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Design and Evaluation of Piroxicam Microemulsion

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ABSTRACT

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The main objective of the present research work was to improve the oral bioavailability of BCS class II drugs which are known to have low solubility but have high permeability. In the present study, Piroxicam is the drug which is having low oral bioavailability and associated with

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KEYWORDS

Microemulsion, Bioavailability, BCS class II drug, Piroxicam, surfactant,

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INTRODUCTION

Colloidal dispersions consist of oil and/or water dispersed in water/oil by an interfacial film of alternating surfactant and cosurfactant molecules. The various attractive advantages of Microemulsions such as nanosize (<200 nm), ease of scale-up and manufacturing, long shelf life, ability to improve lymphatic transport of hydrophobic drugs give them an edge over conventional nanoparticle systems such as liposomes, dendrimers and polymeric delivery. Microemulsions can be considered as a vehicle of choice for oral drug

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format ^{1,2}

Microemulsions emerged during the 1940s as a term to describe systems where oil and water could mix approximately in equal proportions promoted by surfactants and co-surfactants. These systems differed from emulsions by the absence of strong light scattering and it was inferred that the systems contained smaller aggregates. Later it was also realized that the systems were thermodynamically stable. On the basis of what was known for ordinary solubilization, it was natural to assume that the microemulsions contained either globular aggregates of surfactant and oil in water or the reverse with surfactant water aggregates in oil.²

Microemulsions seem to be ideal liquid vehicles for drug delivery because of their several advantages such as thermodynamic stability (long shelf-life), very small droplet size (5–100 nm), easy formulation (low interfacial tension), low viscosity (with Newtonian behaviour) and high surfactant concentration.³

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MATERIALS AND METHODS

Piroxicam Gifted by Zydus Cadila Ltd., India. Caster oil, Sesamum oil, Peanut oil, Cotton seed oil gifted by Sigma-aldrich, USA. Olive Oil gifted by Bretolli, Italy. Tween 20, Tween 40 gifted by Sigma-Aldrich, USA. Tween 60, Tween 80 gifted by Merck, India. Span 20 Fluka, USA. Absolute Ethanol, Glycerine gifted by Merck, India. Water used was semi-quartz distilled (Qualigens). All other chemicals and reagents used were of A.R. grade, procured commercially and used as received.

Solubility Studies

Solubility is of prime importance for developing solution that can be injected either intravenously or intramuscularly. In general, solubility is the function of chemical structure. The solubility measurement was carried out for piroxicam in different oils (water immiscible solvents), surfactant, co surfactant (water miscible solvents) and water.

Construction of Phase Diagram^{14, 15}

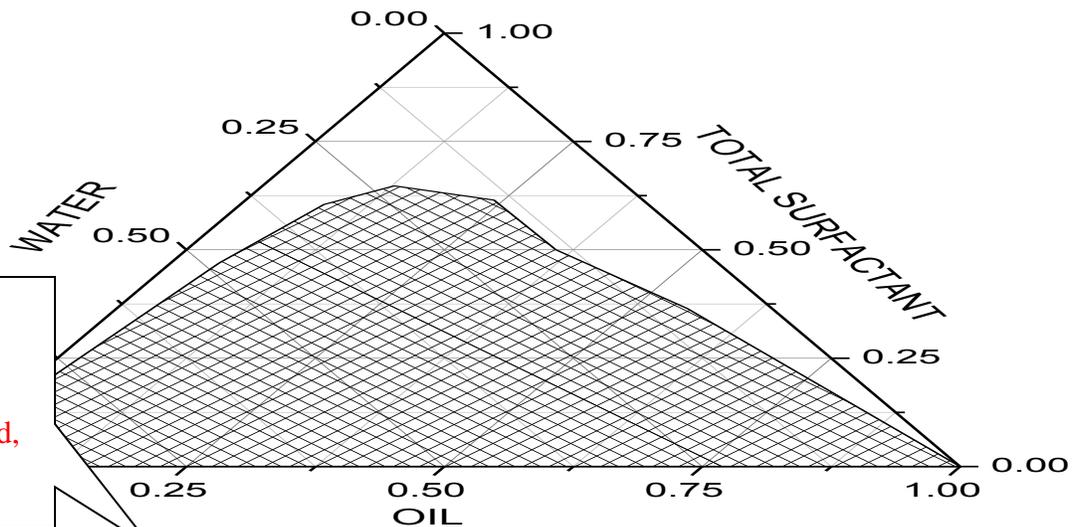
Pseudo ternary phase diagram was constructed to examine the formation of microemulsion using four components, oil surfactant, cosurfactant and aqueous phase system. The four component system consisted of oil as sesame oil, surfactants as Tween80 (Polysorbate 80), and a cosurfactant glycerin and double distilled water as aqueous phase. These components have been taken on weight basis.

Pseudo ternary phase diagram was constructed keeping the ratio of Tween80 and glycerin constant and varying the remaining two components. For convenience, the phase diagram was constructed by drawing “water dilution lines” representing increasing water content and decreasing surfactant and cosurfactant levels. The water was titrated along dilution lines drawn from the surfactant, cosurfactant apex (100% surfactant – cosurfactant) to the opposite oil side of triangle. The line was orbitarily denoted as the value of the line intersection with the oil scale. If turbidity appeared followed by phase separation were considered to be biphasic. If clear and transparent mixtures were visualized after stirring, the samples were considered monophasic. The samples were marked as points in the phase diagram. The area covered by these points was considered to be the microemulsion zone. The phase diagrams were generated using Origin 6.0 software (Microcal, US).

RESULTS AND DISCUSSION

Phase Diagram

For developing a suitable formulation of microemulsion, the classical pseudo ternary phase diagram technique was followed. Briefly, oil was mixed with surfactants and cosurfactant and titrated with water till a turbid emulsion is reached. This was further verified by back titrating the turbid mixture of oil, surfactant and cosurfactant with water till a clear endpoint was reached. Phase diagram was subsequently constructed from the data generated by plotting % (weight) of oil (sesame oil), water and total surfactant and cosurfactant (Tween80 and glycerin) mixture at different ratios as three vertices of a triangle.



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Figure: 1 Phase diagram of sesame oil: glycerin system (4:1)

Optimization of Formulation

Certain points from the phase diagram were selected from the microemulsion system for conductivity, clarity, dilution studies. The results are discussed below for the each parameter.

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glycerin/ water (Km 4:1) was evaluated for pH, intestinal permeability studies.

Table: 1 pH and Conductivity Determination

Sr No.	Formulation Code	Before Dilution		After Dilution 1:10		After Dilution 1:25	
		Cond.* μS	pH	Cond.* μS	pH	Cond.* μS	pH
1	F1	311.00	6.95	110.00	6.15	97.90	6.05
2	F2	143.00	6.98	157.00	6.24	47.80	6.10
3			6.24	128.00	5.70	80.10	5.55

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* Conductivity

CONCLUSION

Through this work, an attempt was made to improve the oral bioavailability of Piroxicam by formulating it in a microemulsion system. A microemulsion system consisting of a Sesame Oil (oil), Tween 80 (surfactants), Glycerin (cosurfactant) and double distilled water as aqueous phase with a drug load of 1mg/ml was evaluated for various parameters such as conductivity, pH, clarity, dilution studies and epithelial permeability profile, using isolated rat ileum segment. The stability studies and zeta potential studies has been carried out.

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