# 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  $\mu$ g (15, 30, and 60  $\mu$ g doses) and 120  $\mu$ g pens (60 and 120  $\mu$ g 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  $\mu$ g] for the 60  $\mu$ g pen and 98.16 to 101.83% (SDs 0.4 to 2.5  $\mu$ g) for the 120  $\mu$ g 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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