

Dose Accuracy and Injection Force of Different Insulin Glargine Pens

Arnd Friedrichs, Ph.D.,¹ Janine Bohnet, Dipl.-Ing. Biotechnology,² Volker Korger, Ph.D.,³ Steffen Adler, Ph.D.,¹ Manfred Schubert-Zsilavec, Ph.D.,^{2,4} and Mona Abdel-Tawab, Ph.D.²

Abstract

Background:

Dose accuracy and injection force, representing key parameters of insulin pens, were determined for three pens delivering insulin glargine-based copies, Pen Royale (WR) and DispoPen (WD) for Glaritus[®] (Wockhardt) and GanLee Pen (GL) for Basalin[®] (Gan & Lee), compared with pens of the originator, ClikSTAR[®] (CS) and SoloSTAR[®] (SS) for Lantus[®] (Sanofi).

Methods:

Using the weighing procedure recommended by DIN EN ISO 11608-1:2000, dose accuracy was evaluated based on nonrandomized delivery of low (5 U), mid (30 U), and high (60 U) dosage levels. Injection force was measured by dispensing the maximum dose of insulin (60 U for the GL, WR, and WD; 80 U for the SS and CS) at dose speeds of 6 and 10 U/s.

Results:

All tested pens delivered comparable average doses within the DIN EN ISO 11608-1:2000 limits at all dosage levels. The GL revealed a higher coefficient of variation (CV) at 5 U, and the WR and WD had higher CVs at all dosage levels compared with the CS and SS. Injection force was higher for the WR, WD, and GL compared with the CS and SS at both dose speeds. In contrast to the CS and SS with an end-of-content feature, doses exceeding the remaining insulin could be dialed with the WR, GL, and WD and, apparently, dispensed with the WD.

Conclusions:

All pens fulfilled the dose accuracy requirements defined by DIN EN ISO 11608-1:2000 standards at all three dosage levels, with the WR, WD, and GL showing higher dosage variability and injection force compared with the SS and CS. Thus, the devices that deliver insulin glargine copies show different performance characteristics compared with the originator.

J Diabetes Sci Technol 2013;7(5):1346–1353

Author Affiliations: ¹LWS Risk Management Consult, Brannenburg, Germany; ²Central Laboratory of German Pharmacists, Eschborn, Germany; ³sanofi-aventis Deutschland GmbH, Frankfurt, Germany; and ⁴Institute of Pharmaceutical Chemistry, J.W. Goethe-University, Frankfurt, Germany.

Abbreviations: (CS) ClikSTAR, (CV) coefficient of variation, (GL) GanLee Pen, (SD) standard deviation, (SS) SoloSTAR, (WD) DispoPen, (WR) Pen Royale

Keywords: dosing accuracy, injection force, insulin pens

Corresponding Author: Arnd Friedrichs, Ph.D., LWS Risk Management Consult, Bahnhofstr. 9, D-83098 Brannenburg, Germany; email address arnd.friedrichs@lwsgroup.com