CERTIFICATE OF ANALYSIS

(Certificate No. KMS009034-02)

Release Date: 13/11/2025 **Re-test Date:** 12/11/2028

Albuterol EP Impurity O

Identification

Chemical Name:

4-(2-(Tert-butylamino)-1-hydroxyethyl)-2-(ethoxymethyl)phenol Formate Salt

Alt. Name : Levalbuterol USP Related Compound

Ε

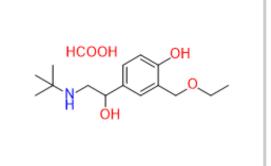
CAT No. : KMS009034

CAS No. : Not Available ; 754926-25-5 (Free

Base)

Molecular Formula : C15H25NO3 : CH2O2

Molecular Weight : 267.4:46.0



Analytical Information

Batch No. : S009034-102-369 Solubility : Methanol : Water

Description : Off White Solid : (1:1)

13C NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition: Product is stable to be Shipped at Room Temperature

% Potency = [100 - 1.87(Weight Loss By TGA)] x [99.55(HPLC Purity)]/100 = 97.69 %

Recommendation : Released

| | Department | Name | Signature | Date |
|------------------------|-----------------|---------------|-----------|------------|
| Prepared By | Analytical | Jignesh Patel | | 14/11/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel | | 14/11/2025 |

Attachments : COA, HPLC, MASS, 1HNMR, 13CNMR, IR and TGA