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Assessment of a Self-Micro Emulsifying Drug Delivery System for Enhancing the Dissolution of Atorvastatin and Apigenin

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ABSTRACT

Introduction: Poorly water-soluble orally administered drugs often encounter dissolution challenges due to limited aqueous solubility. This study focuses on enhancing dissolution through self-micro emulsifying drug delivery systems (SMEDDS). It aims to improve the dissolution of atorvastatin and apigenin in fixed dose combination, both Biopharmaceutical Classification System Type 2 drugs, using well-optimized SMEDDS formulations in various vehicles. **Methods:** Lipid-based systems were meticulously developed for atorvastatin-apigenin, capable of forming Self-Micro Emulsifying Drug Delivery Systems (SMEDDS). These systems incorporated key components, including an oil phase (Capmul MCM and black seed oil) and a surfactant/co-surfactant or co-solvent phase (Cremophor RH40, Transcutol HP, PEG400). Evaluation of the SMEDDS encompassed critical quality attributes like size distribution and drug dissolution profiles, alongside assessments of dilution effects, transmittance, zeta potential, polydispersity index (PDI), and solubility profiles. **Results:** SMEDDS formulations yielded negatively charged dispersions, typically sized between 20-80 nanometers at varying dilutions. All SMEDDS showed rapid drug release, with about 90% released within 10-20 minutes, indicating improved release compared to unprocessed drug powder. Formulations remained stable upon dilution. Visual inspection, size distribution, and zeta potential of SMEDDS stored at 25°C and 40°C remained unchanged. Enhanced drug release in SMEDDS was attributed to stable nano-sized dispersions and high drug solubility within the formulation. **Conclusion:** The lipid-based systems incorporating Capmul MCM or black seed oil, along with Cremophor RH40, Transcutol HP, or PEG400, successfully generated Self-Micro Emulsifying Drug Delivery Systems (SMEDDS). These SMEDDS formulations resulted in a substantial improvement in the dissolution of both atorvastatin and apigenin, accompanied by optimized particle size, distribution, and long-term stability.

Keywords: Self-Micro Emulsifying Drug Delivery Systems (SMEDDS), Poor Water-Soluble Drug, Dissolution, Atorvastatin, Apigenin