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Development and In-vitro Assesment of Self Nano Emulsified Systems of Sertralline Hydrochloride

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ABSTRACT

Enhancing the bioavailability of BCS class II drugs is a great deal for the formulators to exploit their therapeutic advantages. Many of the techniques had been developed to enhance the solubility which been the rate limiting step for the proper bioavailability. In this study the technique of micro emulsification had been used to reach the objective for the enhancement of solubility of Sertralline hydrochloride an oral Antipsychotic drug. The use of surfactants to reduce the interfacial tension between the water and oil phase was studied in this work.

Keywords: Nano emulsions, SNEDDS, SMEDDS

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1. Introduction

Oral Drug Delivery System:

Significant advances have been made in drug delivery technologies throughout the past 3 decades, and drug delivery at a desired release rate is now possible. Even highly sophisticated drug delivery technologies often fail to produce marketable oral dosage forms, as a result of the physiological limitations of the gastrointestinal (GI) tract or the utilization of non-feasible pharmaceutical components. In oral drug delivery, there are many scientific challenges that could be studied for years to come, and breakthrough technologies are required to generate novel dosage forms

raising drug delivery to higher level. Oral route is the most convenient and easiest route for non-invasive administration. Poor water solubility is widely recognized as the main reason for the poor oral absorption of many new chemical entities. Conventional solubilisation approaches such as co-solvents, salt formation and more recently surfactant-based micellar formation are now widely employed in enhancing the oral absorption of drugs, primarily poorly soluble drugs.

The drugs which are poorly water soluble will be inherently released at a slow rate owing to their limited solubility

within the GI contents. Hence, it shows incomplete and erratic absorption ultimately limits its clinical utility. Further, poorly soluble drugs are generally administered at much higher doses than the actual dose in order to achieve necessary drug plasma levels leading to increased adverse reaction & cost of therapy and often yields erratic pharmacological response limiting factor in their successful launch in market in spite of their potential pharmacokinetic activity.

2. Materials and methods

Drug Profile

Drug: Sertralline hydrochloride

Description: It is an antidepressant in a group of drugs called SSRIS

Synonym: Sertralline hydrochloride (Zoloft)

Structure:

IUPAC name: (1s,cis)-4-(3,4-dichlorophenyl)-N-methyl - 1-1,2,3,4- tetra Hydro naphthaline -1-aminehydrochloride

BCS: Antidepressant (SSRI)

Chemical formula: C₁₇ H₁₇ Cl₂ N

Molecular formula: 306.229 g/mol

Watersolubility : 3.8 mg /ml at 25 c

Melting point : 243 – 2450 C

Log pH : 5.3

Half life : 22 – 36 hrs

Cmax : 20 -55 mg/ml

Protein Binding : 98.55%

Bio Excretion : Renal

Availability : 44%

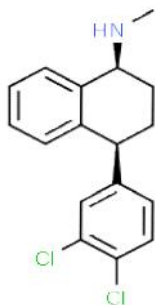


Figure 1

Table 1: Materials used for the study

Materials	Suppliers
Sertraline hydrochloride	Gift sample from AurobindoPharma, Hyd, India
Gingelly oil	Local market
Tween 20	S.D.FineChem .Ltd,Mumbai
Tween 80	S.D. Fine Chem. Ltd., Mumbai
Propylene Glycol	S.D. Fine Chem. Ltd., Mumbai

Table 2: Equipments used

Equipment	Manufacturer	Model No.
UV-Visible spectrophotometer	Agilent technologies	G11038
Dissolution Apparatus	Electro Lab	TDT-08L
FT-IR Spectrophotometer	Agilent technologies	IR 200
Zetasizer	Malvern Instruments Ltd	HAS 3000
SEM	Hitachi	S-3000N

3. Results and Discussion

Table 3: Standard plot for in Sertraline hydrochloride 0.1 N HCl and methanol

Concentration (µg/ml)	Absorbance at 270 nm	
	0.1 N HCl	Methanol
2	0.186 ± 1.1	0.182 ± 1.3
4	0.313 ± 0.5	0.422 ± 0.4
6	0.439 ± 0.7	0.581 ± 0.9
8	0.577 ± 0.3	0.748 ± 1.4
10	0.748 ± 0.8	0.926 ± 0.7

All the values represented as mean± % RSD; n=6

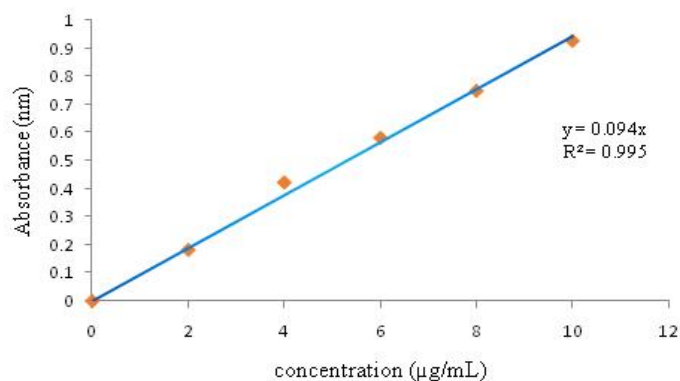


Figure 2: Calibration plot for Sertraline hydrochloride in methanol

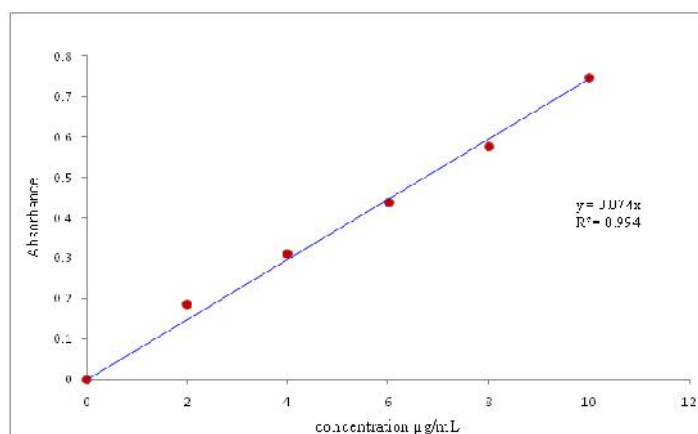


Figure 3: Calibration plot for Sertraline hydrochloride in 0.1 N HCl

All the standard plots of Sertraline hydrochloride analysed at 270 nm in Beers limit of 2 – 10 µg/ml, were found to be linear with correlation coefficients of 0.994 and 0.995 in 0.1 N HCl and methanol respectively.

Saturation solubility study:

Table 4: Solubility study of Sertraline hydrochloride in various oils

Type of component	Solubility (mg/ml)
Oils	Sertraline hydrochloride
Canola oil	0.276±1.12
Gingelly oil	6.52±0.66
Isopropyl myristate	5.23±1.23
Oleic acid	5.07±0.44
Olive oil	1.62±1.23
Peanut oil	6.1±0.86
Rice bran oil	6.05±0.41
Soya bean oil	3.45±0.39
Sun flower oil	5.41±1.57
Surfactants	Sertraline hydrochloride
Tween 80	16.81±0.88
Tween 20	15.87±1.57
Span 80	12.01±1.23
Span 20	8.78±0.87
Co-surfactants	Sertraline hydrochloride
PEG 400	16.5±1.21

Propylene Glycol 21.9±1.67

Ethanol 36.4±0.29

Glycerin 19.7±0.85

All the values represented as mean± % RSD; n=6

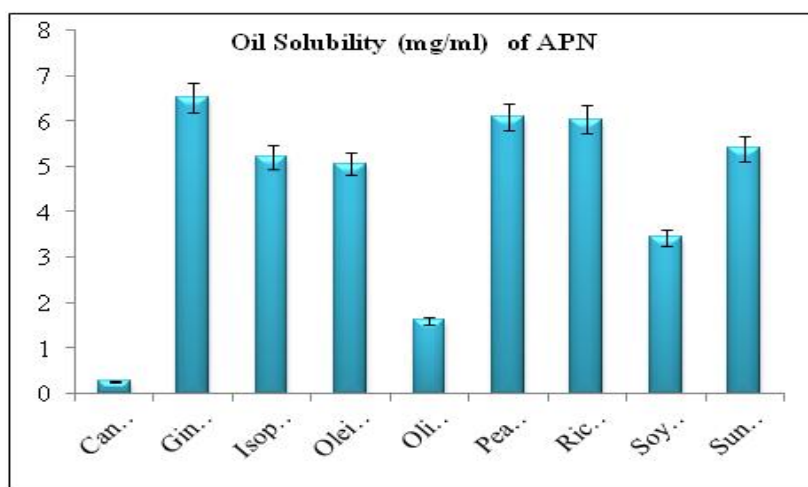


Figure 4: Solubility of Sertralline hydrochloride in oils

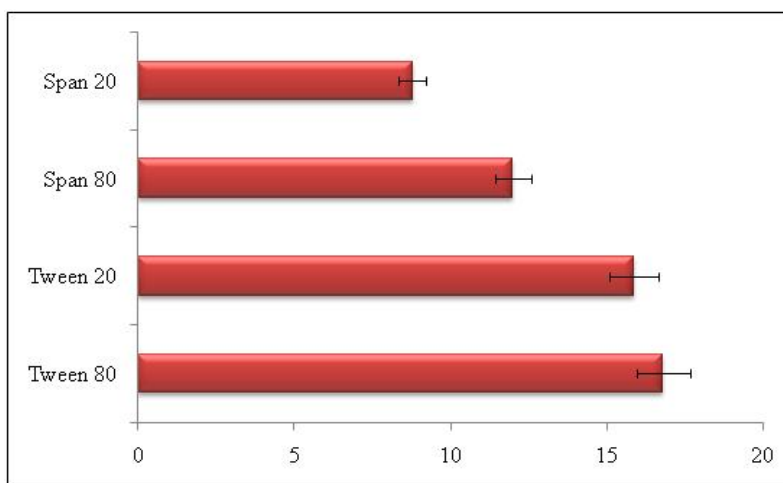


Figure 5: Solubility of Sertralline hydrochloride in surfactants

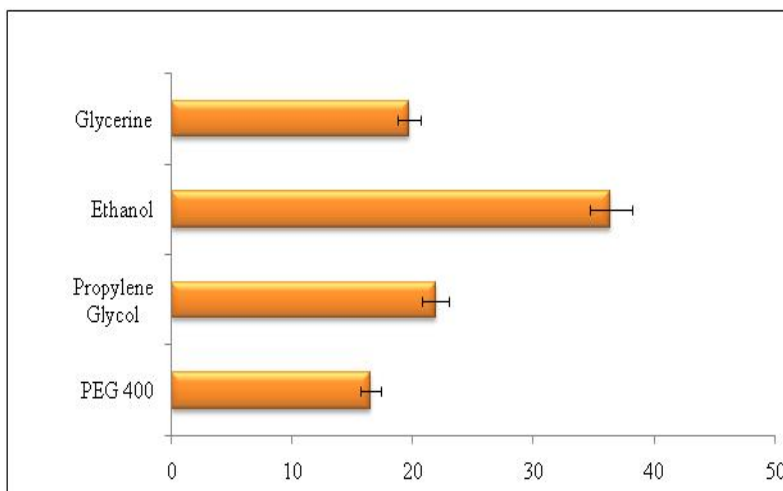


Figure 6: Solubility of Sertralline hydrochloride in co-surfactants Identification of the nano emulsification region

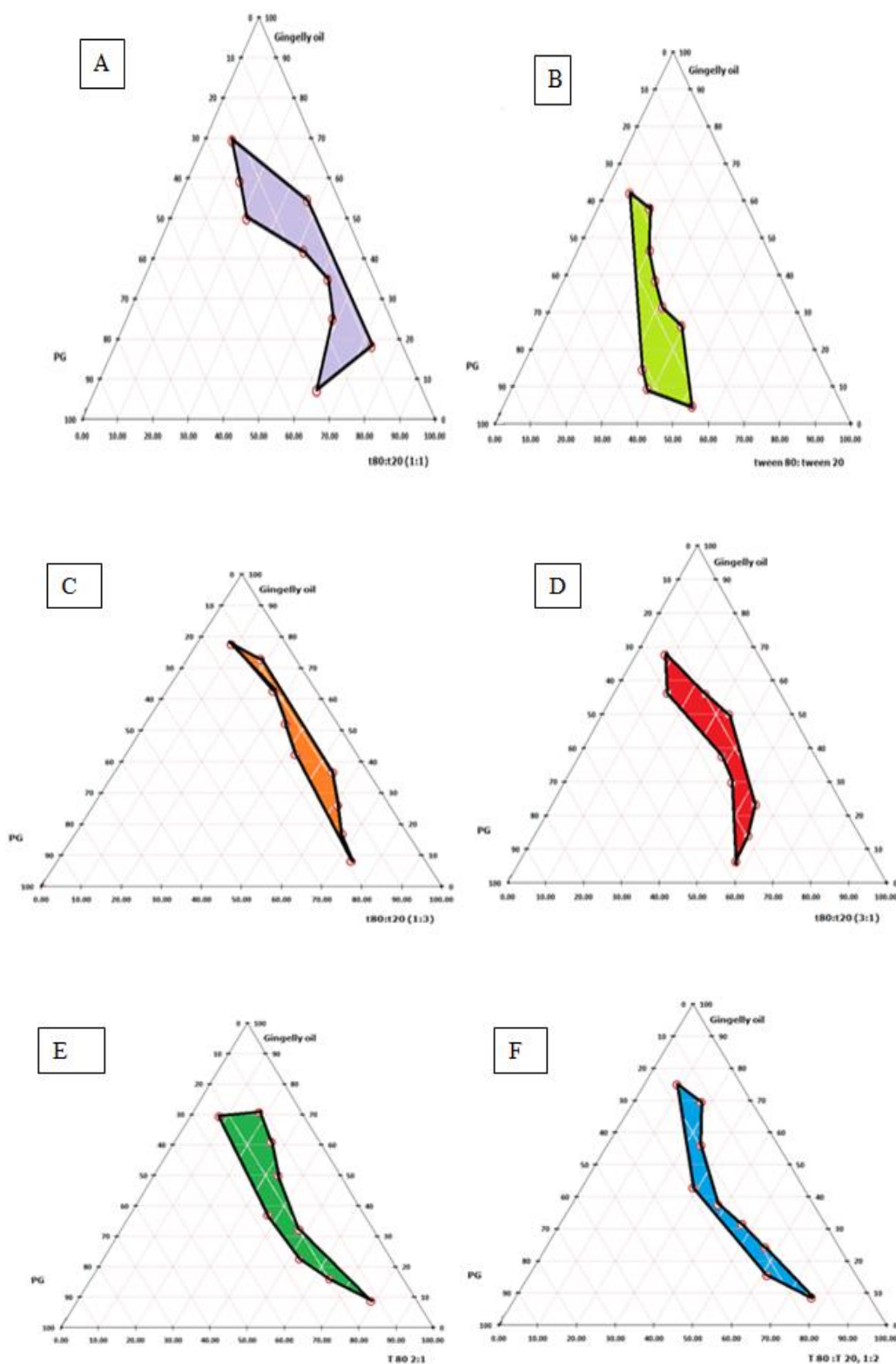


Figure 7: Ternary phase diagrams A- 1:0, B- 1:1, C-1:2, D-1:3, E-2:1, F-3:1

4. Conclusion

Solubility studies of sertraline hydrochloride were conducted in various oils and the emulsification region was identified from the pseudo ternary phase diagrams resulted from different ratios of surfactant and co-surfactant. Sertraline hydrochloride SNEDDS has been employed to

produce at various concentrations. The different formulation variables are surfactant and co-surfactant ratios and the composition of oil and aqueous phases. The prepared Nano-emulsions were characterized for viscosity, pH, globule size, zeta potential. The optimized formulations were evaluated for pH and viscosities found to be in the

same range without any deviation. The electro kinetic properties are reported with low zeta potential due the effect of surfactants, and the negative charge is imparted by oil. The size range of self-emulsion globules was confirmed by the zeta sizer analysis. It is concluded that the Sertraline hydrochloride SNEDDS increase the bioavailability through enhancing the solubility by size reduction and also effective treatment for psychosis. Further the contribution of surfactant in combination and its effect, solidification of liquid SNEDDS using different methods and stability studies should be carried out.

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