

ViViCap Stabilizes Insulin in Extreme Temperature Conditions

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Introduction

For long-term storage, Insulin is to be kept at 4-8° C (~ 39°F to 47°F) until use and once opened, is supposed to be stable for up to 30 days at room temperature. Extreme cold or heat lead to insulin degradation in a very short time with loss of its glucose-lowering efficacy. ViVi-Cap is a calorimetry-based portable storage device, which fit all existing disposable pens. It works without external power supply requirements based on space-derived vacuum insulation and additional heat consumption by phase-change material. ViViCap can be used with the Kwikpen (Eli Lilly, Indianapolis, IN), FlexPen or FlexTouch (both NovoNordisk, Copenhagen, Denmark) and the Solostar device (Sanofi, Paris, France). It is designed to keep the insulin cool within safe temperatures below 29°C/84.2°F for a minimum of 12 hours even in a constant environmental temperature of 37.8°C/100°F

Methods

The purpose of this experiment was to evaluate the performance of the ViVi Cap-1 device, comparing it to an insulin pen without any protection, and to an insulin pen, which employs commonly used water evaporation based device for temperature protection. Three disposable insulin pens (FlexPen, Insulin aspart) were kept for one week under extreme temperature conditions for 5 days (each day: 8 h at 50 °C and 16 h at 22 °C) either without protection, in a frio device (freshly prepared each day) and in the ViViCap. Samples were taken every day and insulin degradation was determined in accordance with EU pharmacopoea by appropriate HPLC methods for insulin aspart. High (HMW) and low molecular weight (LMW) degradation molecules. Each experiment was performed in triplicate.

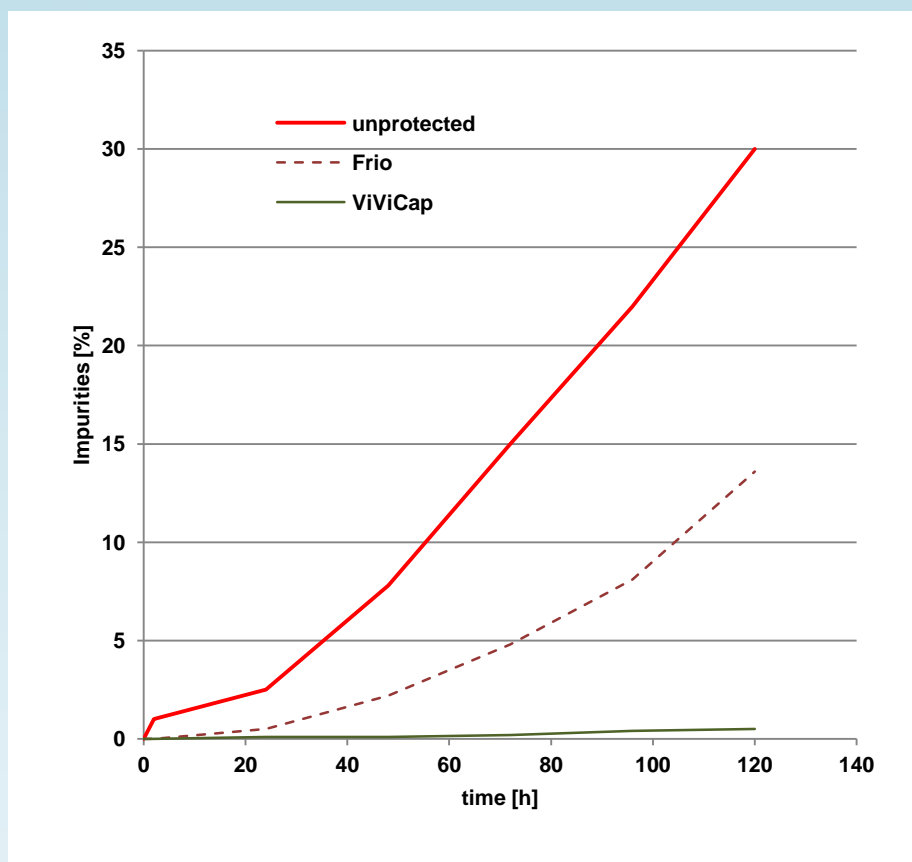
Results

Insulin aspart without protection was shown to have more than 2 % impurities already after one day, while it took 2 days for the pens in the Frio device. The pens with ViViCap did not reach this level of impurities during the experiment (0.5 % after 5 days, see Fig. 2). High molecular weight products > 1 % occurred after two days without protection, three days with Frio, but no HMW products were seen in the pens protected with ViViCap.

Fig.1: The ViViCap Device



Fig.2: Results of the HPLC-Analysis for Impurities



Conclusions

ViVi-Cap was superior to the other tested conditions with respect to stabilizing insulin aspart under extreme temperature changes. It is of note that the ViVi device automatically regains its temperature protecting each time when placed for 6 hours at regular room temperature conditions (22-25 °C/~72-77 °F-), while the Frio device requires an active renewal procedure and filling with water every day. The ViViCap device provides an easy to use and convenient solution for maintaining insulin efficacy under daily life conditions.

Further product information: www.my-vivi.de or www.my-vivi.com