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Original Article

Formulation and optimization of microemulsion-based organogels containing propranolol hydrochloride using experimental design methods

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Abstract:

*Background and the purpose of the study:*Lecithin organogels are formed spontaneously by adding a given amount of water to lecithin/organic solvent mixture. The aim of this research was to develop and optimize a semisolid preparation with appropriate release profile.

Methods: Lecithin organogels containing Propranolol hydrochloride (PR) were formulated, based on phase diagram studies, using soybean lecithin (Epikuron 200), isopropyl myristate (IPM) and propranolol hydrochloride (PR) solutions (10, 20, 30, 50 % w/w) or water at various lecithin/ IPM weight ratios. The flux and the viscosity of the prepared formulations were determined and further chosen as two responses for optimization, using experimental design and optimization methods (i.e. Modified Simplex and Central Composite Designs, respectively). Results of modified simplex runs (i.e. lecithin: 30-50%, PR: 20-40% and water: 3-4%) were also used as constraints for constructing central composite design space. The numerical and graphical optimizations were then run and the "sweet spot" corresponding to the most desirable formulation region compromising both responses were achieved.

Results: Phase diagrams showed a narrow area of existence of non-birefringent, transparent, viscoelastic region, which was extended as %PR incorporated into the system was increased. It was observed that as the lecithin concentration increased from 30 to 60 % w/w, drug incorporation capacity and viscosity increased while the flux of PR from organogels decreased remarkably. Also it was found through optimization that among the organogels investigated, those formulations containing 31.5-37.5 % w/w lecithin, 30.5-34.5 % w/w PR solutions and 3-3.35 % w/w water possessed the highest flux.

Major conclusion: Data confirmed that the choice of lecithin/IPM weight ratio and the amount of drug incorporated may be crucial in determining the performance of an organogel.

Keywords:

Lecithin organogels ، Propranolol hydrochloride ، Release rate ، Microemulsion-based gels ، Modified Simplex ، Central Composite

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