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## Chitosan lactate wafer as a platform for the buccal delivery of Tizanidine HCl: *In vitro* and *in vivo* performance

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Tizanidine HCl is a skeletal muscle relaxant that suffers from extensive hepatic metabolism resulting in 34 to 40% oral bioavailability. It also suffers from short half-life (2.1-4.2 hrs) that necessitates frequent administration thus reducing patient compliance. In addition, Tizanidine HCl is water soluble, so it is a challenging candidate for controlled drug delivery. In our study, Tizanidine was encapsulated in chitosan lactate beads cross-linked with sodium tripolyphosphate. The beads were further incorporated into chitosan lactate wafer to be easily applied to buccal mucosa, aiming to bypass the hepatic metabolism. A Central Composite Face-centered Design was applied to statistically optimize the formulation variables; tripolyphosphate concentration, chitosan lactate concentration and polymer/drug ratio. The optimized formula suggested by the software composed of; 3.03% tripolyphosphate, 4.92% chitosan lactate and 2.13 polymer/drug ratio. It provided encapsulation efficiency of 56.5% and controlled Tizanidine release over 8 hours. It is also characterized by being mucoadhesive and nonirritant. Pharmacokinetic parameters of Tizanidine from the optimized formula were compared to those of the immediate release tablet, Sirdalud<sup>®</sup>, as reference in human volunteers using a randomized crossover design. Significant increase was observed for  $T_{max}$  and  $AUC_{(0-\infty)}$ . The increase in relative bioavailability of TIZ from the optimized formula was 2.27 fold.