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Review Article

SELF MICROEMULSIFYING DRUG DELIVERY SYSTEM: A LIPID BASED DRUG DELIVERY SYSTEM

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ABSTRACT

The self-micro-emulsifying drug delivery systems (SMEDDS) are developed to enhance solubility, absorption and bioavailability of poor water-soluble drugs. The globule size between 0-100 nm. Due to poor of lipophilic or hydrophobic drug absorption and dissolution causes least or minimal oral bioavailability. Thus, not able to achieve intended therapeutic effect of the poor water-soluble drugs will led to discover and develop novel drug delivery systems which will fulfill by this route led to development of novel drug delivery systems that will fulfill therapeutic needs with minimum dose of drug. SMEDDS are employed to enhance oral absorption of highly lipophilic compounds. The multiple-lipid based drug delivery systems are widely reported in literature. In multiple lipid-based drug delivery systems include coarse, dry and multiple emulsions and more complex micro emulsifying, Self emulsifying, nano emulsifying drug delivery system.

INTRODUCTION:

At present drug formulation development of hydrophobic drug is a major problem. The hydrophobic drugs have poor water solubility causes low dissolution in the gastrointestinal fluids (GIT fluid) thus poor bioavailability. [1] The low soluble drugs are the BCS class-II in biopharmaceutical classification system. The bioavailability of such drugs are low can be enhanced by increasing the dissolution rate and solubility in the GIT fluids [2-4]. Such hydrophobic (which have lipophilic characteristics) drugs are absorbed by microemulsion which have significant potential for use in self-microemulsifying drug delivery system. A self microemulsifying drug delivery system (SMEDDS) have been used to increase the absorption of lipophilic drugs which are taken by mouth. [5-7]. The SMEDDS are utilized for the oral administration of biologics [2]. Due to iron pairng of appropriate surfactant the hydrophilic macromolecular are incorporated into lipohilic phase which forms oily droplets in the gut and are sufficiently stable towards lipases [3,4].

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These oily droplets permeate the mucus layer in sufficient quantities and show permeation enhancing properties thus the oral bioavailability of variuos drugs are strongly improved [5,6]. Cyclosporin is the first marketed SMEDDS which have better bioavailability compared with the conventional dosage forms. Ritonavir and Sauinavir are the examples of SMEDDS [7,8]. The actual applications of self-microemulsifying drug delivery system (SMDD) remain rare.the cyclosporin is the first marketed SMEDDS which have significantly improved bioavailability compared with the conventional solution. Saquinavir and ritonavir are the examples of SMEDDS. [6,7]

NEED OF SMEDDS

The poor water-soluble drugs or lipophilic drug causes lower bioavailability. Therefore, a self-micro emulsifying drug delivery system (SMEDDS) are developed to improve its solubility and oral bioavailability. The oral delivery of poorly water-soluble compounds are to pre-dissolve the compound in a suitable solvent thus as it overcomes the initial rate-limiting step of particulate dissolution in the aqueous environment within the GIT [12].

SELECTION OF DRUG FOR SMEDDS: The BCS Class II and

BCS class IV drugs in Biopharmaceutical Classification System are used for formulation of SMEDDS [13].

BIOPHARMACEUTICAL ASPECTS OF SMEDDS: The solubility of poorly water soluble are low in natural lipids with intermediate partition coefficient (2<logP<4) and greater in amphiphilic surfactants, co-solvents and co-surfactant thus it provides increased drug loading capacity . The partition coefficient (log p) are the prime criterion of designing lipid based systems. The which have low melting point and low dose drugs are desirable for development of lipidic system [14].

FORMULATION OF SMEDDS

The SMEDDS formulations forms clear dispersion of two phase i.e. oil and water and remains stable. The hydrophobic drugs are absorbed by the SMEDDS and the release of drug from the formulation. The release of drug from the formulation depends on the two causes, first one globule size and second is polarity of the droplets. In the formulation of oil in water microemulsion the drug are incorporated into oil phase because the release of drug does not depend upon the polarity of oil [15,16].

The following parameters can be considered during the formulation of SMEDDS:

- The selection of surfactant, oil and co-solvents depend s on the solubility of drug and preparation of the phase diagram.
- The solubility of the drug in different oils, cosolvents and surfactant.

FORMATION OF MICROEMULSION

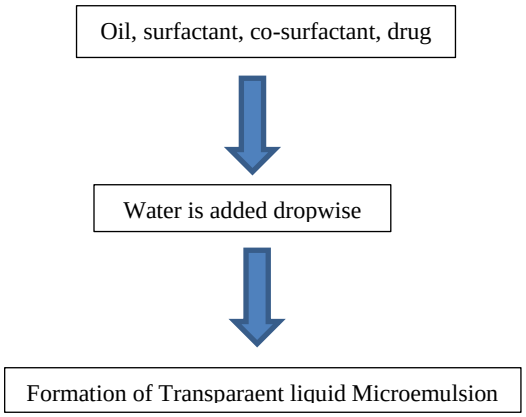

Fig.1. Flow chart for the preparation of SMEDDS

ADVANTAGES OF SELF MICROEMULSIFYING DRUG DELIVERY SYSTEM (SMEDDS) [17]

- Manufacturing is easy and intensify as compare to other lipid dosage forms.
- Oral bioavailability is more by increasing solubility and efficient drug transport.
- Ability to deliver peptides that are likely susceptible to enzymatic hydrolysis in gastrointestinal tract (GIT).
- It gives prolonged release of medicament if polymer is incorporated in the composition of SMEDDS.
- There is no lipid digestion like other lipid based drug delivery system causes lipid digestion

DISADVANTAGES OF SELF MICROEMULSIFYING DRUG DELIVERY SYSTEM

1. Need of *in vitro* model for further validation and development
2. There is lack of good predictive in vitro models for the assessment of formulation.
3. High surfactant concentration in formulations (near about 30-60%) causes GIT irritation.
4. Chemical instability of drug.
5. The drug upon dilution causes precipitation and is higher due to the dilution effect of the hydrophilic solvent.

APPLICATIONS OF SMEDDS [19]

1. High solubility and bioavailability: SMEDDS formulation increases the solubility of drug thus enhance the bioavailability and also reduce the GIT irritation.
2. Super saturable SMEDDS: The super saturable SMEDDS are developed to overcome the toxic effect of surfactant in GIT when used in very high concentration as typically used in SMEDDS.
3. Protection of drug from biodegradation: The drugs with low solubility and low degradation in GIT result in low oral bioavailability, moreover smedds are useful for such drugs due to the ability to improve absorption as well as reduce degradation.

EXCIPIENTS USED IN SMEDDS FORMULATION

Oil: The oil solubilizes the hydrophobic drug thus self-emulsification. The lipid molecule has tendency to increase the fraction of drug transported through intestinal lymphatic system and thus lipophilic drug absorption can be increase from the GI tract. The oil is responsible for the emulsification in SMEDDS which are depend on molecular structure of oil [20]. The long chain triglycerides (LCT) and medium chain trigycerides (MCT) are used for emulsification. Example of LCTs are Sesame, Soyabean, Olive, Peanut, Corn, rapeseed Oils, Peanut. Example of MCTs are palm seed oil, Fractionated Coconut oil [21,22].

Surfactant

The surfactants which have HLB value of more than 12 are most widely used in SMEDDS. The surfactant are responsible component for formation of stable emulsion upon dilution and prevent precipitation of drug thus stabilize the internal phase in an emulsion in GIT tract [23]. The epolyethoxylated lipid derivative are the surfactant that are widely used in lipid based drug delivery

syste [24]. The emulsifiers of natural origin have poor emulsification property so they are not widely used [25]. The non-ionic surfactant show good emulsion stability and they are less toxic than ionic surfactant [26]. The surfactant concentarion usually arranges between 30-60% w/w to form stable self microemulsifying drug delivery system (SMEDDS) [27]. Very little droplets of SMEDDS promotes rapid gatric emptying and low local concentration of surfactant reduces gastric irritation. There are total 3 types of surfactant ionic surfactants (e.g Sodium lauryl sulfate, Pottasium laurate), cationic surfactants (For e.g. Quaternary ammonium halide) and Ampholytic surfactants (For e.g. Sulfobetaines) [28, 29].

LIST OF SURFACTANTS USED IN SMEDDS [30]

Table No.1. List of surfactants used in SMEDDS

Sr. No.	Chemical or Common name	Trade Name	HLB
1.	PEG 400 caprylic glycerides/capric	Labrasol	14
2	Polyoxyl 35 castor oil	CremophorEL	12-14
3	PEG 1500	lauric glycerides Gelucire 44/14	14
4	Polyoxyethylene 20 sorbitan monooleate	Polysorbate 80	15

Co-surfactant: The surfactants are used to reduce the interfacial tension between water and oil phase, which are harmful. Moreover the co-surfactants are used to reduce the concentration of surfactants. In general co-surfactant which have HLB value 10-14 are mostly used. For example –Propylene glycol, Polyethylene glycol, ethanol [31].

Co-solvents: The organic solvents enable to dissolve large quantities of either the hydrophilic surfactant or the drug in oil phase. For e.g. Butanol, ethanol, propylene dlycol , esters (e.g., ethyl propionate, tributyl citrate), amides (e.g., polyvinyl prrollidine, caprolactum) [32].

Other components: The PH adjusters, flavouring agents, antioxidants are provide strength to the formulation, Lipid peroxidase can be formed due to auto-oxidation, which helps to increase the unsaturation level of the lipid. Thus, the lipophilic antioxidants may be required. For e.g. propyl gallate, ascorbyl palmitate or BHT, α- tocopherol [33].

PREPARATION OF SMEDDS:

The ratio surfactants to co-surfactants are optimized by using ternary phase diagram of formulation. The formulations are prepared by using optimized ratio of surfactant mixtures. The optimized mixture of surfactant and co-surfactants are accurately weigh and then vortexed for 5-10 minutes. Then, surfactant mixtures are placed in oven at 50 °C for 1 h. The oil with different ratio are added to surfactant mixtures then these formulations are vortexed for 5-10 minute then placed in oven at 50 °C for 1 h. thus isotropic mixtures are formed. The drug is loadd to these isotropic formulations at the end and vortexed by vortex shaker until the clear solution is obtained [34,35].

Mechanism of self- emulsification: In self microemulsifying drug delivery system the emulsification take place due to whem the entropy change is greater than the energy required to increase the surface area. For emulsification it is important to reduce interfacial tension significantly causes surface shearing between two phase that id oil and water. The interface between the water (continuous phase) and oil (discontinuous phase) if formed by addition of a binary mixture of aqueous penetration through the interface as a result of aqueous penetration through the interface and solubilization within the oily phase close to the interphase. The aqueous penetration will lead to the formation of dispersed liquid crystal phase which are responsible for the high stability of microemulsion against coalescence [36].

Evaluation of SMEDDS:

Thermodynamic stability studies: For the evaluation of stability study of formulations freeze thawing are employed. In these method the formulations can be subjected to 3 to 4 freeze thaw cycles, consist of free zing at -4°C for 24 hours followed by thawing at 40 °C for 24 hours. After that the formulations are subjected to centrifugation at 3000 rpm for 5 minutes. Then the phase seaparation of formulation can be observed. The formulations that are stable after centrifugation will select for further studies [37].

Dispersibility test:

The USP dissolution apparatus can be used to determine the efficiency of SMEDDS. 1ml of each formulation is added to 500 ml of water at 37±0.5 ˚C. The stainless steel dissolution paddle rotating at 50 rpm provides gentle agitation. The in-vitro dissolution study of the formulations are visually assessed by using grading system. Grade A: Rapidly forming (within 1 min) nanoemulsion, which have a clear or bluish appearance. Grade B: Rapidly forming slightly less clear emulsion which have a bluish white appearance. Grade C: The Fine milky emulsion can be formed within 2 minute. Grade D: Dull, grayish white emulsion which have a little oily entrance that is slow to emulsify (lengthier than 2 minute). Grade E: Formulation, demonstrating either poor or slight emulsification with bulky oil globules present on the surface. Grade A and Grade B formulation when dispersed in GIT that will remain as nanoemulsion, while formulation falling in

Grade C could be recommend for SMEDDS formulation [38].

Turbidimetric evaluation: Nepheloturbidimetric evaluation can be used to monitor the growth of emulsification. The fixed quantity of self emulsifying system is added to fixed quantity of suitable medium (generally 0.1 M HCl) with continuous stirring at 50 rpm on a magnetic plate at ambient temperature. Then the increase in turbidity is measured by using a turbidimeter. Neverthehless the time require to complete emulsification is very short and it is not possible to monitor the rate of change of turbidity [38].

Viscosity Measurement: [39]

The Rheological Properties of micro-emulsion is measured by Brookfield viscometer. The viscometer is used for the determination of emulsion type like whether it is o/w or w/o. If system has high viscosity then it is w/o and if system has low viscosity then it is o/w type of emulsion.

Determination of droplet size and zeta-potential: The droplet size measurement is used to measure the rate and extent of drug release and stability of the emulsion. For the determination of droplet size photon correlation microscopy is used. Zetasizer (For e.g. Malvern instrument, Australia) is used to measure droplet size in the range from 10-5000 nm [1]. This method only employed at relatively low dilutions for accurate droplet size evaluation. The oil droplets shows negative charge on their surface due to the presence of free fatty acids. Moreover, the incorporation of 1-3% cationic lipids yield cationic SMEDDS. Thus, such system has a positive n-potential value of about 35-45 mV. The positive n-potential value is preserved for incorporation of the drug compounds [40,41]

Polarity: Polarity of oil droplet is governed by some parameters such as the HLB, chain length, and degree of unsaturation of the fatty acids, molecular weight of the hydrophilic portion, and concentration of the emulsifier. Polarity has an impact on affinity of the drug for oil and/or water, and the type of forces formed. The highest release will be obtained with the formulation that has oil phase with the highest polarity [42].

***In vitro* release**:

For quantitative determination of drug resease the *in-vitro* release test is performed in 900 ml of purified distilled water, which is based on USP XXIV dissolution method. The self-microemulsifying drug delivery system is placed in dialysis bag at the time of release of drug for comparing release profile with conventional tablet. withdraw 10 ml of sample solution at predetermined time intervals, filtered through the 0.45µ membrane filter, dilute suitably and analyzed by spectrophotometer. The equal amount of fresh dissolution medium is replaced immediately after withdrawal of the test sample. Calculate Percent drug dissolved at different time intervals by using the Beer Lamberts equation. 43

Handling and storage issues with liquid SMEDDS [43]

In SMEDDS are generally viscous liquid which are entered into soft or hard gelatin capsule. The lipid formulation may leak into and interact with the capsule shells. Due to leakage of content and precipitation of drug or excipients causes brittleness or softness of capsule shell specially at low temperature.

MARKETED PREPARATION

Sr. No.	Name of product	Manufactured by	Dosage Form	Use
1	Neora® (cyclosporine A/I)	Novartis Pharmaceuticals Corporation	Soft gelatin capsule	Systemic immunosuppressant
2	Sandimmune® (cyclosporine A/I)	Novartis pharmaceuticals corporation	Soft gelatin capsule	Indicated for the organ rejection prophylaxis in allogenic transplants of kidney, liver, and heart
3	Vesanoid® (Tretinoin)	Roche Laboratories Inc.	Soft gelatin capsule	Retinoid that induces maturation of acute promyelocytic leukemia (APL)

CONCLUSION:

The SMEDDS are promising approach for the formulation of drugs which have poor water solubility. SMEDDS are used to enhance the solubility, dissolution, absorption and bioavailability of hydrophobic drugs. Thus, SMEDDS are superior to reduce dose of drug, reduce production cost. Thus, they are used for delivering the BCS class II and class IV drugs. Self micro-emulsifying drug delivery system is very essential to develop different solid dosage forms for parenteral and oral administration.

CONFLICT OF INTEREST: The authors report that they have no conflict of interest.

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