Dose Accuracy and Injection Force of Disposable Pens Delivering Pramlintide for the Treatment of Diabetes

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Abstract

Background:
The pen injection format, typically used for insulin administration, has been adapted for the injectable, noninsulin diabetes therapy pramlintide. Administered before major meals, pramlintide therapy requires two to four injections/day in addition to the patients' usual insulin injections. The dose accuracy and injection force was determined for the 60 and 120 µg pramlintide pens.

Methods:
Dose accuracy testing was conducted at two sites on multiple 60 µg (15, 30, and 60 µg doses) and 120 µg pens (60 and 120 µg doses) at prespecified temperatures (5–40 °C) and humidities (0–75%) using 29 G half-inch needles. All pens were stabilized under testing conditions for 4 h prior to testing. One site used a compression load cell (Zwick device) to test pens; one site performed tests manually.

Injection-force testing was conducted at one site on multiple 60 and 120 µg pens at multiple temperatures (18–28 °C) and humidities (25–75%) using 29 and 31 G half-inch needles and an injection speed of 150 m/min. Injection-force testing was performed using a Zwick device.

Results:
Dose accuracy for all pens tested, regardless of location, reproducibly met/exceeded acceptance criteria. Mean percentage of dose accuracy was 96.04 to 102.45% [standard deviations (SDs) 0.3 to 1.4 µg] for the 60 µg pen and 98.16 to 101.83% (SDs 0.4 to 2.5 µg) for the 120 µg pen. The average injection force across both pens did not exceed 7 N regardless of needle size.

Conclusions:
High dose accuracy and low injection force were observed for the 60 and 120 µg pens under a variety of conditions.


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Abbreviations: (ISO) International Organization for Standardization, (RH) relative humidity, (SD) standard deviation

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