

## **Excursion Abstract #2**

### Durability of Epinephrine Sublingual Film under Real-World Use

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**Rationale:** During an emergency allergic reaction, prompt administration of epinephrine correlates with enhanced patient outcomes. The drug product must be packaged to withstand real-world conditions in which emergency medication is administered yet remain convenient to carry. Anaphylm is a sublingual film containing a novel prodrug of epinephrine evaluated for durability against conditions that may be likely to occur as part of the normal use of drug product by patients in their daily routine.

**Methods:** Conditions including freeze thaw, hot water submersion, and fold endurance were tested for Anaphylm to show durability against real-world conditions such as accidental laundering, rain exposure, and product folding. Dissolution of hot and cold films demonstrates the product performs when at temperatures that administration may be required.

**Results:** All stability results comply with the applicable proposed specifications. Once frozen and thawed at 25°C, 40°C, and 60°C, the potency after 12 months was 98.0%, 100.7%, and 99%, respectively, exhibiting minimal change in potency. When submerged in 60°C and 25°C water for 30 or 60 minutes, the primary pouch integrity holds. A 180<sup>o</sup> fold test confirmed the product's durability under repeated folding throughout the stability period. Dissolution tests showed consistent drug release from films when frozen to -80°C, heated to 70°C, and brought back to room temperature.

**Conclusion:** Anaphylm demonstrated durability, stability and performance within specification after exposure to extreme real-world conditions. Performance attributes demonstrated that Anaphylm is the sole epinephrine rescue candidate proven effective under sub-freezing conditions, when other liquid-based formulations would freeze.