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Preparation and Characterization of Polymeric Nanoparticles for Sustained Delivery of Insulin

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Objectives: Diabetes is a worldwide disease of near epidemic proportion, with more than a 150 million people currently diagnosed with disease and is expected to double by 2025. Recent developments in insulin formulation and delivery, including ultra-fast acting and intermediate to long-acting(one day) basal injections have encouraged development of basal-bolus insulin administration programs that better mimic the normal pattern of insulin secretion. By combining nanotechnology and chemical modification of insulin molecule, a long-acting insulin product can be formulated which may provide a basal insulin requirement with weekly single dose.

Methods: The present study was aimed at developing and exploring a novel sustained release formulation of PEGylated insulin encapsulated in polymeric nanoparticles that produces prolonged insulin release. Insulin was conjugated with PEG-2000 at specific amino terminus of B chain. PEGylated insulin was encapsulated in PLGA-nanoparticles made by double emulsification method. Nanoparticles were characterized for particle size distribution, SEM, In-vitro drug release, Far-UV circular dichroism, bio-analytical methods and In-vivo studies.

Results: Insulin conformation and antidiabetic activity were retained after PEGylation and PLGA encapsulation. Nano-spherical particles revealed a low burst release, an important safety feature for extended release insulin product. Formulations with high drug content showed very low initial release of insulin over one day and near zero order drug release after a lag of 2-3 days. For animal studies, PLGA-nanoparticles loaded with PEGylated insulin were administered subcutaneously as single injection and produced a release of 15% insulin in first day but then lowered the serum glucose levels of diabetic rats to values <200mg/dL for approximately 2 days.

Conclusions: Based on these findings, it is suggested that combination of two complementary technologies (PEGylation and nanoencapsulation) offers potential for sustained delivery of basal insulin with single weekly dose. Thus, novel PEG–insulin encapsulated PLGA nanoparticles can be used as a carrier for prolonged and sustained release insulin formulation.