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Review Article

Review On Self Micro Emulsifying Drug Delivery System(SMEDDS)

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ABSTRACT

In pharmaceutical industry it is Found that 40% Of Active pharmaceutical Ingredients are poorly water soluble. So, oral delivery of such drugs is complicated because of their low bio-availability .solubility is one of the most important for orally administer drug to achieve desired concentration of drug in systemic circulation for more pharmacological action. For enhancement of solubility there is use an self microemusifying drug delivery system of lipophilic drugs.mainly class II & IV drugs are follows the SMEDDS.this SMEDDS is prepared by combination of drug,oil,surfactant & cosurfectant/co-solvents . SMEDD system as like example diclofenac sodium to improve the rate&extend of absorption such from GI tract .this formulation is evaluated by performing various tests such like as,thermodynamic stability,droplet size analyzer ,liquefaction time ,refractive index,self emulsifying time&drug content study etc.this SMEDD formulation shows faster solubility &dissolution rate than plane drug .when solubility increases then absorption increases also bio-availability increases then shows the maximum therapeutic response.these review provides an updated in advancement in SMEDDS with regard to its components ,characteristics ,various tests & also various pharmaceutical significant.

INTRODUCTION

The oral route of administration is most benign route of of drug delivery.successful oral delivery of drug has always remains challenge to drug delivery field .35-40% of newly launched drugs has low water solubility which leads to their poor dissolution rate and their by low bio-availability.drug absorption rate from improving solubility and oral bio-availability.recently new techniques ,Self gastrointestinal tract is mainly governt by dissolution and improvement in solubility my leads to enhance bio-availability.to overcome this problem various methods & techniques are used for increase therapeutic efficacy of drugs such as,solid dispersion,micronisation, liposomal formation ,salt formation co precipitation, co grinding and emulsification has been used for emulsifying drug delivery system has been formulate for enhancing this poor soluble drugs for

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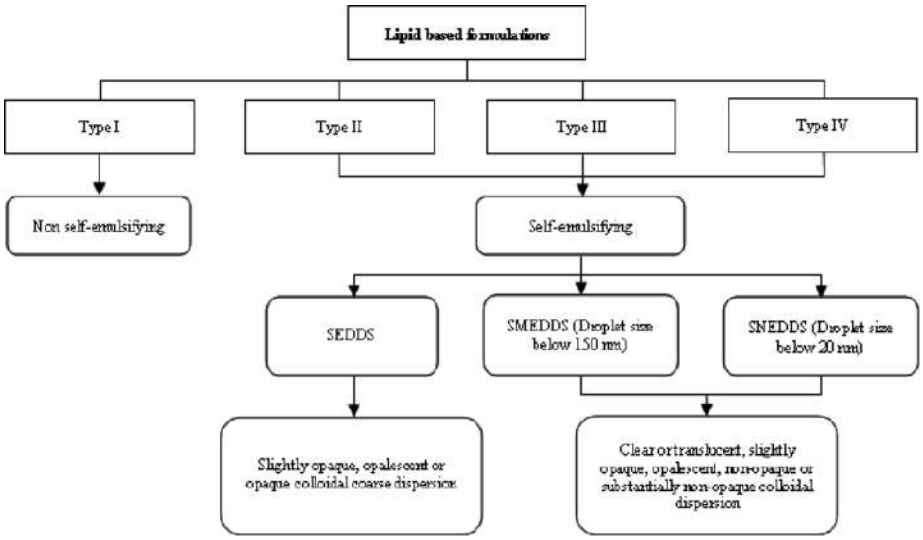
enhancing their solubility.when solubility increases also absorption rate increase then bio-availability increases give more therapeutic response .mainly classII and classIV drugs are responsible for formation of SMEDDs.self emulsifying drug delivery system or self emulsifying oil formulation define as ideally isotropic mixture of natural and synthetic oil alternatively solid and liquid surfactant or one or more hydrophilic substances solvent cosolvants/surfactant.this system forms fine emulsion or micro-emulsion in gastrointestinal tract with small agitation provided by gastric mobility. Self emulsifying drug delivery system's preparation entered and release in the lumen gastrointestinal tract.this SMEDD system can from fine oil/water(o/w) micro emulsion or self micro-emulsifying drug delivery system (SMEDDS).

Lipid formulation classification system -

This classification help to better understand the fate of various lipid formulation in vivo it also helps to use systematic and rational formulation approach avoid trial and error.this system was established by pouton in 2000 and recently updated Based on the type of components divided in 4 types .this shows possible effect of dilution and digestion on their ability to prevent drug precipitation.

Lipid based formulations:



Type I:

This lipid easy formulation it consist highly lipophilic compounds in which oil are present without surfactant such as ,example is glyceride.Which are non dispersing required digestion,this is generally safe but,formulation has poor solvent capacity

Type II:

This lipid formulation consist SEDDs .which consist of oils and water with insoluble surfactant dispersion drug absorption without digestion.further classified in two types ;1) typeIIIA 2)type IIIB to identify more .this SEDDS formed without water soluble components.it gives benefits to overcoming the slow dissolving rate seen in solid dosage form which are unlikely to loose solvent capacity on dispersion but,it is turbid o/w dispersion(particle size 0.25-2µm)

Type III:

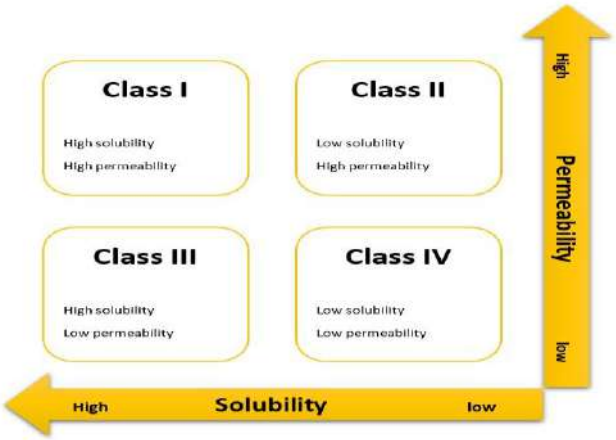
Lipid based formulation commonly for SMEDDS.it consist of oil,surfactant/cosufectant are water soluble .which clear or almost clear hydrophilicity. **typeIIIB** formulation has greater dispersion when compared with typeIIIA.

Type IV:

This formulation content predominantly hydrophilic surfactant and co surfactant which not contain any natural lipid .contain water soluble surfactant and co solvents(no oil). formulation disperse typically to form micellar solution having good solvent capacity for many drugs.

Bio pharmaceutical classification system(BCS):

This system was firstly introduced in year1995 by the scientist Amidon et al and his colleagues.this classification based on in vitro,in vivo correlation(IVIVC)for faster release of drug action.bio-pharmaceutical classification system is scientific makeup for classification of drug substances depends on its aqueous solubility and permeability with dissolution rate.this is save time fast screaming.this drug substances are classify as given below:



This are mainly classify in the four types class I,classII,classIII,class IV In that classes solubility and permeability are given. In the SMDDS system follows only classII and class Iv Drugs because of their low solubility Solubility: it is the ability of solute particles dissolves in the solvent.if more soluble of drugs shows more absorbtion then shows more bioavalability. Permeability:certain molecules are allowed pass through it plasma membrane permeable only two certain types of molecules.

CLASS I:

Class I is ideal for oral route of drug administration in that drug absorb rapidly,dissolve rapidly which having rapid therapeutic action example;propranolol,deltiazem etc.

CLASS II:

These are drug which are given by oral route of administration drug absorb rapidly but,dissolve slowly because of low solubility and high permeability.therapeutic action and bio-availability is controlled by dosage form and rate of release of drug substances example;nifedipine ,neproxene,sodium dicofenac etc.

CLASS III:

These are oral route of drug administration .in which drug absorbance is limited and drug dissolve rapidly.high solubility and low permeability,bio-availability is incomplete drug is not release or dissolve in absorbance window example;insulin,metformin etc.

CLASS IV:

Poor absorb by orally route of administration low solubility and low permeability which both having limitations having low dissolution rate so,bio-availability is produced very less any another route is necessary for drug administration.example;taxol,trihydrate etc.

Advantages of SMEDDS:

- Selective targetting drug possible
- Improve oral bioavailability
- Reduction inter subject and intra subject variability and food effect
- Protection of drug from the hostile environment in GIT
- Protection of more sensitive drug compound
- Versatility of dosage form as can be use with solid or liquid
- High drug payloads
- Consistancy in drug absorption profile
- Target selectiive drug towards specific absorption window in gastrointestinal tract
- More compatible temporal profile of drug absorption
- Better management of delivery profile

- No influence of lipid digestion process
- Increase drug loading capacity
- Ease of manufacturing and scale up
- Oral bioavailability enhancement of poorly water soluble drug
- Ability to deliver peptides that are prone to enzymatic hydrolysis in GIT

Disadvantages of SMEDDS :

- Traditional dissolution method do not work because these formulation potentially dependent on digestion prior to release of the drug
- This in vitro model needs further development and validation before strength can be evaluated
- Traditional dissolution methods do not work, because these formulations potentially are dependenton digestion prior to release of the drug
- The drawbacks of this system include chemical instabilities of drugs and high surfactant concentrations in formulations (approximately 30-60%) which irritate GIT
- Volatile co-solvents in the conventional SMEDDS formulations are known to migrate into the shells of soft or hard gelatin capsules, resulting in the precipitation of the lipophilic drugs
- .Formulations containing several components become more challenging to validate
- High production costs.
- Low drug incompatibility.
- Drug leakage. So it may allow less drug loading.

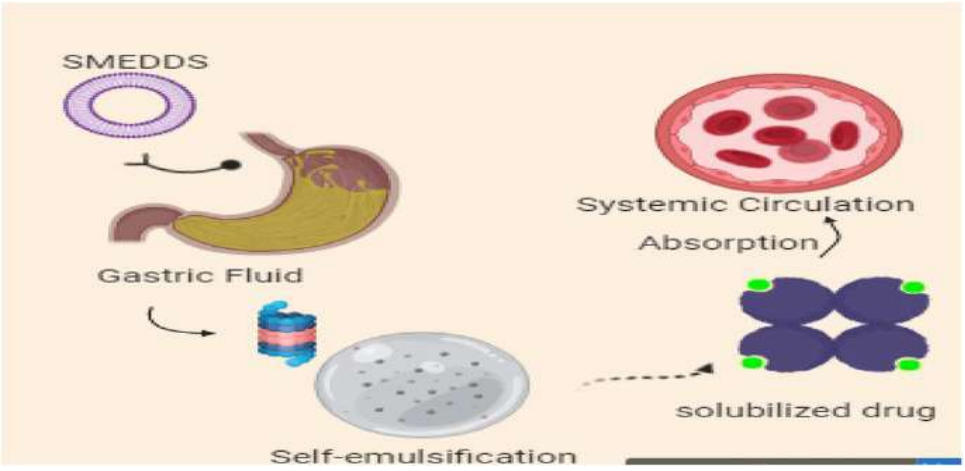
Mechanism of self emulsification:

Self emulsifying processe are related to the free energy is given by

Self emulsifying processes are related to the free energy, ΔG given by:

$$\Delta G = \Sigma N \pi r2 \sigma$$

Where, N = Number of droplets with radius r σ = Interfacial energy It is apparent from the above equation that spontaneous formation of interface between oil & water phase is not favorable due to higher energy level (Reiss, 1975). The system commonly classified as SEDDS have not yet been shown to emulsify spontaneously in true thermodynamic sense



Formulations:

It consist maximum amount of liquidsor excipients which are produced in more quantity from hydrophilic and hydrophobic surfactant are also used co solvent which are soluble in water different oils are used from biological sources all their cominations are form and to give the self emulsifying emulsion.for formulations of SMEDDs different surfactant oil and co solvent are used for enhancing more solubility.this

SMEDDDs preparation in which drug substance is dissolved in mixture of oil ,surfactant and co-solvent this formulation is formulate by addition of polymers or gelling agent.

Ingredients of self emulsifying drug delivery system

Active Pharmaceutical Ingredient (API):

SMEDDS are used to increase the solubility of poor water-soluble drugs, BCS class II drugs are preferred e.g. itraconazole, nifedipine, vitamin E, simvastatin, danazol, ketoconazole, mefanimic acid, naproxen, carbamazepineSEDDS are used to increase the solubility of poor water-soluble drugs, BCS class II drugs are preferred Example: Diclofenac sodium

Oil:

Oil is the one of the key components of self - emulsifying drug delivery system the oil phase should be lipophilic and should be lipophilic and should have a low viscosityA large number of excipients are used in the process of formulation of self-Emulsifying Drug Delivery System.Normally oils having long & medium triglycerides chain with varying in number of double or triple bonds are used for formulation of self-Emulsifying Drug Delivery System. Edible oils provides “Natural” base for lipid containing compounds, but they are no longer used in preparation of self-Emulsifying Drug Delivery System because of their low solubility and low efficiency of self-emulsification, Therefore, modified or hydrolysed vegetable oils are preferred for preparation Self Emulsifying Drug Delivery System formulation Oils can solubilize the required dose of the lipophilic drug and facilitate selfemulsification and also they can increase the fraction of lipophilic drug transported via the intestinal lymphatic system, thereby increasing absorption from the GI tract depending on the molecular nature of the triglyceride.

Table 1:oils with drug products for formulation of SMEDDS,this gives a list of different oils which use to solubilize different drug

Oils	Marketed drug
Corn oil	Valproic acid
Soya bean oil	Ibuprofen, Isotretinoin
Peanut oil	Progesterone, Griseofulvin

Surfactant:

Non-ionic surfactants with high hydrophilic ± lipophilic balance (HLB value) were recommended for the preparation of self-Emulsifying systems, where the tween 80 and numbers of liquid or solid ethoxylated polyglycolyzed glycerides are the mostly used as excipients. Non- ionic surfactants are less toxic as compared to ionic surfactants, but they can cause reversible change in permeability of intestinal lumen. The optimum surfactant concentration in self-Emulsifying system is 30% to 60% w/w surfactant to maintain the stability of emulsifying system .Higher concentration of surface active agents may cause gastrointestinal tract irritation. The surface-active agents are amphiphilic in nature; therefore they have higher affinity of dissolving hydrophobic drugs substances. surfactants with a relatively high hydrophilic lipophilic balance (HLB) and less toxicity than ionic surfactants but they may lead to reversible changes in the permeability of the intestinal lumen. Safety is a major determining factor in choosing a surfactant. water penetration into the oil droplets mediated by the increased surfactant concentration and leading to ejection of oil droplets into the aqueous phase. The surfactants used in these formulations are known to improve the bioavailability by various mechanisms including: improved drug dissolution, epithelial increased permeability, intestinal increased tight junction permeability and decreased/inhibited p-glycoprotein drug efflux.

Table 2: surfactant use with drug substance in self emulsifying drug delivery system list of surfactant used in marketed SMEDDS

Surfactant	Marketed drugs
Tween 20	bexarotene
Span 80	Cyclosporin
Cremophor EL	Loratadine

Co-solvent :

The formulation of SMEDD give high concentration of surfactant but this surfactant cause some gastrointestinal irritation so need to minimize the quantity of surfactant . main purpose of co-solvent is to decrease the interfacial tension to a very low transit negative value . Many organic solvents are suitable for oral use. Some examples are polyethylene glycol, ethanol and propylene glycol, which help to dissolve large concentration of hydrophilic surface active agents or drug in liquid base. Uses of alcohol & other volatile solvents are prohibited in self-Emulsifying system because it results in precipitation of hydrophilic drug substances the lipophilic drug dissolution ability of the alcohol free formulation may be limited. Hence, proper choice has to be made during selection of components.

Table 3: co-solvent used in marketed products

Co-solvent	Marketed products
Glycerine	Soft gelatin capsule
Ethanol	Neoral soft gelatin,neoral oral
Poly ethylene glycol	Gengraf hard gelatin capsule

Evaluation Parameters:

1. Self emulsification time
2. Liquification time
3. Drug content
4. Cloud point measurement
5. Turbid Metric evaluation
6. Dispersibility test
7. Viscosity determination
8. In -vitro diffusion study

1. Self emulsification time :

time required for emulsion to get self emulsify when emulsion dissolved in water it get self emulsify SEDDS should disperse completely and rapidly when subjected to aqueous dilution under mild agitation. The self-emulsification time is determined by using USP dissolution apparatus 2 at 50 rpm, where 0.5 g of SEDDS formulations is introduced into 250 ml of 0.1N HCL or 0.5% SLS (Sodium Lauryl Sulphate) solution. The time for emulsification at room temperature is indicated as self-emulsification time for the formulation 4 The self-emulsification time is calculated by USP dissolution apparatus II (paddle type) at 50 r/ min, where 0.5 g of Self-Emulsifying systems formulations is put into 250 ml of 0.1N HCL or 0.5% SLS solution. The time of occurrence of emulsification at room temperature is determined as self-emulsification time for the formulation.

2. Liquification time:

This test is done to determine the time required by solid SEDDS formulation to melt in vivo in the absence of agitation in simulated gastric fluid21. The formulation is packed in a transparent polyethylene film and tied to the bulb of thermometer. The thermometer is then placed in round bottom flask in which simulated gastric fluid without pepsin is filled. This test is use to determine the time required by solid Self Emulsifying Drug Delivery System formulation to melt in-vivo without agitation in simulated gastric fluid. The formulation is packed in a transparent polyethylene film and tied to the bulb of thermometer .The thermometer is then placed in round bottom flask in which simulated gastric fluid without pepsin is filled. The temperature is maintained at 37+ 0.5°C.

3. Drug content :

Drug from pre-weighed SEDDS is extracted by dissolving in solvent. Drug content in the solvent extract is analyzed by suitable analytical method 14 it can determined by UV spectrometric method. Weighed accurate quantity of liquid SMEDDS formulation equivatent to 10 mg of drug in 100 ml volumetric flask and diluted with methanol to

make up volume upto 100 ml. further 1ml of the solution was dilutednt was analyzed by taking UV absorbance to 10 ml using methnol to make 10 µg/ ml solution.

4. Cloud point measurement:

About 1.0 gm of solid SMEDDS formulation was diluted with distilled water in the ratio of 1:100 and placed in a water bath with gradual increase in temperature and the point at which cloudiness occurred was noted as cloud point cloud point of prepared SMDDS formulation was found to be higher than 85°c

5. Turbid Metric evaluation:

Turbidity is a parameter for determination of droplet size and self-emulsification time 19 Fixed quantity of SEDDS is added to fixed quantity of suitable medium (0.1 N HCL or Phosphate Buffer) under continuous stirring at 50 rpm on magnetic stirrer at optimum temperature and the turbidity is measured using a turbidimeter. Since the time required for complete emulsification is too short, it is not possible to monitor the rate of change of turbidity i.e. rate of emulsification. Turbidimetric evaluation is carried out to monitor the growth of droplet after emulsification. Droplet size analysis & Particle size measurements: Photon correlation spectroscopy (PCS) or dynamic light scattering (DLS) or Laser Diffraction Techniques are used to determine droplet size of emulsion. A number of equipments are available for measurement of particle size viz. Particle Size Analyzer, Mastersizer, Zetasizer etc. which are able to measure sizes between 10 and 5000 nm

6. The dispersibility test:

SMEDDS is carried out to assess its capability to disperse into emulsion and categorize the size of resulting globules. The dispersibility test of SEDDS is carried out to assess its capability to disperse into emulsion and categorize the size of resulting globules. It is carried by using a standard USP dissolution apparatus 2 (Paddle Type). One ml of each formulation is added to 500 ml of water at 37 + 0.5ºC and the paddle is rotated at 50 rpm. On titration with water the SEDDS formulation forms a mixture or gel which is of different type depending upon which the in vitro performance of formulation can be assessed using the following grading system15Grade A: Rapidly forming (within 1 min) nanoemulsion, having a clear or bluish appearance.Grade B: Rapidly forming, slightly less clear emulsion, having a bluish white appearance. Grade C: Fine milky emulsion that formed within 2 min. Grade D: Dull, grayish white emulsion having slightly oily appearance that is slow to emulsify (longer than 2 min).Grade E: Formulation, exhibiting either poor or minimal emulsification with large oil globules present on the surface.Grade A and Grade B formulation will remain as nanoemulsion when dispersed in GIT. While formulation falling in Grade C could be recommend for SEDDS formulation. The stability of the formulation decreases from micro emulsion to emulgel .

7. Viscosity determination

Viscosity determination Turn on viscometer and allow standing must auto zero using L4 spindle for viscous material.level the viscometer by adjust feet and rotate viscometer on shaft until bubble is centre before each use .speed control to 60RPM .upper surface of knob found on left side of housing place the sample and container under viscometer .measure and record the temperature spindle no.should used L4.screw the spindle on to the viscometer

8. In-vitro diffusion study:

In this test the ability of the formulated products to release the active component present in formulation is studied by using dialysis technique where phosphate buffer (pH 6.8) is generally used as dialyzing medium. One end of the dialysis membrane is tied with a thread and 1 ml of the self-emulsifying drug delivery system formulation along with 0.5 ml of phosphate buffer (pH 6.8) is filled in the membrane. The other end of dialysis

membrane is also tied with thread and then rotates in dialyzing medium at 100 r/ min using magnetic stirrer or dissolution apparatus. Samples are withdrawn at different interval of time and then after suitable dilution are analyzed. Same volume of samples withdrawn is replaced with fresh dialyzing medium

Applications :

Supersaturable-SEDDS formulations have a low level of surfactant along with polymeric precipitation inhibitors which makes more stabilized the drug in a super saturated state. HPMC & other cellulose polymers are used to inhibit crystallization and for maintaining supersaturated state of drug for longer time. S-SEDDS are formulated to reduce the side effects of surfactants & to achieve better absorption of poorly soluble drug because high surfactant level may cause GI irritation. It has been observed that the remarkably reduction in concentration of surfactant used in the S-SEDDS formulation gives a better safety profile than the other conventional SEDDS formulation. The mechanism of inhibition of crystal growth and stabilization of super saturation by means of polymers needs further explanation. Indocetaxel and salicylic acid .SEDDS formulation, HPMC is used for inhibition of precipitation in formulation. A five times increase in bioavailability has been observed with PNU91325 when HPMC is placed at the place of propylene glycol, as a precipitation inhibitor Improvement in Solubility and Bioavailability: If drug is formulated in SEDDS, then it increases the solubility of drug substances because it circumvents the dissolution step in case of Class-II drug i.e. Low solubility/high permeability. In SEDDS, the lipid matrix interacts rapidly with water, to forms a fine particulate oil-in-water (o/w) emulsion. The emulsion droplets will release the drug substance in the gastrointestinal tractin a dissolved state readily available for absorption. Therefore, increase in AUC i.e.a bioavailability and Cmax is observed with many drugs when presented in Self Emulsifying Drug Delivery System [8]. Protection against Biodegradation: The capacity of selfemulsifying drug delivery system to reduce degradation as well as it improves absorption, for which both low solubility and degradation in the GI tract contribute to a low oral bioavailability. Many drugs are degraded in physiological system and become in effective, may be because of PH lower than 7 in stomachs, hydrolytic degradation, or enzymatic degradation etc. Such drugs when presented in the form of SEDDS can be protected against these types of degradation processes as liquid crystalline phase in SEDDS might be an act as barrier between this environment and the drug.

Factor Affecting on Self emulsifying drug delivery system:

1. Nature and dose of the drug: Drugs which are administered at very high dose are not suitable for SMEDDS unless they exhibit extremely good solubility in at least one of the components of SMEDDS, preferably lipophilic phase. The drugs which exhibit limited solubility in water typically with logp values of approximately 2 are most difficult to deliver by SMEDDS3 The ability of SMEDDS to maintain the drug in solubilised form is greatly influenced by the solubility of the drug in oil phase
2. Concentration of Surfactant or Co-surfactant: If surfactant or co-surfactant is contributing to the greater extent in drug solubilization then there could be a risk of precipitation, as dilution of SMEDDS will lead to lowering of solvent capacity of the surfactant or cosurfactant.Polarity of the Lipophilic phase: The polarity of the lipid phase is one of the factors that govern the drug release from the microemulsions. The polarity of the droplet is governed by the HLB, the chain length and

degree of unsaturation of the fatty acid, the molecular weight of micronized drug.

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