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Review Article

Nano Tech for Better Drugs: Exploring the Advantages of Self-Nano Emulsifying Drug Delivery Systems

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ABSTRACT

The detailed comprehensive review article carefully examines the revolutionary advancement in treatment modalities,driven by the introduction of Self-Nano emulsifying drug delivery system (SNEDDS), and with some versatile points highlighting the comparing points of the developments with SEDDS. A new era of enhanced solubility, higher bioavailability, and precise targeting of therapeutic agents is ushered in by SNEDDs, which not only overcome the limitations of conventional drug delivery. This study highlights the potential of Nano SEDDS to overcome intrinsic limitations engrained in standard drug delivery technologies by providing an in-depth analysis of the complex molecular mechanisms regulating these drug delivery systems and elucidating the intricate mechanisms underlying their extraordinary effectiveness. With a view to providing a more nuanced understanding of the changing environment of pharmaceutical research and development, the systematic study makes interesting comparisons with SEDDS. By examining the many aspects of these cutting-edge technologies, the article aims to highlight the revolutionary role that Nano-SEDDS has played in reshaping the therapeutic landscape going forward by offering a comprehensive analysis of their uses, benefits, and possible drawbacks..

INTRODUCTION

In the past few years, conventional drug formulations of the drug have shown poor solubility also presenting challenges for researchers in the pharmaceutical industry. Out of 100% of conventional formulations, 40% are insoluble, leading to unstable formulations and reduced bioavailability. [1] [As mentioned in figure -1]

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Email : prasurjyasaikia17@gmail.com
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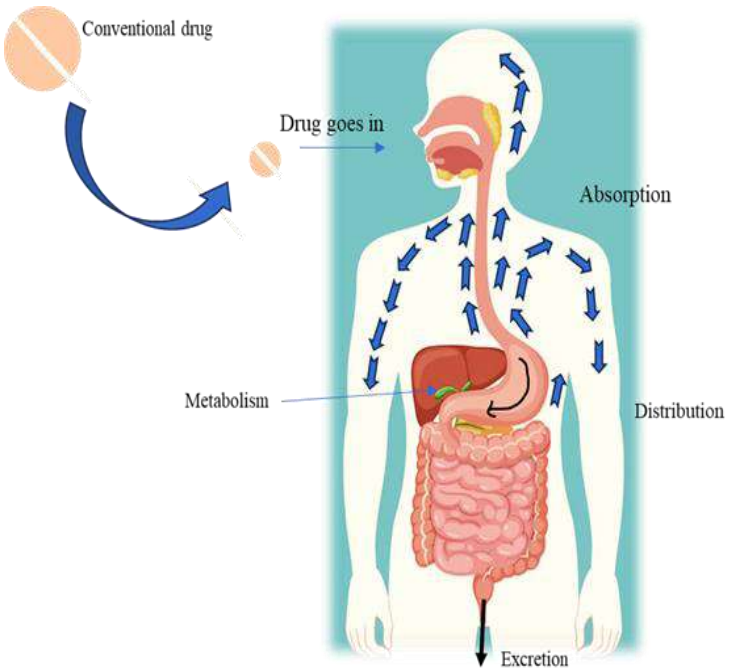


Figure: 1-Basic mechanism of conventional dosage form

Self-nano emulsifying drug delivery systems have shown promising results in improving the bioavailability of orally administered water-soluble and lipophilic drugs. Essentially, these preparations are a mixture of oil and surfactant, occasionally isotropic in nature, and sometimes include a cosolvent.[2] When introduced into an aqueous phase under agitation, a fine oil-in-water emulsion preparation can be produced. Self-emulsifying drug delivery systems (SEDDS) are homogeneous mixtures that are isotropic in nature. They contain a mixture of oil, surfactants, and cosurfactants that form small oil droplets in the nano-size range with the help of an emulsifying agent. SEDDS offers several advantages over poorly soluble drugs. They form a milky emulsion with small droplet sizes after mild agitation in water or gastrointestinal fluid, which enhances the interfacial area and allows for a rapid release of medications. This increases the intestinal permeability of many pharmaceuticals and their bioavailability.[3] While SEDDS normally create transparent microemulsions with droplet sizes between 100 and 250 nm, the self-micro emulsifying drug delivery system (SMEDDS) creates microemulsions with droplet sizes between 100 and 300 nm..[4] In a self-nano emulsifying drug delivery system (SNEDDS), nanoemulsions with a less amount of surfactants and droplet sizes under 100 nm are present. As opposed to emulsions, which are delicate and metastable dispersed forms, these formulations are physically stable. Consistently, for lipophilic drugs with restricted absorption due to dissolution rate.

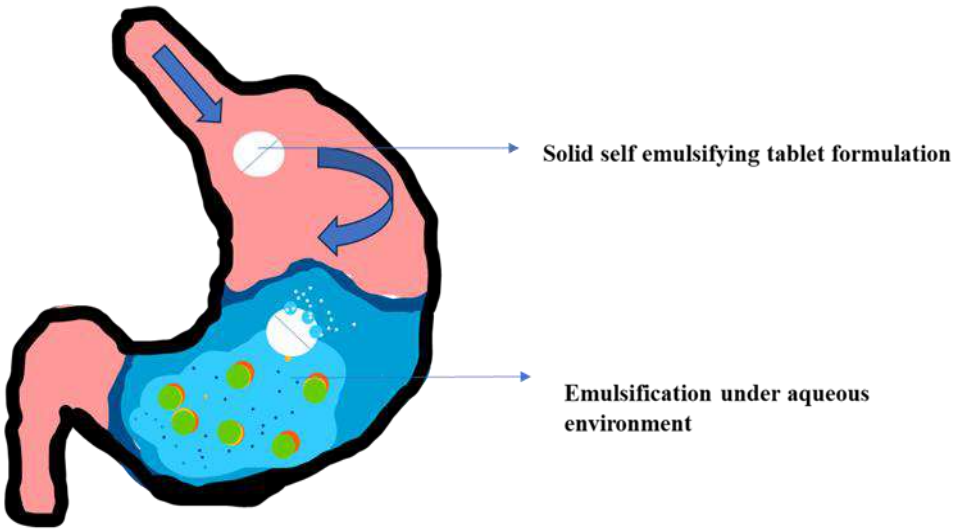


Figure:2- Mechanism of SEEDS

SNEDDS are nano-emulsions that are produced by SEDDS [As mentioned in figure-3]. They are several combinations of immiscible liquids, such as oil and water (O/W) or any other combination. irrespective of production method, having a mean droplet size in water-in-oil (W/O) that is on the nanometric scale (20–200 nm in general).[5]. It is especially important in this case for drugs to improve the solubility.[6] Oral formulations including lipophilic and water-soluble medications have seen an increase in bioavailability thanks to the nano self-emulsifying drug delivery technology. These formulations consist basically of an oil and surfactant combination, which may also include a co-solvent and be isotropic in nature. They are capable of producing fine oil-in-water emulsions when injected into an aqueous phase while being stirred.

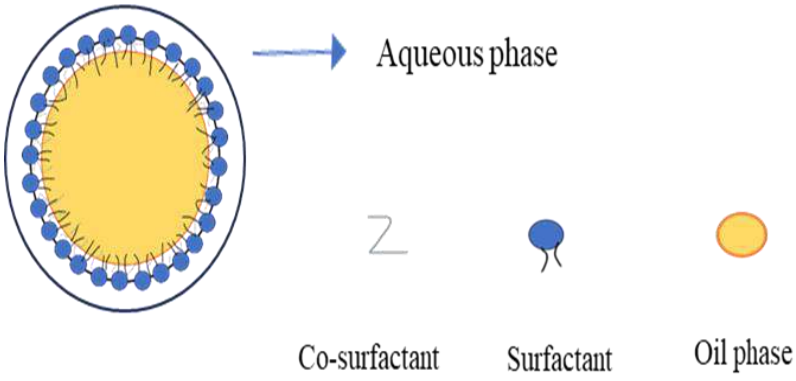


Figure :3- Structure of SNEDDS

From the given detail information, we have gathered some advantages going through the reports-

High potential exists for nano self-emulsifying drug delivery systems in the pharmaceutical The following is a quick summary of it.

It increases bioavailability and makes poorly soluble formulations more soluble. Increased absorption results in increased bioavailability while using SNEDDs.It is made with the patient's comfort in mind and is intended to target a certain spot for the tissues or cells. By preventing the formulation from deteriorating, it increases the

formulation's stability and self-life. The unique capacity to promote medication solubilization and subsequent absorption makes a substantial contribution to the enhancement of the pharmacokinetic profile as a whole. By shielding the active ingredient from deterioration, SNEDDS improve medication stability while simultaneously hastening drug breakdown by forming nanoscale emulsion droplets. The flexibility of SNEDDS in pharmaceutical research is demonstrated by their capacity to adapt to a broad range of therapeutic ingredients and dosage formats. Furthermore, the ability to lessen variation in medication absorption within and across individuals makes SNEDDS a useful tool for enhancing oral drug delivery. Consequently, there is potential for better treatment results. [7]

Components of Nano SEDDS-

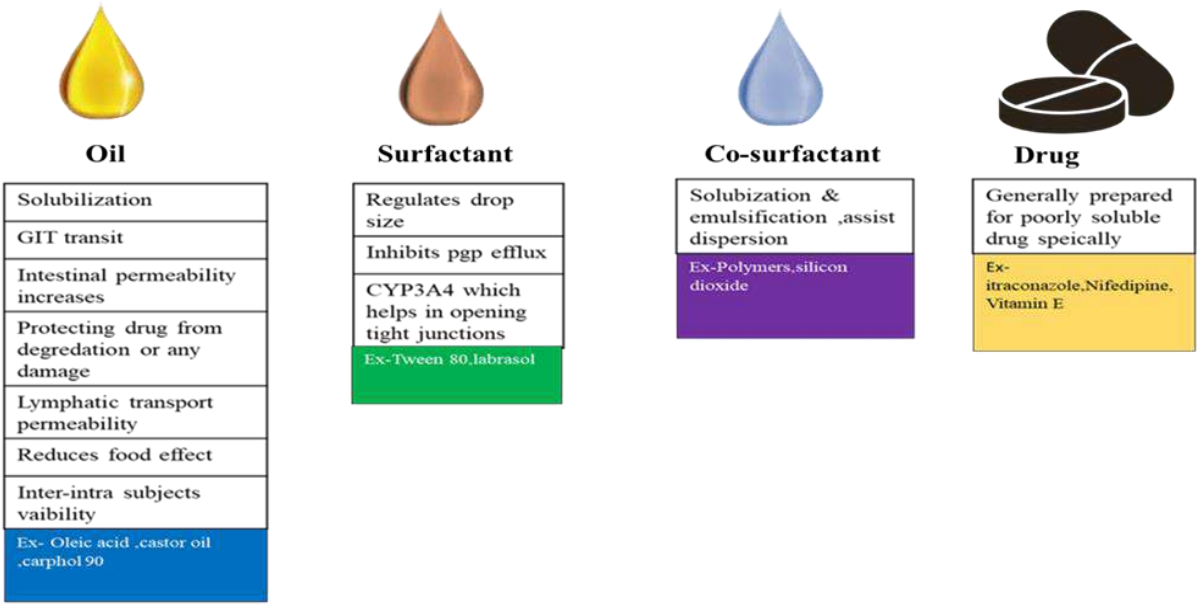


Figure :3- Components of SNEDDs

Mechanism of SNEDDS:

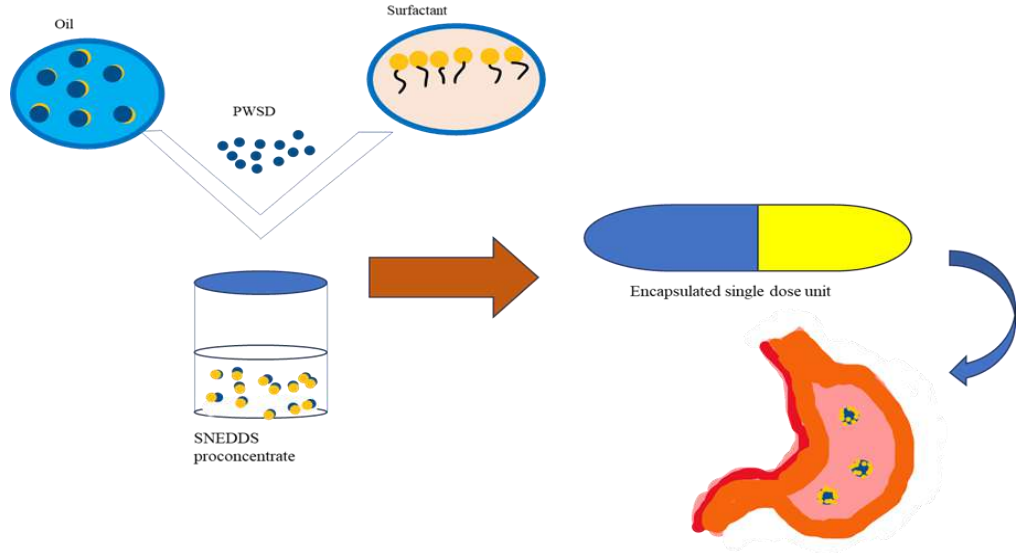


Fig: 6 Representation of Mechanism of SNEDDS

According to the theory of Resis sixteen, Nano self emulsification usually appears when the particular entropy changes that favors dispersion are higher or greater than the entropy required to increase the surface area of the dispersion It is defined through the equation –

$$DG = S\ Npr2s$$

where DG = process-related free energy,
S = interfacial energy, and N = the number of droplets of radius r.

It is believed that the free energy of that particular nanoemulsion is a direct consequence of the two different energies in order to build new surfaces between two unique immiscible phases. These systems are stabilized by the emulsifying agent, which usually lowers the interfacial tension. In order to minimize the system's energy and decrease the interfacial area, the two immiscible phases show a tendency to split. Therefore, stabilizers are needed for such compositions.[8]

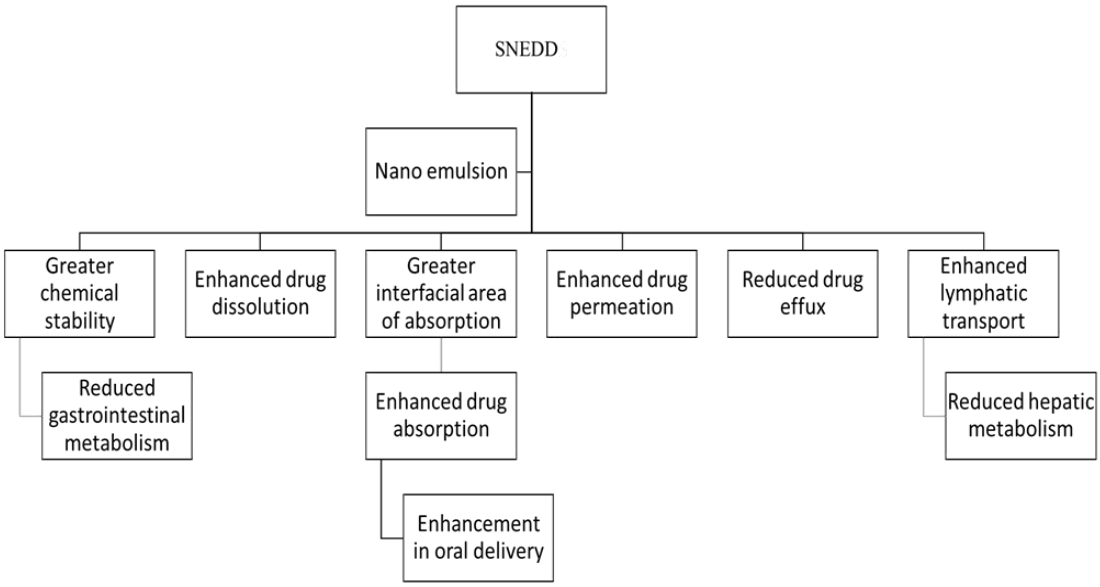


Figure :5 -Mechanism of improvement of oral Bioavailability by SNEDDS

Biopharmaceutical aspects:

1) **Alteration of gastric transit:** Suddenly slowing down the absorption and increasing time for Dissolution [9]
2) **Effectiveness in luminal activity :** The appearance of lipophilic activity in the GIT increases major secretion of Bile salts including endogenous biliary lipids that include phospholipids and cholesterol leading it to on going mixtures of these lipids which increases solubility in GIT.
3) **Permeability of the intestinal lymphatic transport:** Increasing the lipid activity may enhance the permeability of lymphatic transport[10]
4) **Effectiveness of oil in the absorption process:** Usually formulations form oil in a water mixture by applying agitation which helps to provide intestinal motility it also improves the plasma level profile

Selection of Drug Candidate for SNEDDS Formulation:

For lipophilic drugs which exhibit a limited rate of dissolution,absorption, SNEDDS can offer an improvement which exhibits reproducible blood time if we take things logically use of the SNEDDS can be categorized in four

biopharmaceutical classifications BCS class drugs
[11]

(Table-1) Biopharmaceutical Classification [12]

Class	Aqueous solubility	Membrane solubility	Potential advantages lipid-based system
I	Higher	Higher	Potential control release Enhanced bioavailability, possible benefits undergoing chemical degradation
II	Lower	Higher	
III	Higher	Lower	
IV	Lower	Lower	

(Table -2) Comparison between SEDDS & Nano SEDDS [13]

Parameters	SEDDS	Nano SEDDS
1) Particle size	1) 1-10 micrometre	1) 20-200nanometer
2)Surface area	2)covers less surface area	2)covers a bigger surface area
3)Targeted delivery	3)Not that target specific	3)Target specific to cell and tissue level
4)Stability	4) More stable than Nano SEDDS	4)Not stable than SEDDS
5)Application	5)More applicable in sustained and controlled release	5)More applicable in oral delivery
6)Clinical transition	6) successfully translated to commercial products	6) few products are available commercially and it is scrutinized well

(Table -3) Comparison between the parameters of equipment used in SNEDDS

Sr No.	Parameters	By using high energy Homogenizer	By using Sonicator	By Microfluidizer	By Phase inversion method	By Vortex mixer
1	Speed	8000-14000 Rpm [14]	2000 - 35000 rpms	2,000 to 30,000 rpm [15]	8000-14000Rpm	8000-14000Rpm
2	Pressure	700-2000 psi	Ultra sonic frequencies	2,000 to 30,000psi	nil	1 atm
3	Stabilizers	Labrasol	Cremophor EL	Tween 80	polyoxymethylene	Labrasol
4	Types	High pressure homogenizer, Piston Homogenizer	Direct sonicator method, indirect sonicator method	Constant microfluidizer,	Spontaneous phase inversion method, induced phase inversion method	Analog vortex mixer, Digital vortex mixture
5	Sample characteristics	Emulsion	Emulsion	Emulsion	Emulsion	Emulsion
6	Sample temperature	Room temperature	Room temperature	Room temperature	Room temperature	Room temperature

METHOD OF PREPARATION:

High-Speed Homogenizer

This method involves applying high pressure to a solution that contains co-surfactant, aqueous phase surfactant, and oil phase surfactant. There is a limit on how much oil may be used in water (o/w) when using this approach because of the homogenizer's limitations, which include low productivity, component deterioration from problematic mass manufacturing, and excessive heat generation. It is possible to make liquid nano emulsions with less than 20% oil phase, however, it is not possible to prepare cream formulations of nano emulsions with high viscosity or hardness and mean tiny size nano droplet diameters smaller than 200 nm.[16] [As mentioned in the figure -]

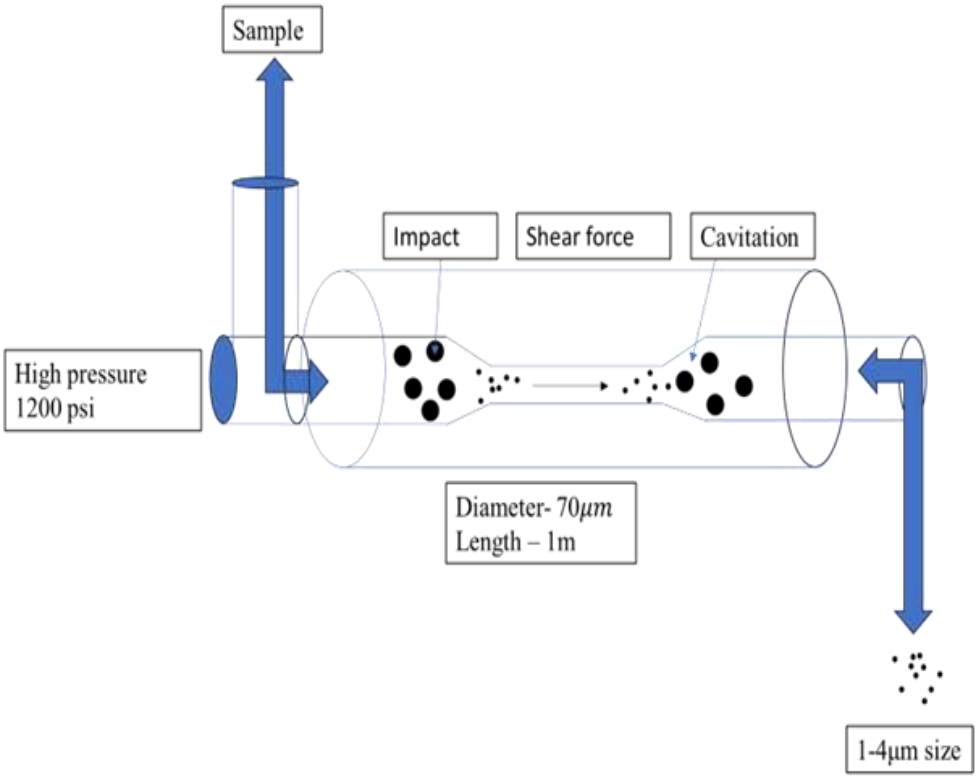


Figure :6- High speed Homogenizer

Ultra Sonicator –

One very efficient way for creating nano emulsions is the sonication method. It includes sonication, or the application of high-frequency sound waves to conventional or microemulsions to reduce droplet sizes. The method for producing nano-sized emulsion droplets is very effective. It's important to keep in mind, too, that sonication works better in smaller batches and might not be as feasible for producing large amounts of nanoemulsion because of the equipment requirements and time limits involved in this process.[17] [AS mentioned in the figure -]

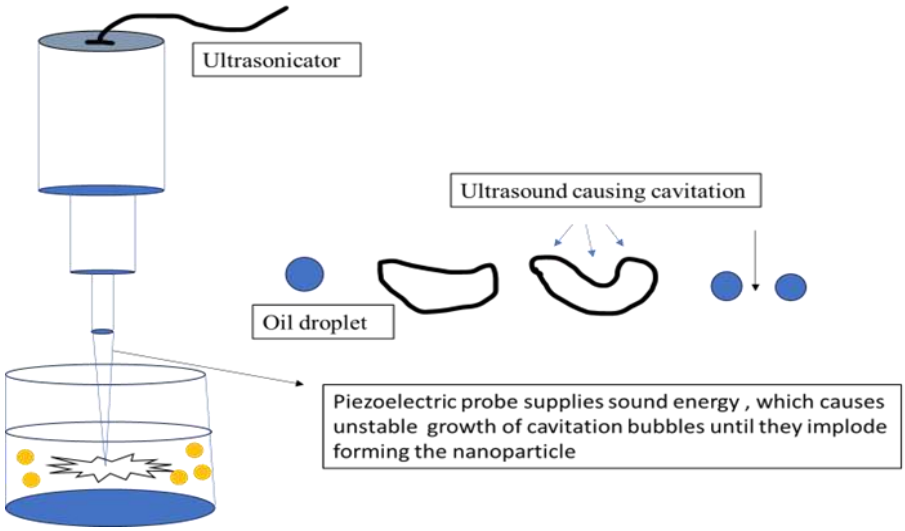


Figure :7– Ultra-sonicator

Micro fluidization –This sophisticated high-pressure homogenization apparatus is widely employed in the biotech and pharmaceutical industries, particularly in the development of Self-Emulsifying Drug Delivery Systems (SEDDS). By subjecting samples to intense shearing and turbulence force through a small interaction chamber, it provides precise control over particle size reduction, emulsification, and fluid mixing. There are several important benefits to using a microfluidizer while preparing SEDDS. It enables homogenous and controlled droplet size, which is essential for raising bioavailability and solubility [18] [As mentioned in the figure -8]

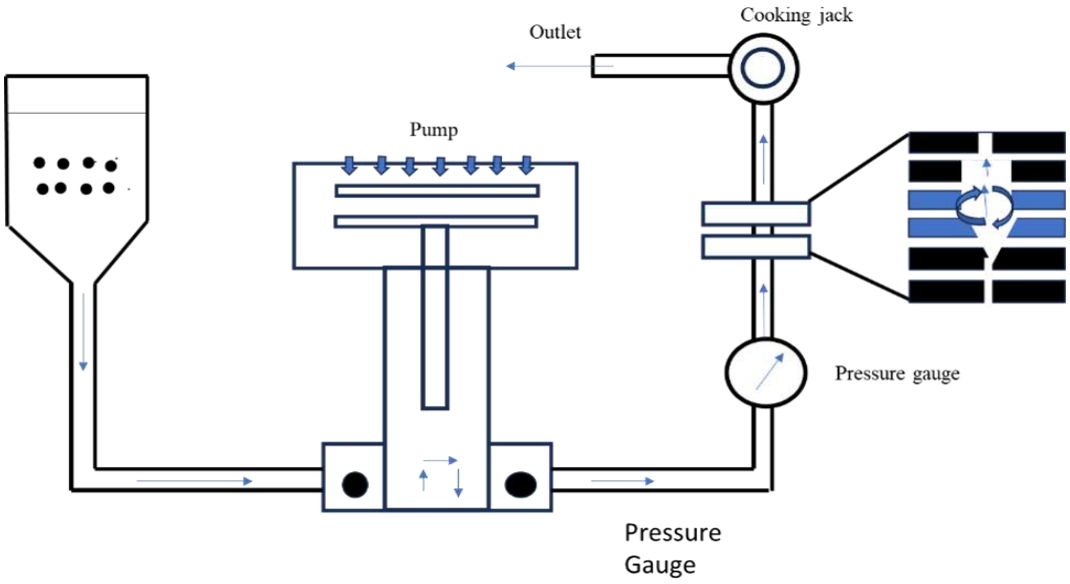


Figure:8 -Microfluidizer

Phase inversion method -Phase inversion is a versatile technique that finds widespread use in formulation and pharmaceutical chemistry. It allows emulsions to be converted from water-in-oil (W/O) to oil-in-water (O/W) and back again in a controlled manner. The foundation of this technique is precisely controlling the proportions of the emulsifying agents, water phase, and oil

phase. First, an emulsion is created in the designated W/O or O/W combination. When the composition is continuously altered, like when emulsifying agents are added in higher concentrations or the oil-to-water ratio is adjusted, a phase inversion occurs. A change in the continuous phase, which results in a fundamentally different emulsion type, indicates this transition. Phase inversion is a helpful technique for meeting specifications and improving factors including solubility, stability, and bioavailability in pharmaceutical formulation.[19] [As mentioned in the figure -9]

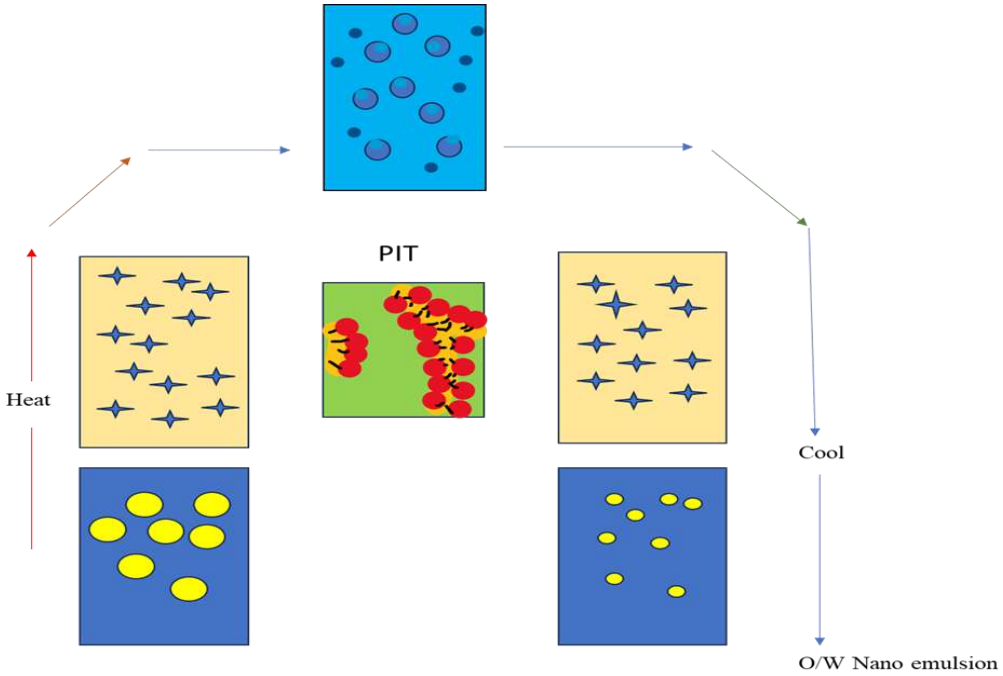
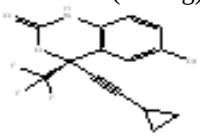
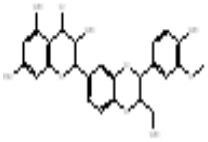
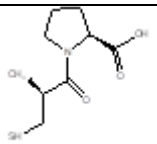
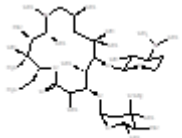
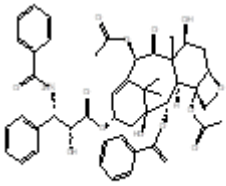
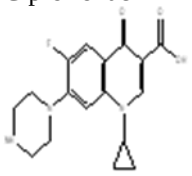
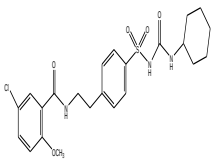
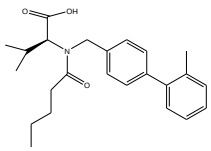
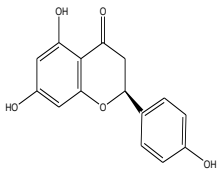
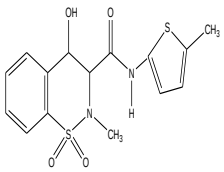
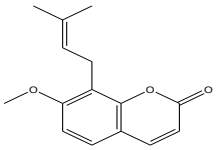
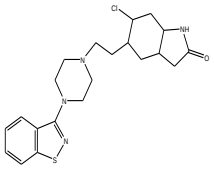
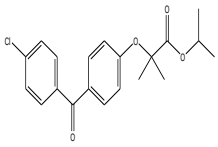
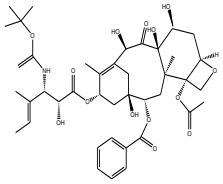
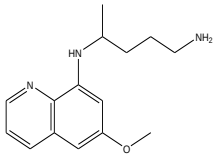


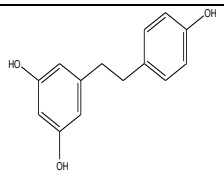
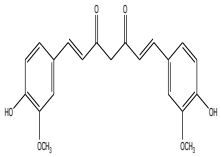
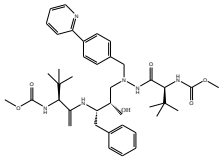
Fig :9- phase inversion method

Table – Preparation of SNEDDs and comparison of therapeutic and permeability effect of the drug

Sr No.	Drug	Disease	Methods of preparation	Oil components	Surfactant	Co-surfactant	Ratio	Findings
1	Efavirenz (150mg) 	HIV	Drug + 1ml mixture of oil, surfactant &co-surfactant mixed in vortex mixer	Labrafil	Tween 80	Transcutol	1:1	Drug solubility increases along with permeation of drug [20]
2	Silymarin 	Liver disease	2 mixtures are taken (oil +surfactant), (drug +co-surfactant) mixed together in homogenizer	Cinamon oil,	Span 80, tween 20	PEG 200	1:1	Drug release was 58.16% & comparing with standard - 57.26% [21]
3	Captopril	Cardio vascular disease	Drug +oil, surfactant and co-surfactant	Castor Oil	Labrasol	Span 80	1:1,2:1,4:1	Improved Drug release and

			mixed together on Thermomixer					permeability of drug [22]
4	Azithromycin 	Bacterial disease	Drug liquid +along with aerosol 200+with oil, surfactant and co surfactant in Vortex mixture	Castor oil	Labrasol	Span 80	5:1	Formulations increases the bioavailability of the drugs[23]
5	Paclitaxel 	Cancer	1mg of paclitaxel loaded liquid +250 mg of aerosil 200+water preparerd in spray drying	Ethyle oelate	Caribtol	PEG 400	**1:1**	Increasing permeation of the drug and solubility of drugs [24]
6	Ciprofloxacin 	Bacterial	Drug +oil +surfactant and co surfactant in freeze dryer	Castor oil	Tween 80	PEG 600	1:1	Increases solubility and bioavailability [25]
7	Glyburide 	Diabetic	Drug +oil+ surfactant +co surfactant +vortex mixture	Migylol 812	Cremophor RH 40	propandiol	1:1	Increases solubility [26]
8	Valsartan 	Hypertensive	Drug +oil+ surfactant +co surfactant +vortex mixture	Castor oil	Tween 80	PEG 600	1:1	Increases permeability in lymphatic transport [27]
9	Naringenin 	Anti-cancer	Drug +oil phase +surfactant +co-surfactant in homogenizer	Triacetin	Tween 80,	Transcutol HP	1:1	Increase solubility [28]

10	Meloxicam 	Antirheumatoid	Drug +oil +surfactant and co surfactant in freeze dryer	Olive oil	Tween 80	PEG 400	1:1	Improvement in drug release [29]
11	Osthol 	Antioxidant	Drug +oil +surfactant +co-surfactant in freeze drying	Castor oil	Cremaphore RH40	Ethyl cellulose	1:1	Invitro results sustained release effect [30]
12	Ziprasidone 	schizophrenia	Drug +oil+ surfactant +co surfactant +vortex mixture	Capmul MCM	labrasol	PEG400	1:1	Shows sustain release effect [31]
13	Fenofibrate 	hypertriglyceridemia	Drug +oil phase +surfactant +co-surfactant in homogenizer	Ethyl oleate	Cremaphore RH40	soluplus	1:1	Shows greater bioavailability than SEDDS [32]
14	Docetaxel 	prostate cancer	Drug +oil phase +surfactant +co-surfactant in homogenizer	Cayprol 90	labrasol	transcutol	1:1	More efficacy in the formulation [33]
15	Primaquinine 	malaria	Drug +oil phase +surfactant +co-surfactant in homogenizer	Cremophor RH40	Glacier	Aerosil 400	1:1	More effective in half dose only [34]
16	Resveratrol	Alzheimer's disease	Drug +oil phase +surfactant +co-surfactant in vortex mixture	SPC	Tween 80	Aerosil 400	**1:1**	Improved dissolution rate is achieved [35]

								
17	Curcumin 	hyperlipidemia	Drug +oil phase +surfactant +co-surfactant in spray drying	L-sulforaphane	Cremaphore RH 40	Caprigly ceride	1:1	Improve drug release and flowability of the drugs [36]
18	Atazanavir(100mg) 	HIV	Drug +surfactant & co-surfactant taken in a glass vial and heatef upto 40C and put in to magnetic stirer	Castor oil	Kolliphor RH 40	PEG 400	**2:1**	Increases flowability and bioavailability of drugs [37]

SNEDDS on animal test models [38]

Drug	**Excipients**	**Effects on oral bioavailability**	**Study model**	**Mechanism behind bioavailability**
Glyburide	Miglyol 812, Cremophor Rh 40,1,2-propandiol maisine 35-1(C_{21}), Transcutol P	1.53-fold increase in bioavailability 2.13- and 2.57-fold increase in Cmax and AUC	Beagle dogs	Increase solubility
Atazanavir	Maisine 35-1(C_{21}), Transcutol P	For triacetin-SNEDDS 5 and 2.4-folds-increase in C_{max} and AUC	Rats	Increase solubility and permeability
Naringenin	Triacetin, tween 80, transcutol HP	4.9 and 2.8 -fold increase in Cmax and AUC	Rats	Increases solubility
Quercetin	Castor oil, tween 80, Peg 400	Three and two folded increases in Cmax &AUC	Rats	Increase in solubility
Talinolol	Triacetin, Brij-721, ethanol	1.4-fold increase in AUC	Rats	Increase in solubility
Simvastatin	Labrafil, Tween 80, and Transcutol	1.55 and 1.5-fold increase in Cmax and AU	Human test model	Increase solubility

Applications of Nano Self-Emulsifying drug delivery system

Personalized medicine-By using NSEDDS the drugs are designed based on to the patient's

conveniences which is basically target site-specific delivery, its a new aged drug delivery system which is more target site specific than normal conventional drug delivery system. The phrase "personalized nanomedicine" refers to the use of nanosized carriers to build treatment protocols that are tailored to each particular patient. In recent years, pharmacogenomic, pharmacoproteomic, and a variety of omic approaches have been developed with the objective of producing patient-specific medicine. These many methodologies give a comprehensive genetic and molecular profile for each patient, which aids in the identification of molecular biomarkers that impact disease development and response to therapy. Thus, personalized medicine is dependent not only on the discovery of biomarkers and genetic polymorphisms but also on the development of systems for disease detection and therapeutic response prediction.[39]

Oral drug delivery system- Going the research which we gathered to know that the results which we have gained,that SNEDDS has the ability to produce a nanometric structure dispersion of a particular controlled size which modulates the encapsulated polymer material based on model drug where solubility ,wettability,dissolution and stability in the desired fashion than that did the compared to conventional dosages form which provides the delivering the drug in a highly solubilized form and rapidly dispersing manner

Brain targeting –Going through the brain targeting from nano emulsion,it has significant potential to target site-specific objects in brain malfunction processes or Neurological disorders,In future aspects for brain targeting we see a lot more potential in treating various disorders of the brain by using nanoformulation emulsion

Ocular drug targeting – Nano emulsions also have some promising advancements in drug delivery which promote enhancing the administration of the eye, These are the types of formulation that increase drug solubility absorption in ocular tissues **[**[40]

Pediatric and Geriatric flexible dosage forms-It give a versatile platform for exhibiting the pediatric and geriatric dosages formulation due to their potential for delivering the precise dosages,Usually in pediatric medicines we often face challenges while delivering medicines in different variations due body, age, etc

Studies carried out in different Dosages form

Dosages forms	**Studies carried**
Dry emulsion	1) Poorly soluble [41] **2)** Enteric coated tables are more applicable [42]
Self-emulsifying, solid dispersion	1) Using the Spray Drying technique, solid dispersion granules were made from seven different medications. Four of the medications in this group had carboxylic acid, one had an amide (phenacetin), one had a hydroxyl group, and one did not have any groups that donate protons (progesterone). For surface adsorption, glacier 50/13 was utilised, and for dispersion, Neusilin US2.[43]
Self-emulsifying tablets	1)studies are done to evaluate the release of drug and to evaluate optimized nano formulation 2)self-emulsifying tablet using Goat fat and Tween and diclofenac [44]

Self-emulsifying nano particles	**1)** A multiple emulsion (o/w/o) approach was used by Rickler et al. (2008) to develop a self-emulsifying nanoparticle system. They used glyceryl monooleate (GMO) and chitosan to deliver paclitaxel. The bio adhesive properties of these nanoparticles improved drug-cell contact. Solvent evaporation was the process used for this [45]

Limitation of SNEDDS-

Even though the formulation provides variety of benefits for the consumers of the society but there is a fact sometimes due to their small reduced in structure that is nano size which might provide some disadvantages which might limited use of these formulation, the limitation are as follows [46]

a) **Scaleup or setup formulation challenges** – The setup formulation of the nano emulsion is quite expensive and due to their smaller in size it is difficult to formulate such formulations with high tech machinery methods such as Homogenizers, Microfluidizers, and ultrasonicator etc.

b) **Forming complexes-** Due to the complex nano structure of the SNEDDS possibilities of forming complex with excipients might happened.

c) **Stability issues –** There are many stability issues, formulation like Oswald ripening which is the factor this is due high rate of curvature of small droplets that shows greater solubility as compared to larger drop with smaller radius sizes.

d) **Drug drug interactions-**Nano emulsion have tendency to react the surrounding particles due to their instability in nature.

e) **Dissolution rate limited absorption –** The drug formulation which already exists has lower solubility in the physiological environment The agents belonging to class II and IV, The poor dissolution rate of these compounds are responsible for the poor absorption from the GT tract ,The formulation of SNEDDS has the ability to preset the drug spontaneously in a very fine droplets of nanoparticles offering high surface area this increases absorption and bioavailability [47]

f) **Permeability –** Due to poor availability it is one of the major drawbacks of the oral drug delivery formulation of BCS class III such drugs are administered in higher dosages. SNEDDS formulations have the ability to increase membrane penetration [49]

Evaluation test for SNEDDS-

A) **X-ray diffraction analysis (XRD) test -** Analysing X-ray diffraction (XRD) is a useful technique for determining if pharmaceuticals included in nano emulsions (NEs) are crystalline or amorphous. Furthermore, XRD provides information on the crystalline material's grain size, lattice parameters, phase properties, and crystalline structure.[50]

B) **Thermostability test for Nano emulsion-** To assess a nano emulsion's thermostability under various thermal circumstances, it is necessary to subject it to a range of temperatures. The purpose of this evaluation is to ascertain how long the nanoemulsion can withstand temperature changes without experiencing appreciable changes to its chemical or physical properties.[51]

C) **Checking the self-emulsifying time-** Analysing a nano emulsion's emulsification time entails determining how long the entire emulsification process takes. This procedure assesses the degree to which the constituents of the nanoemulsion mix well and create a stable emulsion, offering information on the formulation's emulsification performance.[52]

D) **Scanning electron microscope (SEM)-**The shape and structure of the nanoemulsion are examined and visualized at the nanoscale with the use of scanning electron microscopy (SEM) technology. The test yields comprehensive pictures that can provide useful insights into the entire microstructure and properties of the nanoemulsion by revealing information on the size, shape, and distribution of the nanoparticles inside it.[53]

E) **Differential Scanning calorimeter test (DSC)-** Examining nano emulsions using Differential Scanning Calorimetry (DSC) turns out to be a helpful technique. It offers important insights into processes including phase transitions, melting, crystallisation, and other thermal behaviours. It also helps assess the thermal characteristics of nanoemulsion formulations. Understanding the stability and properties of nano emulsions at varying temperature settings is crucial for optimising them for various applications, and the data gathered by DSC is essential for this purpose.[54]

Particle size analysis for Nano emulsion - Examining and measuring the diameters of the particles within the emulsion is necessary to analyse the particle size of nano emulsions. This evaluation contributes to a thorough knowledge of the stability, functionality, and properties of the nanoemulsion by providing important insights on the distribution and average size of nanoparticles. In the context of nano emulsions, dynamic light scattering (DLS), laser diffraction, and other microscopy techniques are frequently used for particle size characterization.[55]

CONCLUSION- Initiative for drug discovery which yields big population of newly chemical substances that can be lipophilic and poorly soluble. SNEDDS shows the vast potential of improved bioavailability and limited aqueous solubility Due to small nano size of these formulations is responsible for providing enhancement for drug dissolution due to its vast surface area. The formulations also have lipidic nature for the lympathic system however several problems like drug excipient interaction, oxidation of vegetable oils, safety should take into consideration in the development of SNEDDS, therefore accommodating of conversion of SEDDS to SNEDDS enables the development of the dosages form, also it gives a platform for new age of dosage form of drugs. Since a lot research is carried out, also with in *vivo* and *invitro* correlation studies

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