SELF EMULSIFYING DRUG DELIVERY SYSTEM FOR IMPROVING BIOAVAILABILITY

Akanksha Agrawal¹, Arti J. Majumdar² and Ankur Jain³

¹Research Scholar, Pharmaceutical dept., Rishi Raj College of Pharmacy, Indore, India
²Assistant Professor, Pharmaceutical dept., Rishi Raj College of Pharmacy, Indore, India
³Professor, Pharmaceutical dept., Rishi Raj College of Pharmacy, Indore, India

Abstract

Oral route is the most common and convenient route for drug delivery, but some drugs are not given by this route. This route is most common problem is low bioavailability. The various challenges faced by the pharmaceutical scientists leads to the improve bioavailability of poorly soluble drugs. SEEDS being a lipid based formulations consist of oils, surfactants, solid lipid nanoparticles, dispersion, emulsion and liposomes. Different type SEEDDS are available in market like as oral drug delivery, Topical delivery, parental drug delivery, ocular & pulmonary drug delivery. Different type of oral dosage forms are available in the market like as Self emulsifying capsule, Self emulsifying controlled release pellets, Self emulsifying sustained/controlled release pellets, Self emulsifying solid dispersion. In drug detection and growth solubility has an important role in various step to import high bioavailability and to gain required pharmacological action due to low aqueous solubility, effect the lipophilic drug. Lipophilic drug has shown low bireability when aqueous solubility has low.

Keywords: self emulsifying drug delivery system, solubility, bioavailability, dissolution, Oral drug Delivery, Controlled Drug release.

I. INTRODUCTION

Oral route has most common, least invasive and easiest route as there has no main complication associated with Oral administration (PO) route (PO stands intended for per os, or by mouth) in patients who take oral medication except first pass metabolism which has a main impact on the systemic plasma concentration of drugs. Oral administration (PO) route of highly lipophilic, poorly H2O soluble drugs outcomes in poor and highly variable bio-availability because of low dissolution in-vivo.

All orally taken medicine have absorbed via the gastric and duodenal mucosa and then transported to liver through the portal venous system. In the liver, these medications go through “first-pass metabolism” before incoming the systemic circulation. This has a main impact on the systemic plasma concentrations of the drugs intended for drugs administered orally, absorption might begin in the mouth and stomach.

The oral route is most perfect route for chronic drug therapy. Approximately 35-40% of new drug candidate have show low water solubility. To overcome these problems new technique were reported to increase solubility and bioavailability including complication with cyclodextrins, solid dispersion, co precipitation, micronization and emulsions.

Emulsions are used as vehicles for the administration of drugs, especially due to its potential of enhancing the oral bioavailability of poorly absorbed drugs.
Self emulsifying drug delivery systems are defined as isotropic mixture of lipid/oil, surfactant, co-surfactant and drug substance that rapidly form a fine oil-in-water micro (SMEDDS) and nano (SNEDDS) emulsions, when exposed to aqueous media under conditions of gentle agitation or digestive motility that would be encountered in GIT. The spontaneous formation of emulsion advantageously presents the drug in a dissolved form, and the resultant small droplet size provides a large interfacial surface area.4

II. SOLID CONTROLLED SELF EMULSIFYING DRUG-DELIVERY SYSTEM

Oral administration of highly lipophilic, poorly H2O soluble medicine often result in poor and highly variable bio-availability because of low dissolution in vivo. Single approach intended for enhancing the incorporation of these medicine involves the use of self emulsifying drug-delivery system (S.E.D.D.S.) which rapidly disperses subsequent Oral administration (PO) route yielding an o/w emulsion or micro emulsion containing the solubilized drug. S.E.D.D.S. formulation have typically develop by an empirical trial and fault approach although some useful guidelines have emerged as of characterization of successful formulation such as Neoral.

The three key in vitro measures of a S.E.D.D.S. formulation are:

- Ease of emulsification
- Dispensability (i.e. droplet size)
- Drug solubilization

III. LIPID-BASED EXCIPIENTS INTENDED FOR ORAL DRUG-DELIVERY

The formulator has hundreds of potential excipients as of which to choose intended for the preparation of lipid-based formulations despite the numeral of possibilities, only a relatively small subset of lipids has found appliance in the clinical formulation development toward a limited or nonexistent history of pharmaceutical appliance or more commonly, a not have of regulatory approval.

The pharmaceutically relevant properties of subsequent, currently marketed classes lipid excipients are:

- Fatty acids
- Natural oils and fats
- Semi-synthetic mono, di and triglycerides
- Semi-synthetic polyethylene glycol (PEG) derivatives of glyceride and fatty acids
- Polyglyceryl fatty acid esters
• Cholesterol and phospholipids

IV. ADVANTAGES

The formulator has hundreds of potential excipients as of which to choose intended for the preparation of lipid-based formulations

- Controlled Drug delivery profile.
- Minimum dose of drug can be used.
- Drug absorption are most effective.
- It acts as substitute for traditional oral formations of lipophilic drugs.
- Selective drug targeting toward a specific site in the GI tract.
- Protection of drug molecules from the hostile environment.  

V. DISADVANTAGES

There are the following disadvantages of SEDDS include

- Less drug loading may allow.
- There may be changes of instabilities of drugs due to presence of high surfactant concentration
- Also the high content of surfactant in self emulsifying formulations irritates the gastrointestinal tract. This problem may be avoided by utilizing optimum less amount of surfactant.
- Degradation problem of drugs due to some times co-solvent remain into the formulation .

VI. EVALUATION PARAMTERS OF SEDDS

IN THIS PAPER DIFFERENT TYPE OF EVALUATION PARAMETERS INCLUDED-

- Visual assessment
  This test is to identify efficient self emulsification by measuring the turbidity to ascertain dispersion equilibrium within the reproducible time.
- Thermodynamic stability studies
  Heating cooling cycle-the formation are subset to six ycle between refrigerators temperature with 45ºC storage condition. The whole process is subjected to 48 hr.
- Droplet size analysis
  Photon correlation spectroscopy is used to ind the droplet size of emulsions between 10 ad 5000 nm using zetasizer
- Viscosity determination
  As SEDDS system is generally administered in soft or hrd gelatin capsule, it is necessary to measure rheological properties of micro emulsion by Brookfield viscometer. This is used to find out the type of system whether it is w/o or o/w.
- Centrifugation
  The formulation are centrifuged cycle between 21ºC to 25ºC with stoage at each temperature not less than 48 hrs. The process is done for 30 minutes with 3500 rpm.
- In vitro diffusion studies
  Invitro diffusion studies are carried out to study the drug release of formulation from liquid crystalline phase around the droplet using dialysis technique.
- Electro conductivity Study-
  Electroconductometer is used to study the electro conductive nature of system whether the SEDD system contains ionoc or non ionic surfactant, oil and water.
VII. APPLICATION

In this paper self emulsifying drug delivery system is improvement of solubility and bioavailability as it cerements he dissolution steps in care of class II drug (low solubility/high permeability).

- Low gastric irritation
- Oral hydrophobic drug delivery to be effective.
- Eminent protection of drugs against biodegradation.

EX-(1) Ketoprofen a moderately drug nonsteroidal anti inflammatory drug has low solubility but ketoprofen reported complete drug release if it is formulated as SEDDS in non crystalline for.

EX-(2) Furosemide a moderately anti diuretic drug has low solubility but urosemide reported complete drug release if it is formulated as SEDDS.

VIII. CONCLUSION

SEDDS were unable to self emulsify upon integration with water under mild agitation or yielded an unsuitable emulsion were discarded. In preliminary study some SEDDS were rejected due to finding of oil droplets upon the surface of the diluted SEDDS, which translates to unfinished emulsification. A few SEDDS were rejected due to construction of milky appearance upon dilution.

Self emulsifying drug delivery system efficiently improves the dissolution of sparingly soluble drugs by rapid self emusification. SEDDS seems to be novel and hence its use can be followed in industry to fasten the oral bioavailability of the lipophilic drugs.

It was likely that oil droplets containing dissolved furosemide diffused out of HPMC matrices subsequent the controlled discharge SSE formulation on contact to water media. Thus, this formulation advance provides the chances of combining the features of controlled discharge & self emulsifying formulation, for the biopharmaceutical necessities of oral low H2Osoluble drugs.

IX. FUTURE PROSPECTIVE

Conductance of human bioavailability studies should be the priority for future research and more emphasis should be given towards the studies on the mechanism of action of this type of SEDDS formulation.

There is still way to go however before added solid self emulsifying dosage forms (except for SE Capsules) appear in the market as there be present several field of solid SEDDS to be more exploited for example study regarding human being bioavaibility and correlation of in-vivo and in-vitro.

It is also important point out several problems to which a lot consideration should be remunerated, for case material aging occurrence related with glycosides’, oxidation of vegetable oils and interaction involving drug and excipients.

Choice of suitable excipients is the major hurdles of budding solid SEDDS. Thus these aspects should signify the major future working route for solid SEDDS.

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BIBLIOGRAPHY


