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Development of a gastric absorptive, immediate responsive, oral protein-loaded versatile polymeric delivery system

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A multifunctional platform to deliver 3 diverse proteins of insulin, interferon beta (INF-β) and erythropoietin (EPO), using a novel copolymeric microparticulate system of TMC-PEGDMA-MAA, was synthesised as an intelligent pH-responsive 2-fold gastric and intestinal absorptive system. Physiochemical and physicomechanical studies proved the degree of crystallinity that supported the controlled protein delivery of the microparticulate system. The copolymer was tableted before undertaking in vitro and in vivo analysis. After 2.5 hours in SGF (simulated gastric fluid), insulin showed a fractional release of 3.2% in comparison to SIF (simulated intestinal fluid), in which a maximum of 83% of insulin was released. Similarly, INF-β and EPO released 3% and 9.7% in SGF and a maximum of 74% and 81.3% in SIF, respectively. In vivo studies demonstrated a significant decrease in blood glucose by 54.19% within 4 hours post dosing and the comparator formulation provided 74.6% decrease in blood glucose within the same time period. INF-β peak bioavailable dose in serum was calculated to be 1.3% in comparison to a SC formulation having a peak concentration of 0.9%, demonstrating steady state release for 24 hours. EPO-loaded copolymeric microparticles had a 1.6% peak bioavailable concentration, in comparison to the 6.34% peak concentration after 8 hours from the SC comparator formulation.

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