating through the gelatin shell of soft or hard capsules, causing the drug to precipitate.

Aqueousphase

The addition of oils, surfactants, co-solvents, and drug molecules to an aqueous media results in the formation of SNEDDS. The pH of the stomach is often acidic (pH 1.5 to 2.5) and different ions in the GIT have a major impact on the properties of nanoemulsions in terms of their size and stability.

Construction of the ternary phase diagram

Once the suitable excipients have been chosen for the SNEDDS formulation, the ternary phase

diagram involving the surfactant, oil and solubilizer must be plotted to determine the self-emulsification region and the likely concentration of the components that could produce spontaneous nanoemulsions. After diluting the various compositions of the ternary phase diagram with the set amount of water, the droplet size of the emulsions or nanoemulsions is measured in order to evaluate the self-nanoemulsification zone in the ternary phase diagram. The area of spontaneous nanoemulsions and droplet sizes less than 200 nm are indicative of the self-nanoemulsification processes[15].

Actors affectring the formulation of snedds

Generally, SNEDDS has been formulated as a combination of oils, surfactants and co-surfactants or co-solvents; based on their properties, various factors affect the formulation of SNEDDS.

SNEDDS are not necessary for the drugs because they are administered at very high doses.

Lipids are the most difficult component for SNEDDS to administer because they are only partially soluble in water[16].

If the surfactant or co-surfactant is enabling to solubilize the medicine to a higher extent, there might be a possibility of precipitation.

The medication's solubility in the oily phase plays a key role in how effectively SNEDDS can maintain the drug in a solubilized state[17].

APPLICATIONS OF SNEDDS

It is employed for target-specific administration via transdermal, parenteral, intravenous, ocular, and intranasal routes.

Skin infections, lung infections and diabetes mellitus are just a few of the conditions that can be treated using SNEDDS.

In order to enhance the oral bioavailability of weakly water soluble drugs and improve their water solubility, the Self-Nanoemulsifying Drug Delivery System (SNEDDS) is essential.

For the delivery of macromolecules such peptides, hormones, and enzyme substrates, which are inhibitors that must be preserved from enzymatic degradation, SNEDDS, SMEDDS, and SEDDS are essential.

It is an innovative approach to the first pass metabolism and it can give 100 percent bioavailability by being instantaneously absorbed into the systemic circulation.

It acts as antimicrobial cosmetics industries[18].

ADVANCED TECHNOLOGY AND TRENDS OF THE SNEDDS

Supersaturated SNEDDS

Self-double nanoemulsifying drug delivery systems (SDEDDS)

Controlled release SNEDDS

Targeted SNEDDS

Super saturated SNEDDS

The lipid content of the SNEDDS has decreased, which has caused the SNEDDS's in vivo solubilizing potential to drop. Therefore, the drugs precipitate. A reduction in the surfactant's solvent capacity following dilution causes drugs that are more soluble in the surfactant than the lipid phase at risk of precipitating. The drug content of SNEDDS is typically lower than the equilibrium solubility due to the above reason. To overcome this drawback, supersaturated SNEDDS with hydrophilic precipitation inhibitors have been developed. Supersaturated SNEDDS with a hydrophilic precipitation inhibitor inhibit drug precipitation in the gastrointestinal system by establishing and sustaining a metastable supersaturated condition. 4. The polymeric precipitation inhibitors that are commonly incorporated in the SNEDDS include polyvinyl pyrrolidone, methyl cellulose, sodium carboxymethyl cellulose and hydroxypropyl methyl cellulose. Based on several research, supersaturated SNEDDS may enhance the bioavailability, dissolving rate and stability of medications including hydrocortisone, simvastatin, silybin and paclitaxel.

Self-double nanoemulsifying drug delivery systems (SDEDDS)

Oral SNEDDS administration of proteins and hydrophilic macromolecules is often challenging.

So, a promising technology that could be able to fix this issue is SDEDDS. The w/o/w spontaneous emulsions in SDEDDS are made up of a hydrophilic surfactant and w/o emulsions that spontaneously developed while being diluted with water and subjected to gentle agitation. SDEDDS can be applicable for proteins, peptides and other macromolecular medications including nattokinase and insulin. They have the ability to enhance medication efficiency by shielding these macromolecules from gastrointestinal tract enzymatic disintegration[19].

Controlled release SNEDDS

For medications that aren't extremely well soluble in water, SNEDDS can be used as prolonged release routes of administration. The following methods are employed to create controlled release SNEDDS: sustained release pellets, polymer coating, controlled release osmotic pump, and microencapsulation. Controlled release SNEDDS are made from a variety of polymers, including microcrystalline cellulose, hydroxypropyl methyl cellulose (HPMC), poly lactic glycolic acid (PLGA), and Gelucire. Melodipine SNEDDS that were created with Aerosil 200 as the gelling agent showed a longer release and the gelled SNEDDS were then encased in Gelucire, according to Patil *et al*.'s study.

Targeted SNEDDS

SNEDDS have the ability to be a targeted drug delivery by surface functionalization. Nanoemulsion droplets possess the capacity to remain in the bloodstream for a prolonged period of time. Cationic nanoemulsions can also directly attach to the anionic membrane barriers. The easiest technique to target the liver and spleen is to use lipid-based SNEDDS, which may be accepted by these organs. Additionally, SNEDDS have the potential to target macrophages and are particularly helpful for drugs that target the lymphatic system. The SNEDDS's surface developing for stealth characteristics can be accomplished by connecting with hydrophilic polymers. such as, PEGylation by polyethylene glycol. Attaching suitable ligands, such as antibodies and peptides of the target receptors, can result in both active and passive targeting[20].

CONCLUSION

The ability of SNEDDS research advancements to increase the oral bioavailability and solubility of class II medications has been thoroughly studied in recent years. An isotropic mixture of oils, surfactants, co-surfactant and co-solvent is known as a self-nanoemulsifying drug delivery system (SNEDDS). It spontaneously emulsifies in the aqueous phase with gentle agitation to produce fine o/w nanoemulsion. Simple and inexpensive methods and additives are employed in the formulation of SNEDDS. SNEDDS have proven to be effective in several commercial items and have increased concentrate in various research fields due to their simplicity of production and high physical stability. Adding polymer to the mixture using this approach might potentially enhance medication release. SNEDDS appears to be a novel, commercially feasible strategy for further advancement.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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