# **CERTIFICATE OF ANALYSIS**

(Certificate No. KMA078011-01)

**Release Date:** 24/09/2025 **Re-test Date:** 23/09/2028

# **Albuterol EP Impurity A**

### **Identification**

#### **Chemical Name:**

4-[(1RS)-2-(tert-butylamino)-1-methoxyethyl]-2-(hydroxymethyl)phenol (as per EP)

**Alt. Name** : Salbutamol BP Impurity A ;

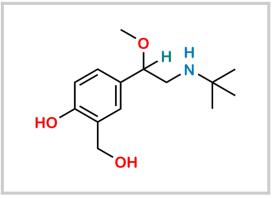
Levalbuterol USP Related Compound H; Salbutamol Methyl Ether;  $\alpha$ -

Methoxy Albuterol

**CAT No.** : KMA078011 **CAS No.** : 870076-72-5

**Molecular Formula** : C14H23NO3

**Molecular Weight** : 253.3



## **Analytical Information**

**Solubility** Batch No. : A078011-102-177 : Water **Description** : Off white Hygroscopic Solid **Mass** : Confirm **HPLC Purity** : 97.82 % : Confirm IR Weight Loss By TGA : 2.18 % 1H NMR : Confirm **13C NMR** : Confirm % Potency : 95.69 %

### **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 - 2.18(Weight Loss By TGA)] x [97.82(HPLC Purity)]/100 = 95.69 %

\*As per client request chemical name change as per EP monograph

-Re-tested in client method on 24.09.2025

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/10/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/10/2025

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