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Rapid Reconstitution Packages (RRPs) for emergency delivery of glucagon: Hypoglycemia treatment in Type 1 Diabetes

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Hypoglycemia is a condition characterized by abnormally low blood glucose (e.g., blood sugar) levels. Glucagon is an effective therapy for severe hypoglycemia however it is reported to be unstable in liquid form. Therefore, smart technological platforms must be engineering to keep its activity and efficacy during an effective and safe hypoglycemia treatment in emergency conditions. Rapid Reconstitution Packages (RRPs) are handy technologies based on microfluidics platforms for rapid reconstitution of lyophilized biopharmaceutical drugs than can be used in time- critical therapies. RRPs were fabricated using computational simulation such as Computational Fluid Dynamics (CFD) that allows for an analytical methodology to maximize fluidic components for mixing, integrating both physical and chemical properties of targeted active ingredients and solvents. Devices were fabricated using 3D printing technology for micrometer structural precision and rapid prototyping. Glucagon was used due its instability and special features as the drug standard to evaluate the new RRPs generation. Current forms of glucagon cannot be kept for long periods of time due its unstable in aqueous solutions. Glucagon is a polypeptide hormone produced by alpha-cell of the pancreatic islet to increases blood glucose levels and relaxes smooth muscle of the gastrointestinal tract. This hormone was stored in lyophilized and aqueous form into the RRPs. Glucagon is essential in the treatment of severe hypoglycemia for which its rapid reconstitution is of supreme importance. RRPs efficiency and hormone stability were evaluated by HPLC to characterize glucagon release kinetics. Spectroscopy methods are also used. Hormone activity was monitored by Enzyme-Linked Immunosorbent Assays (ELISAs) exposing RRPs to various controlled temperature conditions. Experimental results showed that RRPs provide an effective reconstitution of glucagon and that its release kinetics is strongly correlated with computational modeling. The design and fabrication of RRPs can be adapted for others therapeutics applications by taking into account critical key point parameters (e.g., chemical and physical) to maximize efficiency, efficacy, reconstitution and controlled release kinetics of the active ingredients.

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Bioactive PCL matrices with a range of structural and rheological properties

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Safer pharmaceutical and medical devices excipient are being sought as alternatives to polyvinyl polymers that are commonly plasticised by carcinogenic phthalates. This paper demonstrates a biodegradable and non-toxic bioactive polymer matrix whose structural and rheological properties can be easily modified by the amount of added plasticiser, while being only mildly affected by the presence of a low dosage API. Poly(ε–caprolactone) (PCL) was selected as an alternative polymer to polyvinyls as it is biodegradable and has high amorphous content, which improves drug solubility. Bulk PCL and various blends with 5 and 25% polyethylene glycol (PEG, a plasticiser and pore former) and 5% nalidixic acid (NA, the bioactive) were processed using extrusion and pressed into plaques. The resultant material properties were investigated in terms of microscopic, morphological and topographical modification. No evidence of miscibility was found by IR. The rheology and contact angle of the matrix could be easily manipulated through the addition of PEG. An increased loading of PEG to 25% (w/w) caused a 10 fold increase in the melt flow index, a similar increase in the elongational viscosity, and a contact angle decrease of 10°, indicating that the resultant fluid was becoming more Newtonian. It was concluded that the structural and rheological properties of the blend, while easily modified through the addition of PEG, were unaffected by the monodispersion of the API, nalidixic acid.

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