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Mucoadhesive nanoparticles for sustained ocular delivery of bromfenac: *In vitro* and pharmacokinetic studies

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The aim of this study was to prepare bromfenac encapsulated chitosan/sodium alginate mucoadhesive nanoparticles (NPs) for sustained ocular application. In the present study, mucoadhesive chitosan (CS)-sodium alginate (ALG) nanoparticles were investigated as a new vehicle for the sustained topical ophthalmic delivery of NSAIDs, bromfenac. A modified coacervation or ionotropic gelation method was used to produce bromfenac-loaded nanoparticulate systems. It was optimized using design of experiments by employing a 3-factor, 3-level Box-Behnken statistical design. Independent variables studied were the amount of the bioadhesive polymers: CS, ALG and the amount of drug in the formulation. The dependent variables were the particle size, zetapotential, encapsulation efficiency and burst release. Response surface plots were drawn, statistical validity of the polynomials was established and optimized formulations were selected by feasibility and grid search. The optimized nanoparticles were characterized by FT-IR, DSC and TEM. These NPs were characterized by their mean particle size 279 nm, encapsulation efficiency 80.71% and zeta potential +29.9. *In vitro* release exhibited a biphasic drug release profile with initial burst followed by a very slow drug release. The ocular pharmacokinetics of NPs and marketed formulation were evaluated in NZ rabbits. The NPs exhibit significant mucin adhesion. In comparison to the marketed suspension, the nanoparticle formulation exhibits significant enhancement of AUC(0−∞) (~4.02-fold) and clearance was significantly decreased (~5.5-fold). MRT of nanoparticles was significantly higher than that of Megabrom. Thus, chitosan/alginate NPs could be considered useful approach aiming to sustained ocular residence and reduce dosing frequency.

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