Development and in vitro evaluation of gastro-protective Aceclofenac-loaded self-emulsifying drug delivery system

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Abstract

Aim: Chronic use of oral nonsteroidal anti-inflammatory drugs (NSAIDs) is commonly associated with gastric irritation and gastric ulceration. Therefore, the aim of study was to develop a novel oral drug delivery system with minimum gastric effects and improved dissolution rate for aceclofenac (ACF), a model BCS class-II drug.

Methods: Self-emulsifying drug delivery systems (SEDDS) were formulated to increase the solubility and ultimately the oral bioavailability of ACF. Oleic acid was used as an oil phase, Tween 80 (T80) and Kolliphor EL (KEL) were used as surfactants, whereas, polyethylene glycol 400 (PEG 400) and propylene glycol (PG) were employed as co-surfactants. Optimized formulations (F1, F2, F3 and F4) were analyzed for droplet size, poly dispersity index (PDI), cell viability studies, in vitro dissolution in both simulated gastric fluid and simulated intestinal fluid, ex vivo permeation studies and thermodynamic stability.

Results: The optimized formulations showed mean droplet sizes in the range of 111.3 ± 3.2 nm and 470.9 ± 12.52 nm, PDI from 244.6 nm to 389.4 ± 6.51 and zeta-potential from – 33 ± 4.86 mV to – 38.5 ± 5.15 mV. Cell viability studies support the safety profile of all formulations for oral administration. The in vitro dissolution studies and ex vivo permeation analysis revealed significantly improved drug release ranging from 95.68 ± 0.02% to 98.15 ± 0.71% when compared with control. The thermodynamic stability studies confirmed that all formulations remain active and stable for a longer period.

Conclusion: In conclusion, development of oral SEDDS might be a promising tool to improve the dissolution of BCS class-II drugs along with significantly reduced exposure to gastric mucosa.

Biography

Kalsoom has her expertise in evaluation and passion in improving the health and wellbeing. Her contextual evaluation model was based on designing novel formulation for Rhumetoid Arthritis. She has built this model after experience in research. Now, she is continuing her research in field of cancer, tumor targeting, nanoparticles, target drug delivery, etc.

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