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Chitosan and sodium sulfate as excipients in the preparation of prolonged release theophylline tablets

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The major objectives of this study were to monitor the effect of cross-linking of cationic chitosan in acidic media with sulfate anion during granules preparation by wet granulation method prior to tableting using theophylline (TPH) as a model drug. The prepared granules and the compressed tablets were subjected to *in vitro* evaluation. Granules with high friabilities were only those prepared with a high amount of sodium sulfate or low amount of chitosan. Compression of granule batches yield non disintegrating tablets that showed a decrease in tensile strength with the increase of sodium sulfate content at high chitosan:sodium sulfate weight ratio or with decrease of chitosan content. Slow TPH release from the formulated tablets was achieved at 1:0.5 and 1:1 chitosan:sodium sulfate weight ratios where all or most of the cationic chitosan and sulfate anions were used in a cross-linking reaction during wet granulation. Ratios of 1:2 and 1:3 showed fast drug release. Slow drug release was also obtained with high molecular weight chitosan, whereas changing the hardness of the tablets did not significantly change the release profile of the drug as long as the tablets are intact during dissolution. Furthermore, slow drug release was observed as the total amount of chitosan was increased in the formulated tablets. A comparative *in vivo* study between the chosen formulated tablets (1:1 chitosan:sodium sulfate ratio that contains 10% high molecular weight chitosan) and the commercial Quibron1 tablets indicated prolonged appearance of the drug in dogs' plasma for both formulations with no significant differences ($p>0.05$) in rate and extent of drug absorption. The formulated tablets showed 103.16% bioavailability relative to that of the commercial tablets.

Biography

Ibrahim M El-Bagory is Professor of Pharmaceutics, College of Pharmacy, Al-Jouf University. He gained a PhD in Pharmaceutics and Pharmaceutical Technology from the University of British Columbia, Canada. He has more than 30 internationally published research papers focused in nuclear pharmacy, evaluation of degree of crystallinity of drugs and excipients, preformulation studies for some solid dosage forms, bioavailability and pharmacokinetics of number of drugs.

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