Formulation and In-vitro Evaluation of Rosuvastatin Nanoemulsions

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Abstract

Introduction: Rosuvastatin (ROS) calcium is the latest synthetic drug in the statin group that has an anti-hyperlipidemic activity. It is available as tablets, and its poor aqueous solubility, slow dissolution rate and low-absorption extent result in less than 20% bioavailability and about 80% being excreted unchanged in the feces without absorption. The present study aimed at developing an optimal oral nanoemulsion formulation containing rosuvastatin using different proportions of oil and surfactant system for enhancing its water solubility and bioavailability.

Methods and results: The solubility of ROS in different oils, surfactants and co-surfactants was tested. Based on the solubility study, liquid formulations were prepared using Arachis oil as oil phase and Tween 80 as surfactant and polyethylene 400 as co-surfactant. Pseudo-ternary phase diagrams were developed and various nanoemulsion formulations were prepared and evaluated for globule size, zeta potential, and emulsion properties. The formulations were subjected to different thermodynamic stability studies such as centrifugation, heating-cooling cycle and freeze-thaw cycle, to avoid the selection of metastable formulations. Transmittance study and in-vitro dissolution studies were carried out. An optimal nanoemulsion system was successfully developed with the droplet size of 260 nm and a composition of (Arachis oil; 20%), Tween 80 (40%) and PEG 400 (40%). The cumulative percentage drug release from optimal nanoemulsion formulation was found to be 93.29±1.11% for 50 minutes, which was significantly higher than the drug suspension (43.42±1.30%). Thus, in vitro results reveal that the prepared nanoemulsion formulations showed improved solubility of ROS.

Conclusions: Nanoemulsion formulations of ROS represent a promising novel formula with a higher dissolution rate when compared to the drug in suspension.

Key Words: Nanoemulsion; Rosuvastatin calcium; Ternary Phase Diagram; In vitro release