

## **Excursion Abstract #1**

### Stability Results of Epinephrine Sublingual Film Under Extreme Temperature Conditions

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**Rationale:** An epinephrine rescue medication for anaphylaxis should be small, portable and capable of withstanding environmental conditions that match a patient's life without compromising shelf life. Anaphylm is a small, portable, sublingual film containing a novel prodrug of epinephrine being developed for the treatment of Type 1 allergic reactions, including anaphylaxis.

**Methods:** Films were subjected to high temperatures followed by long-term storage, simulating real world conditions, which subsequently returned to room temperature. Samples were tested for critical quality attributes post-excursion followed by 12 months at ICH conditions.

**Results:** The post-excursion 12-month stability data reported for Anaphylm stored at ICH storage conditions of 25°C/60% RH, 30°C/65% RH, and 6-month stability data reported for 40°C/75% RH comply with acceptance criteria. The potency prior to any exposure was 102.2% LC. After being exposed to 50°C for 28 days, the potency was 97.7% LC and 96.9% LC after 12 months at 25°C/60% RH post-excursion. After being exposed to 60°C for 21 days, the potency was 97.3% LC and 95.2% LC after 12 months at 25°C/60% RH post-excursion. After being exposed to 70°C for 7 days, the potency was 96.6% LC and 91.7% LC after 12 months at 25°C/60% RH post-excursion. All other critical attributes were within specification.

**Conclusion:** This study demonstrated that Anaphylm maintains stability across a wide range of extreme temperatures, proving robust resilience to environmental stressors. These findings validate Anaphylm's reliability in real-world conditions, ensuring sustained efficacy and potency throughout its shelf life for patients facing life-threatening allergic reactions.