

TROPICAL JOURNAL OF PHARMACEUTICAL AND LIFE SCIENCES

(An International Peer Reviewed Journal)

Journal homepage: <http://informativejournals.com/journal/index.php/tjpls>



SELF NANOEMULSIFYING DRUG DELIVERY SYSTEM: AN UPDATED REVIEW

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ABSTRACT

Self- nano emulsifying drug delivery system (SNEDDS) is getting popularity for enhancing the solubility of hydrophobic drugs. SNEDDS are employed to solve issues regarding low bioavailability of poorly soluble and greatly permeable compounds. The SNEDDS are isotropic mixtures of solvents, co-solvents, surfactants and oil. The chief characteristic of SNEDDS is their capability to make acceptable Microemulsions or oil-in-water (o/w) emulsions with mild agitation. SNEDDS comprise a less content of lipid whereas greater amount of lipophobic surfactants and co-surfactants. Usually SNEDDS prepared as liquid, but several methods have been developed for converting liquid SNEEDS into solid forms, extrusion, and melting, spray-drying, adsorption onto porous carriers freeze drying. Due to vast development of this technology, SNEDDS will assist novel applications in drug delivery and resolve difficulties related with the poorly soluble drug delivery.

Keywords: Biopharmaceutical classification system, Surfactant, Hydrophobic drugs, Lipid carriers, Bioavailability

INTRODUCTION

The SEDDS usually employed to enhance the oral bioavailability drugs having poor solubility. The nano emulsion of SEDDS is known as SNEDDS. The mean droplet size of these emulsions are 20-200 nm, two immiscible liquid dispersion wither o/w or w/o. The solubility of drugs such as simvastatin and atorvastatin could be enhanced by SNEEDS. The SNEDDS have the capability to enhance the bioavailability of substances belongs to biopharmaceutical classification system II (BCS). The substances belong to BCS II classification are highly permeable and poorly water soluble in nature.¹

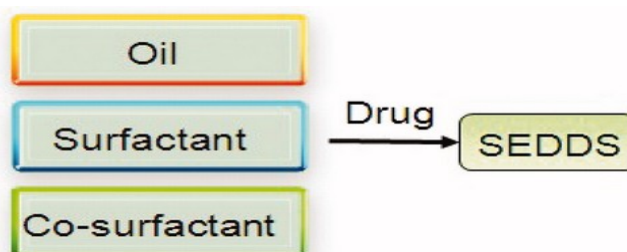


Figure 1: Representation of self-emulsifying drug delivery system

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Properties of SNEDDS²:

- Able to self-emulsify quickly in GI fluids and with gentle agitation provided by peristaltic movements of GIT, they form fine oil in water emulsion.
- Can efficiently integrate hydrophobic drug or hydrophilic drug inside the mixture of oil surfactant.
- Can be employed for solid as well as liquid dosage forms.
- Require lesser drug dose with respect to conventional dosage forms.

Advantages³:

- Rapid onset of action.
- Oral bioavailability enhancement.
- Safe delivery of peptides which are degraded due to enzymatic hydrolysis in GIT.
- Enhanced drug loading capacity with SNEDDS.
- Reeducation in dosage of drug.
- Easy in scale up (pilot plant) process.
- No impact on digestion process of lipid.

Disadvantages:

- Production costs are high.
- Challenges regarding the validation of different components.
- Problems with drug compatibility.
- Less drug loading due to leakage.
- Traditional dissolution methods do not work.
- High concentration of surface active agent in formulation may cause irritation to GIT.
- Volatile co solvents of SNEDDS migrate into capsule shells, cause precipitation of hydrophobic drugs.

Formulations Parameters for SNEDDS⁴:

1. **Active Pharmaceutical Ingredient (API):** SNEDDS are employed to surge the poor water-soluble drugs solubility, drugs belongs to BCS class II are mostly preferred such as carbamazepine, naproxen, nifedipine, , danazol, mefenamic acid, vitamin E, itraconazole and ketoconazole.

2. **Excipients:**

Lipids and Oils: These are the necessary to prepare the SNEDDS.

- ✓ **Fatty acids:** Oleic acid, stearic acid, palmitic acid
- ✓ **Fatty acid esters:** Glyceryl monooleate, Ascorbyl palmitate, Glyceryl dilaurate, Glyceryl behenate
- ✓ **Propylene glycol esters:** Propylene glycol monocaprylate, Propylene glycol dicaprylocaprate
- ✓ **Miscellaneous:** Vitamin E, Bees wax, Phospholipids, Stearyl alcohol

Table 1: Commonly used oil for SNEDDS for oral delivery

| General class | Examples | Commercial name |
|-------------------------------------|---|---|
| Fixed oils | Castor oil, Soybean oil | - |
| Medium chain triglycerides | Tryglycerides of capric/caprylic acids | Miglyol 812, Labrafac CC, Crodamol GTCC |
| | Triacetin | Captex 500 |
| Medium chain mono- and diglycerides | Mono- and diglycerides of capric/caprylic acids | Imwitor 742, Capmul MCM |
| Long chain monoglycerides | Glyceryl momooleate | Peceol, Capmul GMO |
| Propylene glycol fatty acid esters | Propylene glycol monocaprylate | Capryol 90, Capmul PG-8 |
| | Propylene glycol dicaprylate/caprata | Miglyol 840, Captex 200 |
| Fatty acid esters | Ethyl oleate | Crodamol EO |
| Fatty acids | Oleic acid | Crossential O94 |
| | Caprylic acid | - |
| Vitamins | Vitamin E | - |

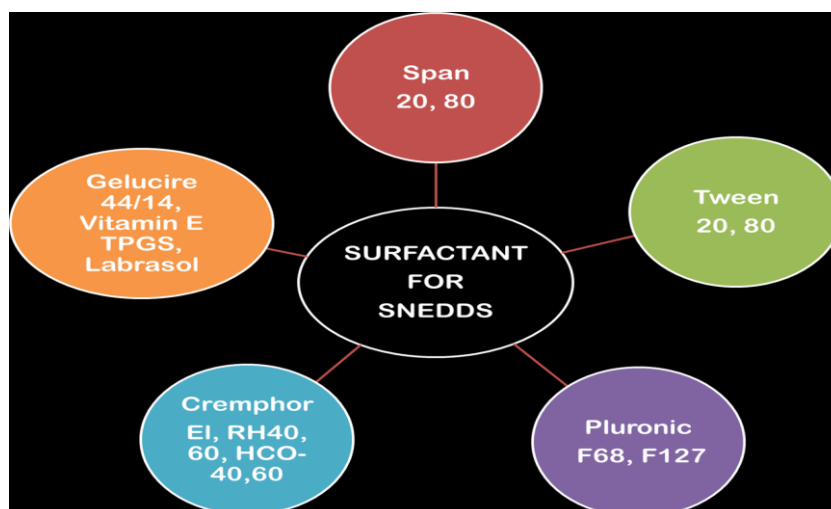
Surfactants: The surfactant from natural origin is suitable as compared to synthetic surfactants. The natural surfactants include extract of *Sapindus mukorossi*, *Verbascum densiflorum*, *Equisetum arvense*, *Betula pendula* and *Bellis perennis* soapwort. Surfactant has pronounced impact on the process of emulsification, droplet size and nano-emulsifying region. The properties which are considered are affinity to oil phase, HLB in oil and viscosity. The screening of surfactants are done on the basis of emulsifying ability and this is achieved by mingling oil and surfactants under warm conditions and then dilute with deionized water to prepare isotropic mixtures.

Anionic surfactants: Potassium laurate, sodium lauryl sulphate

Cationic surfactants: Quaternary ammonium halide

Nonionic surfactants: Polysorbate (tweens), Sorbitan esters (Spans)

Co-surfactants/Co stabilizers: Co-surfactants are employed to enhance the emulsification of the surfactant. The screening is done by mixing several co-surfactants with certain surfactant and oily phase under heating conditions and then diluted with water to prepare the isotropic mixtures. Examples include Glycofurol, Phospholipids, Propylene glycol, PEG, monoethyl ether, ethanol, triacetin.

**Figure 2:** Commonly used surfactants in SNEDDS

Mechanism of action of SNEDDS:

After administration SNEDDS forms oil in water nanoemulsion (less than 200nm) immediately due to gentle agitation rising from gastric movements. These NPs encompassing the drug that is formerly dispersed in the oil phase offers a bigger interfacial surface to enhance the dispersion in the GI fluids. This enhanced interfacial area surges the solubility and permeability of drug by changing transport property. There is quick digestion and rapid absorption of drug occurs in GI tract due to nanosize of droplets. The SNEDDS hold superior drug loading efficiency as compared to other lipid based formulations.⁵

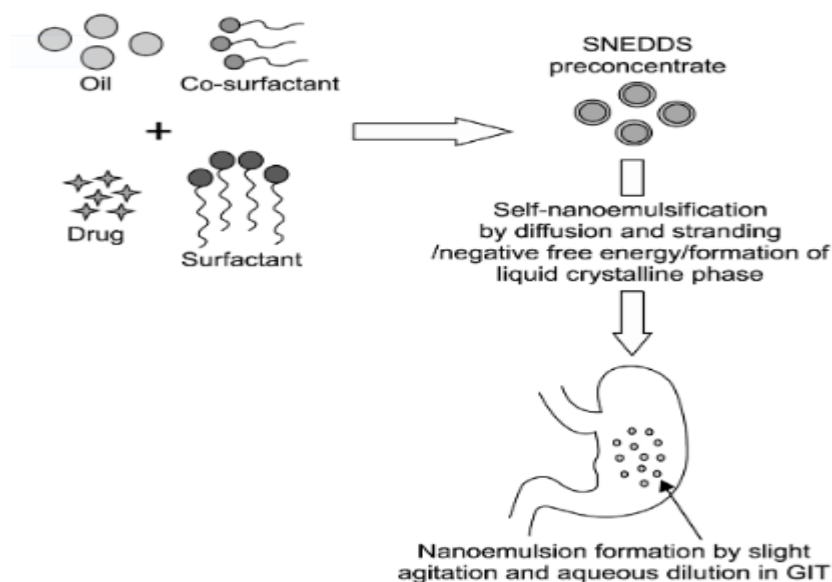


Figure 3: SNEDDS mechanism of action

Preparation methods for SNEDDS⁶:

Method of preparation for SNEDDS includes active pharmaceutical ingredient, excipient, polymers and emulsifier. Different methods for the preparation of Self Nano-emulsifying drug delivery system but, mainly divided into 2 methods:

A. *High-energy-emulsification.*

B. *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. Using combination of both technique, such as high-energy emulsification and low-energy emulsification, for prepared reverse Self Nano-emulsifying drug delivery system are highly viscous system.

High Energy Emulsification Method:**1. High pressure homogenisation (HPH):**

The preparing of Self Nano-emulsifying drug release system want important compel homogenization. This style above all old as higher-pressurized-homogenizer/locate-homogenizer gives Nano-emulsion particularly muffled particle extent (up to 1nm). This scattering in 2 phases (oil-mixture & aqueous-phase) is attained speeding mixed substance through a trivial cove chops at exact excessive load (500-5000 psi), addresses invention in higher disorder and hydraulic-shear develops an awfully charge particles of emulsion.

2. Ultrasonication:

It is the more convenient method lowering drops sized in this method; the energy-range is given through sonotrodes known to be Sonicator-probe. It bottle hold back piezo-electric quartz precious stone that

preserves spread out & tighten the comeback of broken exciting volt. End point in Sonicator contacts the liquid medium; its container produces mechanical throb and captives enrolled. Formation of captives shut down vapour cavities in liquid. Thus, ultrasounds canister straight produces an emulsion. In this mode is above all old for laboratories purpose, everywhere blend drop dimension is soothing as 0.2mm canister is obtained.

3. Micro-fluidization:

Micro-fluidization original addition methodology, that employees the custom of a manoeuvre said micro-fluidizer. manoeuvre was second-hand in above what is usual hassle affirmative disarticulation pump (500-20000psi), which break open the produce through the interaction chamber, consequential incredibly fair particles in the submicron range. This deal with is constant a number of an era to get hold of a beloved range to shaped even or homogenous Nano-emulsion system.

Low Energy Emulsification:

1. Phase inversion emulsification method:

Here is a method employed a transition of phase by applying very increased temperature route in emulsification.

2. Continuous emulsification:

In this system of emulsification is always formed. In which, the groundwork of consistent and standardized organic resolution consisting of grease & lipophilic-surfactant infill with tears miscible surfactant and hydrophilic-surfactant phase. The organic point was injected-in-aqueous stage below unbroken alluring stirring; string Oil-in-Water was prepared. Aqueous-stage was unconcerned as fading below concentrated pressurized.

Different dosage form of Solid SNEDDS (s-SNEDDS):

- Self-emulsifying sustained release microspheres
- Self-emulsifying beads
- Self-emulsifying solid dispersions
- Self-emulsifying sustained/controlled release pellets
- Self-emulsifying sustained/controlled release tablets
- Dry emulsions
- Self-emulsifying capsules
- Self-emulsifying nanoparticles
- Self-emulsifying suppositories
- Self-emulsifying implants

Evaluation parameters for SNEDDS:

- **Morphology:** The SNEDDS morphology can be determined by cryo transmission electron microscopy (Cryo-TEM) and small-angle neutron scattering (SANS).⁷
- **Viscosity:** The Brookfield cone and plate viscometer usually employed to determine the viscosity of liquid SNEDDS. The viscosity is measured in terms of centipoises (CP), which is related to the shear rate.⁸
- **Droplet size and poly dispersity index (PDI):** The droplet size and PDI can be calculated by employing a photon correlation spectroscopy technique. The sample is dissolved in an appropriate solvent to a specific concentration and mixing is done to get the preparation.⁹
- **The refractive index (RI):** To investigate the presence of transparent formulation, RI is generally used. The refractometer is usually employed to measure the RI. It is also used to determine the

thermodynamic stability of the formulation. The persistent structure and thermodynamic stability of the SNEDDS indicated by the insignificant alteration in the RI at the dissimilar time points of the storage.¹⁰

- **Zeta potential:** The Smoluchowski theory is applied to determine the particle charge of developed SNEDDS. The colloidal dispersion stability indicated by the zeta potential. If the value of zeta potential is high or more than ± 30 mV, the fabricated formulation is said to be stable.¹¹
- **Thermodynamic stability of emulsion:** The thermodynamic stability test is done to resolve the problem of metastable formulation. The centrifugation of liquid SNEDDS performed at 3,500 rpm for half an hour. The heating cooling cycle is performed for the formulation which did not exhibit any phase separation. There are 6 cycles will be performed for two days with temperature range of 5°C to 45°C . The stable formulation goes for freeze thaw stress test by doing three cycles for two days with temperature range of -22°C to 25°C . After this the formulation survives or exhibited stability selected as formulation for forthcoming studies.¹²
- **Stability study:** The International Council for Harmonization (ICH) guidelines employed to determine the stability study. The sensitivity towards the moisture and thermal stability tested under different storage conditions for SNEDDS. Usually The ICH storage guidelines for long-term and accelerated stability study are $25^{\circ}\text{C} \pm 2^{\circ}\text{C}/ 60\% \text{RH} \pm 5\% \text{RH}$ and $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/ 75\% \text{RH} \pm 5\% \text{RH}$, respectively.¹²

Application of SNEDDS¹³:

- It is used for target specific delivery for transdermal, parenteral, intravenous, ocular and intranasal administration.
- It is novel approach for stop the problem of first pass metabolism and it can directly absorbed in systemic circulation for giving a cent percent bio availability.
- SNEDDS is applicable for to treat various disorder such as diabetes mellitus, respiratory infection and skin infections.
- It acts as antimicrobial cosmetics industries.
- It is also used to prevent the enzymatic degradations and biodegradations of drugs. It is also useful in biotechnological field.

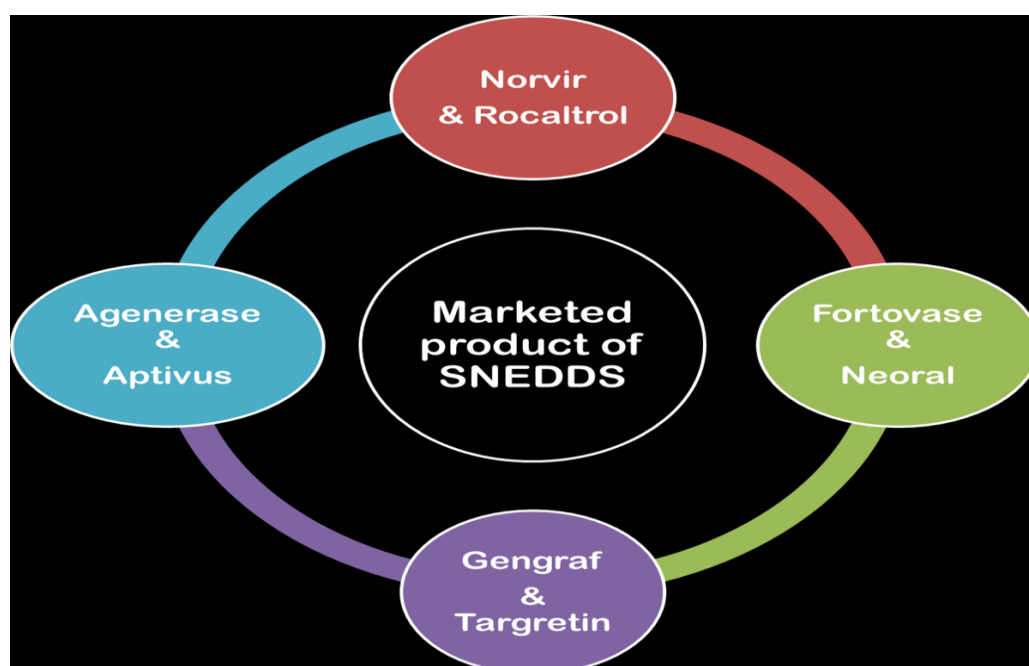


Figure 4: Commercial product of SNEDDS

SNEDDS for controlled release delivery:

The poorly water soluble drugs could be delivered through SNEDDS as extended release delivery systems. Numerous approaches are employed for controlled release of SNEDDS such as polymer coating, controlled release osmotic pump, microencapsulation and sustained release pellets. Diverse polymers are employed in the formulation of controlled release SNEDDS which include hydroxypropyl methyl cellulose (HPMC), poly lactic glycolic acid (PLGA), microcrystalline cellulose, and Gelucire 71/73.¹⁴ Nazzal *et al* prepared eutectic based coenzyme equipped Q10 solid SNEDDS by using tableting technique with the polymers Avicel PH-112, Glucidex 12 and Kollidon VA64.¹⁵

Self-double nano emulsifying drug delivery systems (SDNEDDS):

It is difficult to administer hydrophilic macromolecules and proteins orally in the form of SNEDDS. So, SDNEDDS is an excellent approach that could solve this issue. The SDNEDDS are spontaneous emulsions (w/o/w) that contain surfactant which are hydrophilic in nature and w/o emulsions. These emulsions were formed spontaneously at the time of dilution with water and mild agitation. The SDNEDDS could be employed for various macromolecular drugs like nattokinase, insulin and also have applicability for proteins and peptides. These macromolecules are protected from enzymatic degradation of GIT and also enhance the drug efficacy with the help of SDNEDDS.¹⁶

Supersaturated SNEDDS:

The *in vivo* solubilizing capacity of the SNEDDS diminished due to decline in the SNEDDS lipid content resulting precipitation of drug occurs. Drugs are at risk of precipitation which is having more solubility in the surface active agent as compared to lipid phase. This is the reason SNEDDS commonly consist drug less than equilibrium solubility. This problem or limitation is resolved by supersaturated SNEDDS consisting precipitation inhibitors which are hydrophilic in nature. These inhibitors attenuated the process of nucleation and precipitation of drug in the GIT by forming a metastable supersaturated state.¹⁷

Table 2: Marketed formulations of SNEDDS

| Active pharmaceutical ingredient (API) | Brand name/Manufacturer | Category | References |
|--|-------------------------------|-------------------|------------|
| Valproic acid | Convulex/Pharmacia | Anti-epileptic | (18) |
| Calcitriol | Rocaltrol/Roche | Calcium regulator | (19) |
| Cyclosporin A/I | Neoral/Novartis | Immunosuppressant | (20) |
| Cyclosporin A/III | Gengraf/Abbott | Immunosuppressant | (18) |
| Saquinavir | Fortovase/Hoffmann-lapche Inc | Antiviral (HIV) | (21) |
| Ritonavir | Norvir/Abbott | Antiviral (HIV) | (22) |
| Amprenavir | Agenerase | Antiviral (HIV) | (23) |

Recent developments in SNEDDS:

The most encouraging approach of SNEDDS which is using widely is lipid based drug delivery systems (LBDDS) for the formulation of poorly water soluble drugs. The Nanotechnology become an indispensable method in drug delivery research, affects the therapeutic performance of lipophilic drugs. The SNEDDS is a crucial approach which amalgamates the advantages of nanotechnology and LBDDS.²⁴ Kazi *et al* (2020) fabricated the bioactive SNEDDS consisting piperine (PIP) and Curcumin (CuR) by mixing bioactive natural oil in the preparation. The researchers showed that BIO-SNEDDS having black seed oil exhibited significant self-emulsion properties. The researchers also found that upon solidification, dissolution of CuR-PIP escalated.²⁵ Alwadei *et al* (2019) fabricated SNEDDS comprising CuR and thymoquinone (TmQ) and then with the help of adsorbents such as Syloid and Neusilin converted into solid dosage form. The

investigators revealed enhancement in drug loading and better rate of dissolution were exhibited with SNEDDS consisting CuR and TmQ. The researchers concluded that fabricated SNEDDS could be employed for combined delivery of anti-inflammatory and anti-cancer drugs.²⁶ Bandopadhyay *et al* (2015) developed SNEDDS of valsartan, an antihypertensive drug by using novel approach of QbD with medium chain and long chain triglycerides (MC-LC-T). The researchers established correlations with different levels of *in vitro/in vivo* (IVIVC). The outcome of these exhibited outstanding correlations in between *in vitro* drug release data and *in vivo* absorption data. The researchers concluded that fabricated MCT-LCT-SNEDDS with QbD enhanced the biopharmaceutical approach.²⁷ Kazi *et al* (2019) investigated *in vitro* and *in vivo* activity of poorly soluble drug talinolol (TaL) with SNEDDS. The SNEDDS equipped with TaL showed excellent capacity for drug loading, enhanced dissolution of drug, enhanced gut permeation, increased bioavailability and diminished RBC toxicity.²⁸ Kim *et al* (2018) developed SNEDDS of orlistat (ORT) with less use of lipid excipients. The researchers noted that significant lipase inhibition was observed with ORT-SNEDDS within 45 min. The fat excretion ratio was also noteworthy in rat stool with ORT-SNEDDS, concluding decrease in fat absorption level in rats. The investigators concluded that the fabricated SNEDDS could be a potential approach to treat obesity.²⁹

Nair *et al* (2022) fabricated SNEDDS to enhance the solubility of sertraline. The researchers created the ternary phase diagrams for nanoemulsion region identification. The researchers also applied full factorial design to investigate the effect of independent variables on dependent variables. *In vitro* sertraline release revealed that fabricated SNEDDS was statistically significant ($p < 0.0001$) as compared to plain sertraline. The SNEDDS Pharmacokinetic characterization showed noteworthy enhancement in relative bioavailability (390%), Cmax (4 times) and AUC (approx. 5 times). The researchers concluded that fabricated SNEDDS could be a good alternative to deliver the sertraline orally.³⁰

Zafar *et al* (2022) also fabricated SNEDDS of cephalexin for enhancement of oral delivery and evaluated its anti-bacterial activity. The researchers found that fabricated SNEDDS exhibited significant sustained release profile (95% in 24 h). The SNEDDS showed excellent antibacterial activity against gram positive and gram negative bacteria as compared to cephalexin dispersion. The selected cephalexin SNEDDS formulation exhibited 4 times better oral bioavailability as compared to cephalexin dispersion.³¹

CONCLUSION

The dissolution and absorption rate of poorly water soluble drugs could be increase with the help of SNEDDS, especially when absorption rate is limited because of dissolution rate. The approaches and excipients employed for SNEDDS formulation are cost-effective and simple. The use of SNEDDS in different areas of research enhanced due to excellent physical stability and less complex manufacturing. As per the future perspective, the modification in SNEDDS with newer technology such as polymer science and biological targeting will provide noteworthy benefits to pharmaceutical research and development.

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How to cite this article: VERMA, A., ASIJA, R., & GOYAL, A. (2022), "SELF NANOEMULSIFYING DRUG DELIVERY SYSTEM: AN UPDATED REVIEW ", *Tropical Journal of Pharmaceutical and Life Sciences (TJPLS Journal)*, 9(2), 11-20. Retrieved from <https://informativejournals.com/journal/index.php/tjpls/article/view/81>

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