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ORIGINAL ARTICLES

Compatibility of Insulin Lispro, Aspart, and Glulisine with the Solo™ MicroPump, a Novel Miniature Insulin Pump

Gil Senesh, B.Sc., Doron Bushi, M.Sc., Avraham Neta, B.Sc., and Ofer Yodfat, M.D.

Abstract

Background:

This study compared the stability of commercially available, rapid-acting insulin in the novel tubeless, skin-adhering Solo™ insulin pump over 6 days at extreme environmental conditions.

Methods:

Forty-eight pumps for each tested analog were loaded with three different insulin lots and operated at 30 U/day (three sets of 12 pumps) and 15 U/day (one set of 12 pumps) with basal/bolus delivery patterns for 6 days under extreme climatic (37°C, 40% relative humidity) and mechanical (35 strokes/min) stresses. The insulin solutions dispensed were sampled periodically and analyzed for potency, related substances, high molecular weight proteins (HMWP), and preservative content by high-performance liquid chromatography techniques. Biological activity (bioidentity) was demonstrated by an abrupt decrease in blood glucose in rabbits. Solutions were inspected for visual appearance and measured for pH levels.

Results:

During the 6-day sampling period, the potency of all insulin samples was maintained at 95.0–105.0% of the bulk solution concentration of the insulin vials. The levels of HMWP and related substances remained well below labeling limits. The preservative concentration decreased with time but remained bacteriostatic effective. Solutions maintained pH and clarity and were particulate free. The biological activity was verified.

Conclusions:

Insulin analogs lispro, aspart, and glulisine maintained physical, chemical, and biological properties for 6 days when used in the Solo MicroPump device.

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Author Affiliation: Medingo Ltd., Yoqneam, Israel

Abbreviations: (BP) British Pharmacopoeia, (CSII) continuous subcutaneous insulin infusion, (HMWP) high molecular weight proteins, (SD) standard deviation, (USP) United States Pharmacopoeia

Keywords: Apidra, CSII, Humalog, insulin pump, MicroPump, Novolog, Solo

Corresponding Author: Gil Senesh, Medingo Ltd., Yoqneam Industrial Park, P.O.B. 261, Yoqneam 20692, Israel; email address *gil@medingo.com*