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Título	Evaluation Of Budesonide–Hydroxypropyl-β-Cyclodextrin Inclusion Complex In Thermoreversible Gels For Ulcerative Colitis
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Resumo	Background: New formulations for topical treatment of ulcerative colitis with budesonide inclusion complex ($BUD_{HP\text{-}\beta\text{-}CD}$) and poloxamers (PL) were developed for future clinical use. Aims: This study evaluated the efficacy of such novel formulations in a rat model of colitis. Methods: The PL-$BUD_{HP\text{-}\beta\text{-}CD}$ systems were prepared by direct dispersion of the complex (BUD concentration 0.5 mg mL^{-1}) in solutions with PL407 or PL403. Male Wistar rats underwent TNBS-induced colitis and were treated for 5 days by a rectal route, as follows: BUD 1: $BUD_{HP\text{-}\beta\text{-}CD}$+PL407 (18%); BUD 2: $BUD_{HP\text{-}\beta\text{-}CD}$+PL407 (20%); BUD 3: $BUD_{HP\text{-}\beta\text{-}CD}$+PL407 (18%)+PL403 (2%); BUD 4: plain BUD; BUD 5: $BUD_{HP\text{-}\beta\text{-}CD}$; C1: HP-β-CD+PL407 (18%); C2: HP-β-CD+PL407 (20%); C3: HP-β-CD+PL407 (18%)+PL403 (2%); C4: saline. A negative control group without colitis was also used. Colitis was assessed via myeloperoxidase (MPO) activity, and macroscopic and microscopic damage score in colon tissues. Protein levels of TNF-α, IL-1β, IL-10 and endogenous glucocorticoids were obtained using ELISA. Results: $BUD_{HP\text{-}\beta\text{-}CD}$ poloxamer formulations had similar MPO activity when compared with the negative control group. All formulations presented lower MPO activity than $BUD_{HP\text{-}\beta\text{-}CD}$ and plain BUD ($p<0.001$). BUD 2 produced lower microscopic score values than plain BUD and $BUD_{HP\text{-}\beta\text{-}CD}$ ($p<0.01$). All formulations with $BUD_{HP\text{-}\beta\text{-}CD}$ poloxamers reduced TNF-α levels ($p<0.05$). Conclusion: Novel budesonide inclusion complex formulations improved microscopic damage and reduced colonic MPO activity and TNF-α levels.
Fomento	