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Research Paper

Solubility Enhancement of Ebastine by Self-Nanoemulsifying Delivery Strategy: Formulation, Optimization and Characterization

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ABSTRACT

The aim of the study was to develop and optimize Self-nanoemulsifying drug delivery systems (SNEDDS) for the improvement of solubility and dissolution of an anti-allergic drug, Ebastine, a BCS class II drug. Preliminary screening was carried out to select proper components combination of Oil (Oleic acid): Surfactant (Tween® 80): Co-solvent (Ethanol). Pseudo-ternary phase diagram experimental design was applied to formulate and optimize the SNEDDS containing 3:7 of (oil: S_{mix}). Drug-Excipient compatibility studies were performed by FTIR and found no chemical interaction between the drug and excipients. The systems were assessed for evaluation parameters like optical clarity in three stages by exposing the SNEDDS to heating-cooling cycle at 4 to 45 ^{o}C, centrifugation at 5000rpm and freeze-thaw cycles at -21 ^{o}C to 21 ^{o}C. The droplets of optimized SNEDDS formulation were found to be spherical with a size range of 76-111nm and emulsification efficiency of 97.67 ± 0.3% and 91.1 ± 0.06% drug release at the end of 30 minutes with a significant increase in dissolution rate compared to the marketed drug suspension under the same conditions. The optimized SNEDDS formulation charged for the accelerated stability studies at 40 ^{o}C/75% RH for three months revealed to be stable with 95.31 ± 1.4% drug content and 90.12 ± 1.98% drug release. It was hence concluded that the solubility of poorly soluble drugs like Ebastine can be effectively enhanced using Self nano emulsifying approaches with the use of Oleic acid, Tween 80 and Ethanol as Oil, surfactant and co-solvent respectively.

KEYWORDS: Self nano emulsifying drug delivery systems; Emulsification efficiency; Nano zeta sizer; Freeze-thaw cycles; Drug release; Stability.