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SYMPOSIUM

Stabilized Glucagon Formulation for Bihormonal Pump Use

Solomon S. Steiner, Ph.D., Ming Li, Ph.D., Robert Hauser, Ph.D., and Roderike Pohl, Ph.D.

Abstract

Background:

A promising approach to treat diabetes is the development of an automated bihormonal pump administering glucagon and insulin. A physically and chemically stable glucagon formulation does not currently exist. Our goal is to develop a glucagon formulation that is stable as a clear ungelled solution, free of fibrils at a pH of 7 for at least 7 days at 37 °C.

Methods:

Experimental glucagon formulations were studied for stability at 25 and 37 °C. Chemical degradation was quantified by reverse phase ultra-performance liquid chromatography. Physical changes were studied using light obscuration and visual observations.

Results:

Glucagon content of Biodel glucagon and Lilly glucagon at pH 2 and pH 4, as measured by high-performance liquid chromatography at 25 °C, was 100% at 7 days compared to 87% and <7%, respectively. Light obscuration measurements indicated Lilly glucagon at pH 4 formed an opaque gel, while Biodel glucagon formulation remained a clear solution beyond 50 days at 37 °C. Visual observations confirmed these results.

Conclusions:

Biodel glucagon is a stabilized formulation at physiological pH and remains chemically and physically stable beyond 7 days at 37 °C, suggesting its utility for use in a bihormonal pump.

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Author Affiliation: Biodel Inc., Danbury, Connecticut

Abbreviations: (CGM) continuous glucose monitoring, (UPLC) ultra-performance liquid chromatography

Keywords: artificial pancreas, bihormonal pump, diabetic miniature swine, fibril formation, gelation, stabilized glucagon

Corresponding Author: Solomon Steiner, Ph.D., Biodel Inc., 100 Saw Mill Rd., Danbury, CT 06810; email address ssteiner@biodel.com