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*Original Research Article*

# Formulation and Optimization of Self Emulsifying Drug Delivery System (SEDDS) of Poorly Soluble Herbal Drug

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***Abstract***: Developing a self-emulsifying drug delivery system (SEDDS) for Commiphora wightii extraxt was the aim of this study in order to increase its solubility, in vitro dissolving efficiency, and bioavailability. The extract of Commiphora wightii was found to be soluble in a range of oils, cosurfactants, and surfactants. The prepared SEDDS was assessed for stability, in vitro dissolution, drug content, and emulsification time. Maximum solubility, reduced emulsification time, good stability, and enhanced in vitro release were all demonstrated by the optimized formulation. In this investigation, data was imported using pre-existing historical data. It was determined that SEDDS would be a viable oral medication delivery method for poorly water-soluble plant extract.

**Keywords**: Self-Emulsifying Drug Delivery System (SEDDS), Commiphora wightii Extract, Solubility Enhancement, In Vitro Dissolution, Oral Bioavailability.

## INTRODUCTION

Approximately 40% of new drug candidates have poor water solubility, and the oral deliveries of such drugs are frequently associated with low bioavailability.To overcome these problems, various formulation strategies are exploited including the use of surfactants, lipids, permeation enhancers, and micronization. Majority of these approaches have their limitations because of the need for specialized equipment, complicated manufacturing process, longer processing time, and regulatory complexity. Lipid-based formulation approaches, particularly the self-emulsifying drug delivery system (SEDDS), are well known for their potential as an alternative approach for delivery of hydrophobic drugs, which are associated with poor water solubility and low oral bioavailability.SEDDS is among the methods used to improve the oral bioavailability of poorly soluble drugs by presenting and maintaining the drug in a dissolved state, in small droplets of oil, all over its transit through the gastrointestinal tract (GIT).

SEDDSs are the isotropic mixtures of oil, surfactant, cosurfactant, and drug which form oil in water microemulsion. These formulations spread readily in the GIT, and the digestive motility of the stomach and intestine the agitation necessary for self-emulsification. In a good self-emulsifying system, small emulsion droplets containing dissolved drug are formed on contact with the gastrointestinal fluid. The drug in the fine emulsion droplets is exposed to a large interfacial area, thus allowing for greater diffusion through the membrane to take place.

**Formulation of self-emulsifying drug delivery system (SEDDS)**

**Solubility Profile:** Solubility of *Commiphora wightii* extract was checked visually in distilled water, methanol, ethanol, DMSO, chloroform, acetone and phosphate buffer (pH 5.4). Accurately weighed 1 gm

 

of drug was transferred in a clean and dry test tube followed by addition of the solvents individually and shaken vigorously and the solubility of drug was checked visually. Determination of solubility in DMSO and phosphate buffer pH 5.4 mixture for determination of ratio; accurately weighed 20 mg of *Commiphora wightii* extract was added individually to ten clean and dried volumetric flasks each of 10 ml capacity. DMSO and phosphate buffer pH 5.4 solvent system was added in the ratio 1:9, 2:8, 3:7, 4:6,5:5, 6:3, 7:3, 8:2, 9:1 and the samples were shaken for 1 hour on linear motion shaker (Model no. REMI RQ 123, Spectra Whirlmatic Lab,India). The solutions were checked visually for their clarity.

**Analytical Methodology:** The ultraviolet absorption spectrum of a solution of *Commiphora wightii* extract in DMSO and (8:2) mixture of DMSO and Phosphate buffer pH 5.4 was obtained using UV/VIS spectrophotometer over a wavelength range of 200 to 400 nm. Maximum absorption (λmax) values were determined and further used for plotting calibration curve.

**Characterization of Oil, Surfactant and Co-Surfactant for Microemulsion [8-9]**

**Determination of Solubility in various Oil, Surfactant and Co-surfactant:** Preformulation solubility analysis was done to select the vehicle in which drug is more soluble and suitable for formulation of SEDDS. The solubility of drug in various oils, surfactants and co surfactants was measured and the solvents for the study were selected based on the good solublising capacity for drug. In present study the solubility of drug was investigated in different oils like soyabean, olive oil, Capryol 90 etc, surfactants and co-surfactants like labrasol, RH 40 and PEG, Propylene glycol etc. An excess amount of drug was added into each vehicle followed by vortex mixing for 30sec (Remi mixer, Mumbai). Mixtures were shaken for 48 h at 300 C, followed by equilibrium for 24 hr. The equilibrated samples were then centrifuged at 1000 rpm for 10 min to remove the insoluble drug and clear supernatant liquid was decanted. An aliquot of the supernatant was diluted with DMSO and solubility of drug was estimated by UV spectroscopy at 328 nm.

**Screening of oils and surfactant:** The oils and surfactants were selected on the basis of their tendency for instant emulsification and solubility in extract. The oils selected for this investigation were Capryol 90, Olive oil and Soyabean oil. The surfactants selected were Cremophor RH-40, Labrasol and Cremophor EL. The oils and surfactant were mixed in a ratio of 1:1. Briefly, 150 mg of the surfactants were added to 150 mg of the oily phase. Each mixture, 100 mg, was then diluted with distilled water to 100 ml in a stoppered conical flask. Ease of emulsification was judged by the number of flask inversions required to yield homogenous emulsion. Emulsions were allowed to stand for 2hr and their % transmittance was evaluated at 638 nm by UV-Visible spectrophotometer using distilled water as a blank. Emulsions were furthermore observed visually for any turbidity or phase separation.

**Preliminary screening of co-surfactants:** The selected oily phase and surfactant were used for further screening of the different co- surfactants (Propylene glycol, PEG 400 and Tanscutol) for their emulsification ability. Mixtures of 200 mg of co-surfactant, 400 mg selected surfactant, and 600 mg screened oil were prepared and evaluated in a similar fashion as described in preliminary screening of surfactants.

**Formulation of Self Emulsifying Drug Delivery System[8-10]**

Self-emulsifying drug delivery system of *Commiphora wightii* extract was prepared by mixing oil, surfactant and co-surfactant with different component ratios. The amount of *Commiphora wightii* extract was kept constant in all the formulations and different proportions of oil and surfactant and co-surfactant mixture were added. The required amount of *Commiphora wightii* extract was dissolved in the selected oil at room temperature by constant stirring and then the mixture of surfactant and co-surfactant was mixed with gentle stirring and sonication. Then appropriate amount of water was added drop by drop to the mixture while continuously stirring. Microemulsion of Commiphora whitei extract was spontaneously obtained by stirring the mixture at ambient temperature. Various formulation proportions (GF1 to GF8) are given in Table. The self-emulsification process was monitored for the rate of emulsification and the presence of emulsions produced. Visual properties registered against the increase of applied surfactant component in ternary triangular diagrams. Plotting points of preferential combinations were selected according to the calculations.

**Table 1: Compositions of *Commiphora wightii* extract (SNEDDS) (1–8)**

| Formulation code | Capryol | Propylene Glycol | RH 40 | Labrasol |
|---|---|---|---|---|
| GF1 | 33.33 % | 33.33 % | 33.33 % | - |
| GF2 | 25 % | 50 % | 25 % | - |
| GF3 | 20 % | 60 % | 20 % | - |

| | | | | |
|---|---|---|---|---|
| GF4 | 25 % | 25 % | 50 % | - |
| GF5 | 33.33 % | 33.33 % | - | 33.33 % |
| GF6 | 25 % | 50 % | - | 25 % |
| GF7 | 20 % | 60 % | - | 20 % |
| GF8 | 25 % | 25 % | - | 50% |

**Evaluation of Formulation Self Emulsifying Drug Delivery System [10-15]**

**Drug excipient compatibility studies:**
Fourier transforms infrared spectroscopy is a useful analytical technique utilized to check the chemical interaction between drug and other excipients used in the formulations. Drug and the intended excipients interaction were studied by FT-IR. The intended samples were powdered and intimately mixed with dry powdered potassium bromide. The powdered mixture was taken in a diffuse reflectance sampler, and the spectrum was recorded by scanning in the wavelength region of 4000-400 cm−1 in FT-IR spectrophotometer.

**Drug content:** Self-emulsifying drug delivery systems formulation equivalent to 100 mg of *Commiphora wightii* extract was taken and dissolved in small quantity of methanol. Volume was made up to 100 ml with DMSO solution (1 mg/ml). From the above stock solution, 0.2 ml (200 µg/ml) was withdrawn and diluted up to 10 ml with methanol (20 µg/ml). Samples were prepared in triplicate and absorbance measured at 328 nm using UV-visible spectrophotometer. DMSO was used as a reference solution.

**Self-emulsification assessment:** SMEDDS should form stable microemulsion instantaneously in GI fluids upon administration. Efficiency of selected combination of surfactant and co-surfactant in self microemulsification was assessed by dispersing the SMEDDS in 250 mL of water with magnetic stirring at 100 rpm to create gentle turbulence that mimic in vivo condition and assessed visually.

***In-vitro* dissolution studies:** The quantitative *in-vitro* dissolution studies are carried out to assess drug release from oil phase into aqueous phase by USP type II dissolution apparatus use of 900 ml of pH 6.8 phosphate buffer solution at 75 rpm and maintain the temperature at 37°C ± 0.5°C. Aliquots of 5 ml samples were withdrawn at regular intervals of time (5, 10, 15, 30, 60 min) and volume withdrawn was replaced immediately with fresh medium. Samples taken were then analyzed by use of UV spectrophotometer at *328* nm.

**Accelerated Stability Studies**
The optimized formulations SEDDS were filled in the glass vial, sealed with rubber cap and crimped for storing in the stability chamber. Samples were subjected to a stability testing for six months as per ICH norms at a temperature and RH of 40°C ± 2°C/75% RH ± 5% RH respectively. The selected formulations were analyzed for the change in droplet size, zeta potential, self-emulsification capacity and drug content .

## SOLUBILITY PROFILE

Solubility of powdered extract of *Commiphora wightii* in various solvent are presented is in Table.2 It can be revealed from table that *Commiphora wightii* is soluble in Acetone and DMSO, thus DMSO or Acetone was selected for further studies.

**Table 2: Solubility Profile of *Commiphora wightii* extract**

| S. No | Solvent | Solubility |
|---|---|---|
| 1. | Distilled Water | Sparingly Soluble |
| 2. | Methanol | Sparingly Soluble |
| 3. | Ethanol | Sparingly Soluble |
| 4. | Acetone | Sparingly Soluble |
| 5. | Chloroform | Sparingly Soluble |
| 6. | Phosphate Buffer (5.4 pH) | Sparingly Soluble |
| 7. | DMSO | Soluble |

**Analytical Methodology UV-Visible Spectroscopy**
The Lamda max (λmax) of *Commiphora wightii* extract in DMSO was found to be 328 nm.

**Characterization of Oil, Surfactant and Co-Surfactant Selection of Excipients**
In this study, we selected Cremophor EL and Labrasol as a surfactant. Transient negative interfacial tension and

 

fluid interfacial film are rarely achieved by the use of single surfactant; usually, addition of a co surfactant is necessary. The presence of co surfactant decreases the bending stress of interface and allows the interfacial film sufficient flexibility to take up different curvatures required to form microemulsions over a wide range of composition.

**Table 3: Solubility of *Commiphora wightii* in Various Oil, Surfactant and Co-surfactants**

| S. No. | Solvent | | Solubility (µg/ml) of *Commiphora wightii* |
|---|---|---|---|
| 1. | Oil | Olive Oil | 25.01 |
| | | Capryol 90 | 66.33 |
| | | Soyabean Oil | 33.35 |
| 2. | Surfactant | Cremophor EL | 72.21 |
| | | Labrasol | 75.32 |
| | | CremophorRH-40 | 71.31 |
| 3. | Co-surfactant | Propylene Glycol | 57.14 |
| | | PEG 400 | 39.76 |
| | | Transcutol P | 41.21 |

Thus, co surfactant selected for the study was Propylene glycol, which has an HLB value of 5-6. Surfactants and co-surfactants were selected on the basis of their emulsification efficiency and ability to solubilise *Commiphora wightii* extract.

**Drug content**

The % drug content of all SEDDS formulations was found to be within the acceptable limits of drug content test. The Assay results are shown in table no7.4.

**Table 4: Drug Content of SEDD formulation with *Commiphora wightii* extract**

| S. No. | Formulation | Percentage of Drug contents (X ± SD) |
|---|---|---|
| 1 | GF1 | 98.3±1.7 |
| 2 | GF2 | 98.5±0.5 |
| 3 | GF3 | 99.2±0.7 |
| 4 | GF4 | 96.8±96 |
| 5 | GF5 | 98.6±0.9 |
| 6 | GF6 | 98.4±0.8 |
| 7 | GF7 | 98.4±1.3 |
| 8 | GF8 | 94.8±1.8 |

SD = Standard deviation

**Determination of self-emulsification time**

Emulsification time is an important index for the assessment of the efficiency of emulsion formation. SEDDS should disperse completely and rapidly when subjected to aqueous dilution under mild agitation. Formulation should disperse quickly when subjected to aqueous dilution under gentle agitation of GIT due to peristaltic activity. The emulsification time of all formulations was reported in Table The lowest emulsification time 58 seconds was found in GF3 formulation and highest emulsification time 157 seconds was found in F8 formulation. After observation it was found that the GF3 formulation forms microemulsion in a short time relatively among all other formulations which indicate that the GF3 was best of all prepared formulations.

**Table No.6: Self Emulsification time of SEDDS formulation**

| S. No. | Formulation | Self-Emulsification Time |
|---|---|---|
| 1 | GF1 | 87 ± 1.8 |
| 2 | GF2 | 62 ± 0.4 |
| 3 | GF3 | 58 ± 0.6 |
| 4 | GF4 | 110 ± 2.8 |
| 5 | GF5 | 90 ± 0.7 |
| 6 | GF6 | 79 ± 5.6 |
| 7 | GF7 | 73 ± 1.3 |
| 8 | GF8 | 157 ± 2.4 |

***In-vitro* dissolution study**

 

In-vitro dissolution study was conducted to compare the pure extract release from the developed *Commiphora wightii* extract SEDDS formulation. Quantitative in vitro dissolution studies are performed to assess drug-release from the oil phase to the aqueous phase by USP Type II dissolution apparatus.

The results of the in vitro dissolution studies were listed in the table and figures below. After looking at the results, it was found that, about 93.27% drug was released from *Commiphora wightii* SEDDS GF3 formulation within 60 minutes as compared to other formulations, i.e. GF1, GF2, GF4, GF5, GF6, GF7 and GF8, which were 67.45%, 85.41%, 56.61%, , 61.65%. 77.42,85.56% and 50.25% of the drug respectively. Thus, the drug release from *Commiphora wightii* SEDDS SF3 formulation was found to be significantly higher as compared to the remaining SEDDS formulation and pure extract. It could be suggested that the SEDDS GF3 formulation resulted in the spontaneous formation of a microemulsion with smaller droplet size, which allowed a faster release rate of the drug into the aqueous phase. Thus, greater availability of dissolved *Commiphora wightii* extract from the SEDDS GF3 formulation may lead to higher absorption and higher oral bioavailability.

The release data obtained in this study was extrapolated by zero order, first order, Higuchi, Korsmeyer-Peppas, Hixon-Crowell equations to know the mechanism of drug release from the formulation. The in vitro drug release profile of the optimized formulationGF3 was best expressed by the Higuchi equation as the plots showed the highest linearity (coefficient of determination, R2 = 0.993).

The formulations showed good linearity when plotted according to Higuchi equation. It can be inferred that the release was dependent on both motility and polymer relaxation.

**Table 8: In-vitro drug release profile of SEDDS formulation**

| Time | SEDDS Formulation | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | GF1 | GF2 | GF3 | GF4 | GF5 | GF6 | GF7 | GF8 |
| 5 | 22.63 | 27.85 | 32.85 | 16.45 | 18.69 | 21.82 | 26.4 | 14.95 |
| 10 | 39.32 | 40.11 | 46.88 | 29.28 | 33.32 | 35.64 | 37.97 | 23.91 |
| 15 | 43.23 | 52.79 | 54.55 | 36.43 | 40.22 | 48.76 | 48.89 | 32.46 |
| 30 | 53.83 | 64.18 | 73.68 | 46.24 | 48.87 | 58.98 | 65.67 | 41.64 |
| 45 | 59.85 | 74.45 | 88.45 | 50.27 | 56.81 | 68.75 | 76.98 | 46.45 |
| 60 | 67.45 | 85.41 | 93.27 | 56.61 | 61.65 | 77.42 | 85.35 | 50.25 |

**Stability Studies**

Samples from stability chamber were withdrawn at regular intervals and evaluated for self emulsification efficiency, droplet size and zeta potential measurements. Results were represented in Table. There was no significant change in the droplet size, zeta potential and self-emulsification capacity. Clear dispersion with closer droplet size with initial samples indicates the stability of SMEDDS.

**Table 9: Stability studies of Formulation**

| Formulation Code | Self-emulsification time (min) | Drug contents |
|---|---|---|
| GF3 | 69 ±0.4 | 98.83 |

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