Poster 593

# FMXIN002 Epinephrine Intranasal Powder Spray is Stable Throughout 3 Freeze-Thaw Cycles

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## Rational:

- Stability and shelf-life of Epinephrine products for the emergency treatment of anaphylaxis is a critical characteristic.
- Nasus Pharma has developed a Powder-based epinephrine nasal spray (FMNXIN002), which has been successfully evaluated in published clinical trials [1],[2].
- This study aimed to simulate potential temperature excursions that could occur during the product's shipment and in real life usage.

## Methods:

- **Freeze-thaw:** Ten devices of FMNXIN002, were tested at time point 0, and then were subjected to 3 freeze-thaw cycles. Each consisted of -20 °C freezer for 24 hours, followed by 25 °C ± 2 °C and 60% ± 5% relative humidity (RH) for an additional 24 hours.
- **Storage conditions:** Devices were stored at RT, 30 °C /65%RH and 40 °C / 75%RH for various periods, up to 5 years.

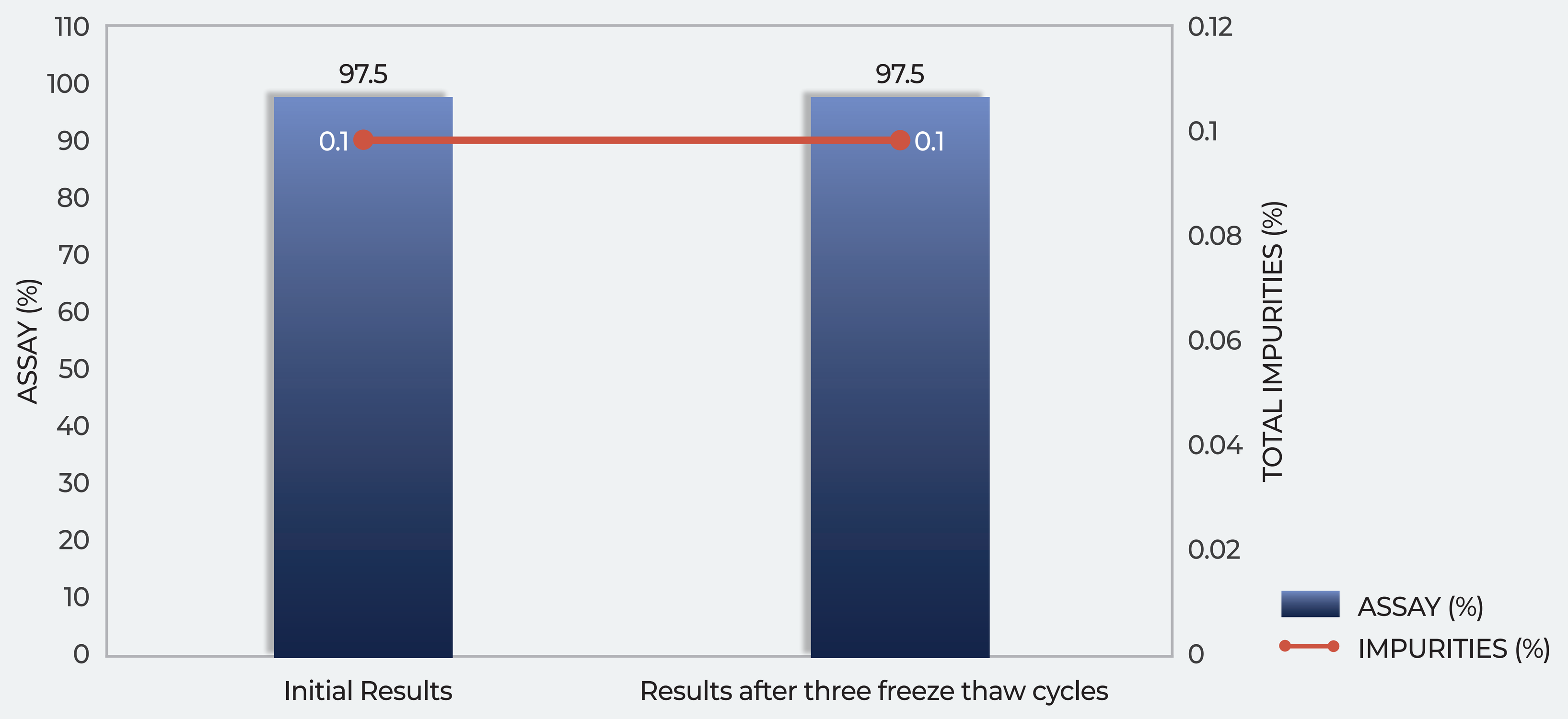
The devices were analyzed for appearance, Assay, and impurities using HPLC, as well as for powder content and microbial stability .


## Results:

| Storage Condition | Interval | Assay Result | Specification Benchmark |
|---|---|---|---|
| **Room Temperature** | 5 years | 97.5% | 90% – 110% (ICH Standard) |
| **Intermediate 30°C /65% RH** | 6 Months | 92.2% | 80% – 120% (Development) |
| **Accelerated 40°C /75% RH** | 6 Months | 87.5% | 80% – 120% (Development) |

[1]. Tal, et al. JACI: In Practice (2023)    [2]. Lapidot, et al. JACI: Global (2025).

**Stability of Epinephrine powder nasal spray after 3 Freeze-thaw cycles**




| Test | Initial Result | Results after three freeze thaw cycles |
|---|---|---|
| **Assay of Epinephrine** | 3.9 mg in device (97.5%) | 3.9 mg in device (97.5 %) |
| **Impurities** | 0.1% | 0.1% |
| **Net powder content** | 38.7 mg (100.5%) | 37.9 mg (98.4%) |

## Conclusions:

**The powder-based epinephrine nasal spray (FMNXIN002) demonstrated stability throughout various storage conditions and freeze-thaw cycles, indicating its ability to withstand robust environments during shipping and handling by patients.**

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