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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 and this number is expected to double by 2025. Recent developments in insulin formulation and delivery, including ultra-fast, intermediate to long-acting(one day) basal injections have encouraged development of basal-bolus insulin administration programs that better mimic 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 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 its 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. The formulations with drug content of approximately 14.4% 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 release of 15% insulin in first day but then lowered the serum glucose levels of diabetic rats to values <200 mg/dL for approximately 2 days.

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