Development of Pancreatic Enzyme Replacement Therapy (PERT): A Natural Enteric Delivery System to Protect Digestive Enzymes in Gastric Fluid to Preserve Activity in the Duodenum

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Exocrine Pancreatic Insufficiency (EPI) is a disorder characterized by inadequate secretion of pancreatic enzymes, leading to malabsorption, nutrient deficiencies, and reduced quality of life. Pancreatic Enzyme Replacement Therapy (PERT) is the standard treatment; however, commercial formulations of the medicine rely on pharmaceutically engineered enteric coatings, which increase costs or may produce inconsistent results. This study evaluated whether low-cost, food-grade biopolymer matrices could serve as an alternative enteric-style delivery system by protecting pancreatic enzymes during gastric exposure while preserving activity in intestinal conditions. Pancrelipase containing lipase, protease, and amylase was encapsulated in three matrices: alginate beads, alginate beads with a starch-pectin bilayer, and gelatin beads. Encapsulated enzymes were exposed to simulated gastric fluid (SGF, pH 2) at 37 °C for 30 minutes and then transferred to simulated intestinal fluid (SIF, pH 7) at 37 °C for 30 minutes. Enzyme activity was measured using iodine colorimetric assays for amylase, Biuret reagent assays for protease, and titration of free fatty acids for lipase. Results were normalized to a positive control, and all conditions were tested in triplicate. Gelatin beads demonstrated the most significant preservation of enzyme activity among the three enzymes following gastric exposure, with activity levels closest to the positive control and the lowest variability across replicates. These results indicate that gelatin is a promising low-cost, food-grade matrix for protecting pancreatic enzymes and may support more accessible and consistent PERT formulation, particularly in low-resource settings.

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