Continuous Delivery of Stabilized Proteins and Peptides at Consistent Rates for at least 3 months from the DUROS® Device

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Introduction

DUROS® technology encompasses an osmotically driven delivery device consisting of a small tube located transdermally on the skin. The device's ability to deliver drugs for an extended period of time is achieved through a combination of design features, including a polymer-based reservoir, an absorbent polymer, and a barrier membrane. This technology is designed to ensure a consistent delivery rate over a specified period, providing a controlled release of medications.

Methods & Materials

Omega interferon is a recombinant protein that is used to treat type 1 diabetes. It is a glycosylated type 1 interferon with 60% homology to alpha interferon and 40% homology to beta interferon. The selected formulations maintained the stability of omega interferon and of exenatide for at least 6 months without significant changes. For example, the omega interferon content was unchanged and the potency remained between 90% and 110% of the nominal concentration.

Results and Discussion

The selected formulations maintained the stability of omega interferon and of exenatide in DUROS® devices at 25°C for at least 12 months and at 37°C for at least 6 months without significant changes. For example, the omega interferon content was unchanged and the potency remained between 90% and 110% of the nominal concentration.

Conclusions

Omega interferon and exenatide deliver each therapeutic molecule at continuous and consistent rates for at least 3 months from the DUROS devices. Omega interferon is stable in DUROS devices at multiple dose levels for at least 3 months at 37°C. The release rate maintained constant for every dose level.

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