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Development and Characterization of an Alginate-Based Self-Nanoemulsifying System for Enhanced Solubility of Fenofibrate

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ABSTRACT

Introduction: Overcoming the challenge of low solubility in pharmaceutical research is critical, particularly for poorly soluble drugs. This study focuses on the development and characterization of a self-nano emulsifying drug delivery system (SNEDDS) based on alginate, intending to enhance the solubility of fenofibrate, a BCS class II drug known for its low aqueous solubility.

Methods and Materials: The process of formulation optimization involved the preparation of SNEDDS formulations using varying proportions of oleic acid (as the oily phase), Tween 80 (as the surfactant), and PEG 400 (as the cosurfactant). A ternary graph depicting oil-water and surfactant/cosurfactant combinations was constructed to analyze different formulations. Dynamic light diffraction determined the formulations' particle size and polydispersity index. Based on these results, four SNEDDS formulations were selected for further investigation. Different ratios of alginate, an adhesive mucus polymer, were incorporated into these formulations. The particle size, polydispersity index, and light transmission were measured for each formulation with varying alginate ratios. Optimal alginate ratios were selected based on these measurements. The solubility of fenofibrate was also assessed in a solution without polymer. Rheology tests were performed on formulations in the absence and presence of polymer using the selected alginate ratios. Validation studies were performed according to the US Pharmacopoeia for fenofibrate, with accuracy determined by measuring the absorbance of standard samples at different concentrations and precision calculated by analyzing the mean value and standard deviation. The physical stability of the selected formulations was evaluated over three months at room temperature. The fenofibrate release pattern from the SNEDDS was also conducted using the dialysis method with a cellulose membrane dialysis bag in the simulated gastric and intestinal environments without GI enzymes.

Results: The results demonstrated that the optimized SNEDDS formulations, comprising appropriate amounts of oleic acid, Tween 80/PEG 400 surfactant mixture, and alginate polymer, exhibited desirable particle sizes ranging from 149.9 to 210.6 nm and polydispersity index values between 0.314 and 0.451. Rheological analysis indicated increased viscosity with the addition of alginate. In vitro drug release studies revealed a sustained release pattern for polymer-containing formulations compared to polymer-free formulations, with 102 mg/g solution rates and 124 mg/g for the two final formulations. Moreover, the nanosystem formulation significantly improved the dissolution rate of fenofibrate compared to the free drug form in both simulated gastric and intestinal environments.

Conclusion and Discussion: The developed alginate-based self-nano emulsifying system shows promise in enhancing fenofibrate's solubility and dissolution rate. This research contributes to exploring novel strategies for improving the bioavailability of poorly soluble drugs.

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