

Systematic Formulation Development and Evaluation of Self-Nanoemulsifying Systems of Rosuvastatin Employing QbD Approach and Chemometric Techniques

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Abstract : The current studies entail development of self-nano emulsifying drug delivery systems (SNEDDS) of rosuvastatin, employing rational QbD-based approach for enhancing its oral bioavailability. SNEDDS were prepared using the blend of lipidic and emulsifying excipients, i.e., Peceol, Tween 80, and Transcutol HP. The prepared formulations evaluated for in vitro drug release, ex vivo permeation, in situ perfusion studies and in vivo pharmacokinetic studies in rats, which demonstrated 3-4 fold improvement in biopharmaceutical performance of the developed formulations. Cytotoxicity studies using MTT assay and histopathological studies in intestinal cells revealed the lack of cytotoxicity and thereby safety and efficacy of the developed formulations.

Keywords : SNEDDS, bioavailability, solubility, Quality by Design (QbD)

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