





Development and Evaluation of Sustained Oral Ketorolac Tromethamine Particulate Matrix via Bioadhesive Chitosan Based Freeze-Dried Solid Dispersions



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Authors: K. Abdul Rasool, Bazigha; Sajad Aziz, Uday; Abu-Gharbieh, Eman; A. Khan, Saeed

Source: Current Drug Delivery, Volume 13, Number 2, 2016, pp. 275-286(12)

Publisher: Bentham Science Publishers



Objectives: This study aimed to develop and evaluate chitosan (CTS) solid dispersion particulate matrix (SDPM) for sustained oral delivery of ketorolac tromethamine (KT). Methods: SDPM formulations were prepared by freeze drying method and characterized for their effectiveness and biological activities via in vitro and in vivo assessment. Key findings: Powder's flowability and bioadhesion of SDPM increased compared to KT-CTS physical mixtures and the raw materials. DSC analysis proved that the extent of drug crystallinity in matrix particles reduced as the amount of CTS content increased. FT-IR spectroscopy suggested drug-polymer interaction that was prominent in SDPM (1:7). In vitro drug release and simulated plasma profiles showed the superiority of SDPM (1:7) in sustaining drug release up to 12h. The optimized formula was stable during the storage time whereas the similarity factor (f2) for in vitro release data before and at the end of the study was 92%. Furthermore, in vivo bioactivity studies confirmed that the ulcerogenic property of SDPM (1:7) remarkably decreased compared to the standard drug while the analgesic and anti-inflammatory properties were maintained. Conclusion: Results suggested freeze-dried chitosan based SDPM (1:7) as a potential candidate for sustained oral administration of KT.

Keywords: Bioadhesion; Chitosan; Convolution; Freeze-drying; Ketorolac tromethamine; Solid dispersion

Document Type: Research Article Publication date: March 1, 2016 More about this publication?