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Review Article

Self-Nanoemulsifying Drug Delivery System: Formulation, Characterization and Solidification Approaches

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Abstract

Self-nanoemulsifying drug delivery systems (SNEDDS) represent a transformative approach to overcoming the challenges of poor aqueous solubility and low oral bioavailability, which affect approximately 40% to 70% of new therapeutic moieties. These lipophilic drugs, often categorized as BCS Class II or IV, typically suffer from incomplete dissolution and precipitation in the gastrointestinal tract. SNEDDS are isotropic mixtures of drugs, oils, surfactants, and co-surfactants that spontaneously form fine oil-in-water nanoemulsions with droplet sizes of 200 nm or less when exposed to aqueous media and gentle agitation. This small particle size provides a massive interfacial area, significantly accelerating drug dissolution and enhancing absorption rates. The formulation process involves optimizing components through pseudo-ternary phase diagrams to identify ideal self-emulsification regions. While traditional SNEDDS are liquid-based, modern research focuses on converting them into solid forms (S-SNEDDS) using techniques like spray-drying, physical adsorption, and hot-melt extrusion. These solid dosage forms improve physical stability, reduce manufacturing costs, and prevent issues such as drug leakage or capsule shell interactions. Beyond oral delivery, SNEDDS show immense potential for ocular, transdermal, and parenteral applications. By protecting drugs from enzymatic degradation and providing consistent plasma profiles, SNEDDS stand as a commercially viable and scientifically robust strategy for enhancing the delivery of challenging lipophilic compounds in modern medicine. Therefore, the preparation, components, self nano emulsification process, biopharmaceutical features, characterization techniques, and applications of self-nanoemulsifying delivery systems (SNEDDS) are described in this study.

Keywords: Self-nanoemulsifying drug delivery systems; BCS Classification; LBDDS

1. Introduction

About 40-70% of the novel therapeutic moieties investigated recently fall into class II or IV of the biopharmaceutical classification system (BCS), which restricts their oral delivery due to their poor aqueous solubility[1]. One of the primary causes of the low oral bioavailability is the lipophilic nature of the drugs which causes them to partially dissolve and precipitate in the gastrointestinal (GI) fluids. Since the lipid-based drug delivery system greatly increases the oral bioavailability of these poorly soluble drug components, they are intriguing candidates[2]. LBDDS have become more and more popular recently because to their capacity to increase bioavailability and lessen the inconsistent dietary effect of poorly water soluble components. Lipids can be used as a drug delivery carrier in a variety of systems, such as emulsions, suspensions, and most enticingly self-nano emulsifying drug delivery systems (SNEDDS)[3]. SNEDDS was created to increase the therapeutic efficacy (bioavailability) and solubility of drug that are not very soluble in water.

This SNEDDS was the most effective in improving solubil ity by forming micelles. The SNEDDS are a fantastic substitute for conventional oral formulations because of their nano size[4]. The GI tract acts quickly as a result of the rapid drug release of SNEDDS inside the stomach caused by the formation of nanosized oil droplets as given in figure no. 1. The quick dispersion of SNEDDS and the ease with which a drug can be partitioned between oil and water result in a greater interfacial area[5].

SNEDDS are described as an isotropic or homogeneous mixture of drug, solid or liquid surfactant, and cosurfactant that tends to form fine oil in water (o/w) emulsion formulation following dilution in the gastrointestinal (GIT) aqueous fluid and slight agitation cause by peristaltic movement [6]. Every commercial product based on SEDDS is a liquid that is encapsulated in a soft gelatine capsule (Sandimmune, Neoral, Norvir,

Fortovase, Agenerase, Depakene, Rocaltrol, Targretin, Vesanoid, Accutane, and Aptivus) or a hard gelatine capsule (Gengraf, Lipirex, and Neoral) [8,9]. Only a small number of commercially viable solutions are available because of their high manufacturing costs, stability and mobility issues, potential for drug precipitation upon dilution, lack of predictive *in vitro* methodologies, and specialized manufacturing equipment[7].

Developing a solid dosage form of this liquid SEDDS to improve physical stability and reduce manufacturing costs is the most common approach to address these issues[7,8]. In nanoemulsions, ultrafine emulsions, and submicron emulsions, a drug experiences dissolution rate limiting absorption, which enhances the rate of drug absorption and shows repeatability of the plasma profile of drug concentration. As a result, SNEDDS may be regarded as nano emulsions that offers a high interfacial area for drug partitioning between oil and aqueous phase, improving drug dissolving rate and increasing drug formulation bioavailability [8].

Drugs of Classes III, II, and IV dissolve less readily in water. Class II and Class IV drug can improve their oral bioavailability and water solubility under the Self-Nanoemulsifying Drug Delivery System as explained in figure no. 2. SNEDDS is essential for preventing the enzymatic degradation problems related to Class I and Class III drugs in addition to enhancing solubility and bioavailability[9]. A schematic representation of the BCS, which has four kinds of systems according to the examination of permeability and solubil ity.

By avoiding a layer of decreased water insoluble solubility, lipidized formulations of Class II drugs improve absorption. They also demonstrate their breakdown in the stomach by transferring their membrane to the bile-salt mixed micellar phase this allows for easy absorption[8]. Because they are unable to forecast the effects in vivo, the drug's characteristics, such as its water solubility and log P, do not offer enough information on whether a lipid-based formulation is appropriate[10].

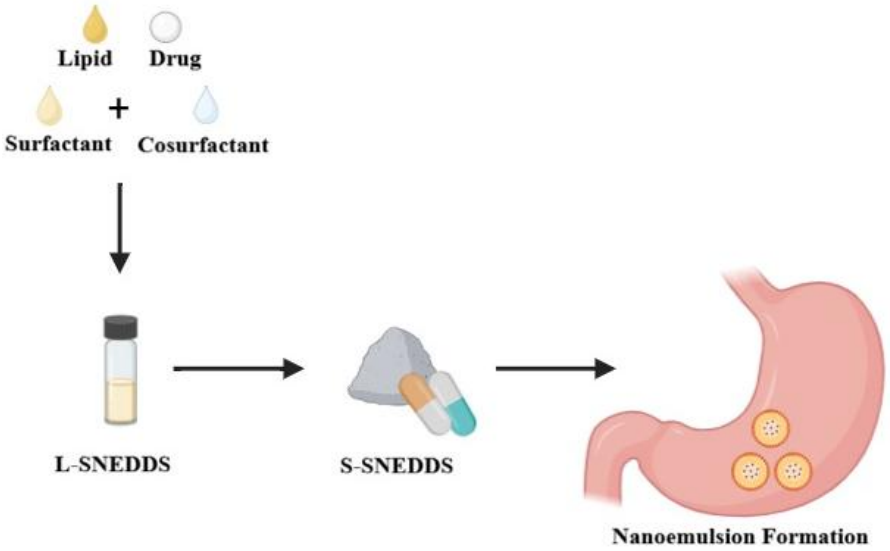

Figure 1: Self nano emulsion

2. Basic Principles of SNEDDS Formulation

Natural surfactants as well as and cosurfactants make up SNEDDS, a drug delivery system that autonomously forms a nanoemulsion in freshwater. Unlike nanoemulsions or microemulsions, SNEDDS is a hydrophobic preparation that, when in contact with stomach liquids, produces a nanoemulsion in situ[11]. This unique characteristic serves to improve physical stability during storage because the presence of an aqueous phase could lead to phase separation or deterioration prior to administration [10].

3. Mechanisms of SNEDDS

According to the organization, self-emulsification occurs when the entropy shift that encourages dispersion is greater than the energy required to increase the dispersion's surface area [12]. Equation 1 describes the free energy of a typical emulsion formation, which is a direct function of the energy needed to construct

$$\Delta G = \sum N i \pi r$$

Where N is the number of droplets of radius, r is the interfacial energy, and σ is the free energy related to the process[11].

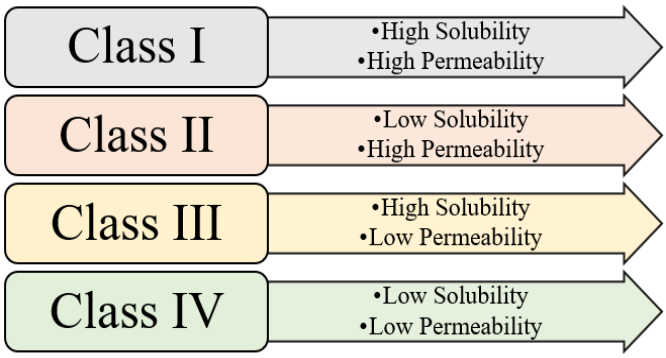

Figure 2: BCS Classification

4. Lipid Based Classification System

Lipid-Based system established LFCS in 2000 and it was most recently revised in 2006 to assist in grouping formulations into those with comparable component parts. Based on their composition and the potential impact of digestion and dilution on their capacity to avoid drug precipitation, the LFCS divides lipid based formulations into four categories. a schematic representation of the lipid formulation classification system and ingredient [11,12].

Type I: It includes formulations with the drug in solution in triglycerides, mixed glycerides, or an oil-in water emulsion stabilized by low emulsifier concentrations like 1.2% (w/v) lecithin and 1% (w/v) polysorbate 60 [13].

Type II: Isotropic mixture gets self-emulsified to generate thin oil-in-water emulsions are commonly known as self-emulsifying drug delivery systems, or SEDDS.

Type III: Generally, these are characterized of cosolvents such as ethanol, propylene glycol, and polyethylene glycol as well as hydrophilic surfactants (HLB >12). To find Type III formulations can be further separated (rather arbitrarily) into Type IIIA and Type IIIB formulations for more hydrophilic systems (Type IIIB), where the content of hydrophilic surfactants and cosolvents increases and the lipid content decreases[14]. Therefore, SMEDDS formulations (which contain higher concentrations of hydrophilic surfactants and co-solvents) disperse to give smaller droplets with particle sizes <100 nm and provide optically clear or slightly opalescent dispersions [15].

Type IV: Type IV formulations, which are devoid of natural lipids. These formulations create very fine particles and offer larger drug payloads since the drug is more soluble in the surfactants and co-solvents. Increased drug absorption and quick drug release result from this. The current capsule formulation of the HIV protease inhibitor amprenavir (Agenerase), which includes co-solvents and TPGS as a surfactant, is an example of a Type IV formulation[16-18.]

5. Composition of SNEDDS

5.1. Liquid/ Oils

SNEDDS are often made from oils with medium and long chain triglycerides (TG) that exhibit different levels of saturation. Because it has a significant impact on both formulations loading capacity. The oil that has the greatest capability to solubilize a particular drug is typically chosen[19]. The research revealed a demonstration that the highest drug absorption was observed in SNEDDS. Although they still make sense and are preferred oil ingredients, natural edible oils (such as castor, soybean, coconut, etc.) have a low drug loading capacity and poor emulsification efficiency usually used to improve the drug's solubility in the formulation [20,21]. The specific component had been diluted with methanol. Using a known formula, the total amount of the solubilized drug was calculated. The average findings from the three runs of the study were presented. All of the selected excipients were deemed human-safe and generally recognized as safe[22].

5.2. Surfactant

Surfactants ions are molecules that are adsorbed at the contact are known as surfactants. It is capable of providing interfacial area and preventing interfacial tension. Another crucial factor in the creation of SNEDDS [23]. The process of nano emulsification, the self-nano emulsification region, and consequently the nanoemulsion droplets are greatly influenced by surfactant characteristics such as hydrophilic lipophilic balance (in oil), cloud point, viscosity, and affinity for the oily phase. When choosing a surfactant, it is also necessary to take into account the surfactant's regulatory status and suitability for the intended administration method [24]. As reported in the literature, for selection of surfactant, 300 mg of the selected oil phase and 300 mg of the approved surfactant were mixed. The oil and surfactant were then encouraged to mix by vortexing the liquid for 60 seconds. This isotropic system was precisely weighed at 100 mg and then diluted with 25 mL of distilled water to produce a fine emulsion [24]. The transmittance percentage of the emulsions was measured at 638.2 nm using a UV VIS Spectrophotometer (UV1800, Shimadzu, Japan) after two hours of settling [25]. To identify which surfactant is best for a given function, a variety of surfactants have been tested for their ability to emulsify using double-distilled water as a control [26].

5.2.1. Classification of surfactants

1) Cationic surfactants: The hydrophilic group head of an ionic surfactant has an internal electrical charge. If the charge is positive, the surfactant is referred to as a cationic surfactant. Primary, secondary, tertiary amines and quaternary ammonium salts containing higher alkyl groups, such as octadecyl trimethyl ammonium chloride and C12-14alkyldimethylbenzyl ammonium chloride, are the principal types of cationic surfactants [27].

2) Anionic surfactants: The surfactant is referred to as anionic surfactant if the charge is negative. Typically, anionic surfactants Soybean phospholipids (lecithin), sodium lauryl sulfate, sodium laureth polyoxyethylene ether sulfate, sodium cetyl polyoxyethylene ether phosphate, fatty acid soaps, carboxyl ($RCOO^-$), sulphonate (RSO_3^-), or sulphate ($ROSO_3$). Sodium lauryl sulfate and potassium laurate.

3) Ampholytic surfactants: All positive and negative charges make up the surfactant unit. Sulfobetaines are an excellent illustration.

4) Non-ionic surfactants: Although the hydrophilic group is charge-free, it can have powerful polar functional molecules like polyoxyethylene or hydroxyl, which make it soluble in water (OCH_2CH_2O)[28].

5.3. Co- Surfactant

The emulsifying ability of co-surfactants should be considered more important than their solubilizing ability. Tests like as turbidity, transmittance, and flask inversions are performed to determine which surfactant and co-surfactant are best for creating SNEDDS. Because of their lower toxicity, non-ionic surfactants were generally

chosen over ionic ones[29]. Additionally, solubility of the drug has been raised by surfactants with a higher hydrophilic-lipophilic balance that create o/w solution and chain length of the co-surfactants have a significant impact on their performance. Because they cause water to permeate the interface, co-surfactants with shorter molecular chains were most frequently utilized[25]. Because of their shorter molecular chain length and improved miscibility with medium-chain triglycerides (MCT), lipophilic co-surfactants (such Imwitor 988) have a stronger emulsifying ability than hydrophilic co-surfactants[30].

6. Characterization of SNEDDS

6.1. Morphological Analysis

Morphological analysis is crucial since it offers details on the formulation's external appearance, including color, odor, consistency, density, and appearance. The globules in the (SNEDDS) have been examined using a transmission electron microscope (TEM) has been employed in the (SNEDDS) to investigate globules [27].

6.2. Thermodynamics Stability Studies

A lipid-based formulation's efficacy depends on its physical stability, which may be impacted by drug precipitation in the excipient matrix. Additionally, insufficient physical stability in the development can lead to excipient phase separation, which can impact both the composition's performance and appearance. Additionally, incompatibilities between the formulation and the gelatin capsule shell could lead to inefficient drug release, delayed disintegration, or cracking or deformation[27, 28].

6.3. Heating cooling cycle

The study participants examined six cycles with storage durations of at least 48 h at each temperature, ranging from 40°C [28].

6.4. Centrifugation

Centrifuged thaw cycles between 21°C and 25°C are carried out at 3500 rpm for 30 min with preservation at each temperature for at least 48 hours. Formulations without separation of the phases are subjected to the freezing and thawing stress test[27, 28].

6.5. Freeze thaw cycle

Freeze thawing the stability of SNEDDS. The formulations underwent three freeze thaw cycles, freezing for 24 h at 4°C and thawing for 24 h at 40°C. Centrifugation was carried out at 3000 RPM for five min. The preparations were then checked for phase separation. The substances indicated high stability [28].

6.6. Turbidimetric Evaluation

Nepheloturbidimetric analysis is used to track the development of emulsification. A turbidimeter was used to measure the increase in turbidity under continuous stirring (50 rpm) on a magnetic plate at room temperature set amount of self-emulsifying system to a determined quantity suitable medium (0.1N HCL). When the time needed for full emulsification is too short, it is hard to track the rate of turbidity change (rate of emulsification)[30].

6.7. Viscosity Determination

Soft or hard gelatin capsules are typically used to administer the SEDDS system. Because of this, pouring into capsules is often simple, and a system like this shouldn't be too thick to be problematic. The rheological characteristics of the micro emulsion are tested using a viscometer. Viscosity determines whether the system is water/oil or oil/water. Low viscosity indicates an o/w kind of system, while high viscosity indicates a w/o type of system [31].

7. Advantages of SNEDDS

a) SNEDDS lower dosage frequency by improving the drug's pharmacokinetics[32]

b) SNEDDS makes it possible to focus drugs selectively to a certain GI tract absorption window

c) SNEDDS have a very stable formulation and simple production methods

d) Broader distribution in GI tract was made possible by drug diffusion with SNEDDS, which lessened the irritation brought on by the drugs extensive contact with the gut walls[33]

e) SNEDDS protects the drug from the irritating GI tract environment.

f) SNEDDS improve drug partitioning between water and oil in terms of surface interfacial area [34]

g) The pace and degree of drug absorption are enhanced by SNEDDS

h) SNEDDS increase drug's bioavailability, which lowers dosage frequency [35]

8. Disadvantages of SNEDDS

a) Considering SNEDDS require digestion prior to dissolution, traditional dissolving methods cannot be used for them

b) For strength evaluation, more investigation and validation are required for the models of SNEDDS

c) The in vitro-in vivo connections of SNEDDS require more investigation.

d) The chemical instability of the drugs

e) Higher production costs [36]

f) Potential for drug precipitation and leaking

g) Further study and validation are needed for SNEDDS in vitro models to assess strength

9. Factors affecting SNEDDS

a) The extremely high doses, are not appropriate for SNEDDS [35]

b) The drug's water solubility is restricted, and SNEDDS finds it most challenging to deliver lipids [36]

c) The drug's solubility in the oily phase greatly influences SNEDDS's capacity to keep it in a solubilized condition

d) If the surfactant or co-surfactant is making a larger contribution to drug solubilization, there may occasionally be a risk of precipitation

10. Application of SNEDDS

a) The Self Nanoemulsifying Drug Delivery System (SNEDDS) is crucial to enhancing the water solubility and bioavailability in the mouth area of treatments that are poorly soluble in water [26]

b) Nanoemulsion drug delivery systems have made use of nanoemulsions (SNEDDS), such as transdermal cancer treatment, vaccine delivery, cell culture technology, formulations that are crucial for boosting ocular systems, intranasal drug delivery, parenteral drug [24]

c) Protection Against Biodegradation: For the delivery of macromolecules such peptides, hormones, and enzyme substrates inhibitors be shielded from enzymatic degradation SNEDDS, SMEDDS, and SEDDS [23]

11. Formulation of SNEDDS

11.1. Pseudo Ternary Phase Diagram

A pseudo-ternary phase diagram was developed in order to determine the ideal formulation composition for L-SMEDDS. The oil, surfactant, and co-surfactant chosen for this purpose were decided based on the extent to which they could dissolve the drug. Surfactant and co-surfactant (Smix) mixtures have been prepared with multiple weight ratios, including 1:1, 1:2, 1:3, 2:1, and 3:1 [37]. Smix mixtures were blended with oil in various ratios, from 1:9 to 9:1, resulting in 9 distinctive mixtures. The produced combinations were titrated with distilled water and magnetically stirred [38]. The process went on till a shift in clarity, usually turbidity, signalled the emergence of a micro-emulsion. Visual observation was employed to determine the system's ability to spontaneously produce a microemulsion. The results were used to create a pseudo-ternary phase diagram to locate a self-emulsifying area using CHEMIX School software [39].

11.2. Preparation of Liquid-SNEDDS

To formulate the Smix, the surfactant and co-surfactant were mixed in various ratios, like 1:1, 1:2, 1:3, 2:1, and 3:1 as reported in the literature [40]. Glass vials were then filled with oil and surfactant after the drug was dissolved in the co-surfactant. The final formulation was then agitated using a vortex mixer to produce a homogeneous isotropic mixture. The L-SMEDDS were then kept at room temperature until they were needed for analysis[41]. Challenges with L-SNEDDS include drug leakage, poor stability, SNEDDS interactions with capsule shells, and carriers with large surfaces[23].

11.3. Methods of Preparation of Solid-SNEDDS

11.3.1. Physical Adsorption

The benefits of a solid dosage form and L-SNEDDS are combined in this SNEDDS, various different methods of solidification of L-SNEDDS are explained in figure no. 3. Because L-SNEDDS is adsorbable, it can be converted into a free-flowing powder in different weight ratios of 1:1, 1:1.5, and 1:2 via combining carriers such Aerosil 200, Aeroperl 300, and Neusilin US2 [36]. Few studies also reported using various tools like SeDeM-SLA to investigate the solid particles' flowability and compressibility, determining carrier's suitability for additional considerations [40].

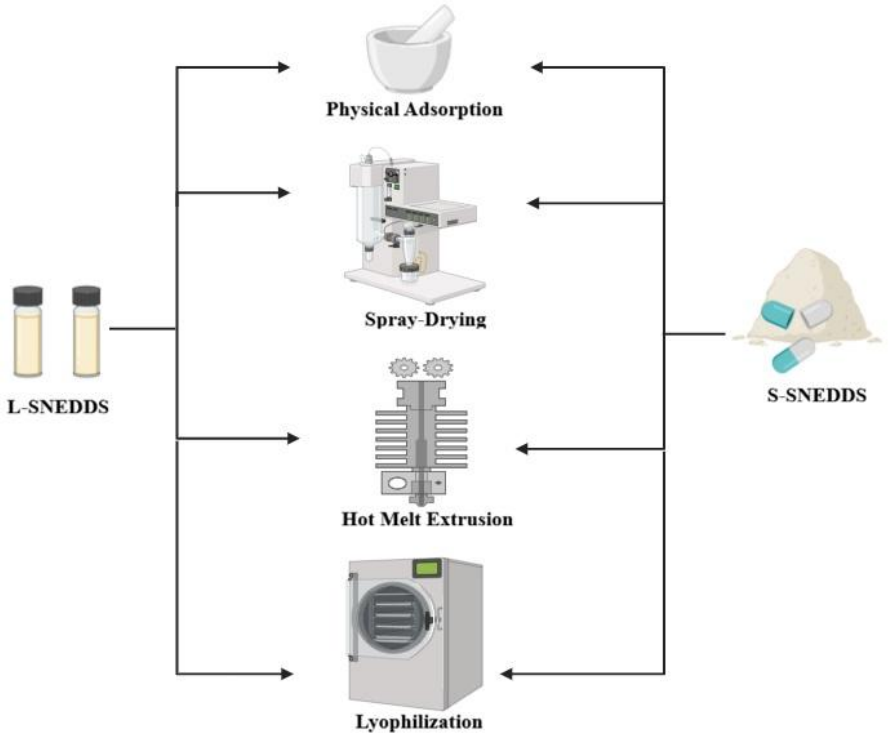

Figure 3: Conversion methods of Liquid-SNEDDS to Solid-SNEDDS

11.3.2. Spray-Drying

Another method to create S-SNEDDS is the Buchi 190 nozzle type mini spray drier. Solid SNEDDS are prepared by suspending carriers in 100 milliliters of solvent. One can suspend hydrophilic carriers in 100 milliliters of water and hydrophobic carriers in 100 milliliters of ethanol [31]. To create good emulsions, the liquid SNEDDS will be introduced to these solutions while being continuously mixed at room temperature. The solution can be sprayed dried at intake temperatures of 100° and 60° outlet temperatures by using a peristaltic pump to send the solution through the nozzle (0.7 mm diameter) at a flow rate of 5 mL per min [32]. The product should be sprayed in the one direction as the air flow. Solid carriers include hydrophobic substances like silicon dioxide and magnesium stearate [33] hydrophilic substances like [37] polyvinyl alcohol (PVA), sodium carboxy methyl cellulose (Na-CMC), and hydroxypropyl-β-cyclodextrantrin (HP- β-CD). The most common solid carrier that effectively increases the drug's solubility is silicon dioxide [24].

11.3.3. Hot Melt Extrusion

In the very first attempt, the viability of Hot Melt Extrusion for producing S-SMEDDS was examined in carvedilol (CARV), where using a mortar and pestle, the components of Liquid-SMEDDS, which made up 20% (w/w) of the solid formulation's total mass, were precisely weighed and combined. The mixture was then homogenized for two minutes after the drug (2, 3.5, or 5%, w/w) was added. Carriers were then added to the mixture one after the other, with two-minute mixing intervals in between.
Using a manual feed hopper, the resultant mixture (7.5 g) was subsequently fed into a lab-scale vertical twin screw hot-melt extruder (EHM 5, Labmaq do Brasil Ltd., Brazil) [42]. As per reported literature, drug-loaded L-SNEDDS were prepared, characterized, and then co-extruded in HME methods using various (co)polymers. Soluplus®, Kollidon® VA 64, Kollidon® 17 PF, Affinisol® HPMC 100 LV, and other marketed (co)polymers that have already been proven to improve solubility were utilized as polymeric carriers, together with a variety of ModE copolymers with varying molecular weights [43].

11.3.4. Lyophilization

Microcrystalline cellulose (MCC) was employed as a water-soluble carrier to lyophilize liquid-SMEDDS. In short, the produced SMEDDS was lyophilized for 6 hr using a bench-top vacuum freeze dryer (FD-10, LABFREEZ INSTRUMENTS GROUP CO., LTD, China) after 5% (w/v) of MCC was added[44].

12. Future perspective

Recent developments in SNEDDS research have been thoroughly investigated to improve the solubility, it is crucial to understand microenvironment modulation techniques. It is necessary to investigate the pH-catalyzed and solution-state drug degradation in SNEDDS. Considerable study is being done on the SNEDDS to a solid form, such as pellets and tablets. The ability of drug delivery scientists to address this feature of SNEDDS is critical to its commercialization.

13. Conclusions

In order of class II drug advances in SNEDDS research have been thoroughly examined in recent years. Drug degradation was slowed down but not completely eliminated by the switch from liquid to solid SNEDDS. An isotropic combination of surfactant and co-solvent makes up the self-nanoemulsifying drug delivery system (SNEDDS). It spontaneously emulsifies in the aqueous phase under light agitation to produce a fine o/w nanoemulsion. SNEDDS is an excellent substitute for the formulation of drug. Because SNEDDS increases the drug molecule's surface area on dispersion and absorption rate, it improves drug solubility. SNEDDS improves the solubility of pharmaceuticals by increasing the surface area of the dispersion and the absorption rate of the drug molecule. SNEDDS often make it possible for lipophilic drugs to be distributed orally, which is essential for enhancing oral bioavailability. By adding polymer to the mixture, it is possible to enhance drug release. SNEDDS seems to be a novel, commercially feasible strategy for further advancement.

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