

# **CERTIFICATE OF ANALYSIS**

(Certificate No. KMA078012-01)

**Release Date:** 10/01/2025

**Re-test Date:** 09/01/2028

## **Albuterol EP Impurity B**

### **Identification**

**Chemical Name :**

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

**Alt. Name**

: Salbutamol BP Impurity C ; Albuterol  
USP Related Compound I ;  
Levalbuterol USP Related Compound B  
; Buctopamine ; t-Butylorsynephrine

**CAT No.**

: KMA078012

**CAS No.**

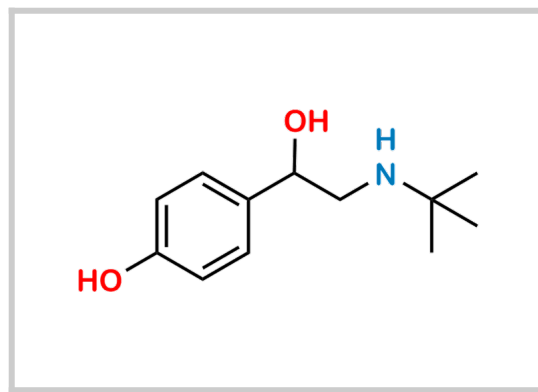
: 96948-64-0

**Molecular Formula**

: C<sub>12</sub>H<sub>19</sub>NO<sub>2</sub>

**Molecular Weight**

: 209.3



### **Analytical Information**

**Batch No.**

: A078012-091-127

**Solubility**

: ACN : Water (1:1)

**Description**

: Light Brown Solid

**Mass**

: Confirm

**HPLC Purity**

: 99.15 %

**IR**

: Confirm

**Weight Loss By TGA**

: 2.31 %

**<sup>1</sup>H NMR**

: Confirm

**% Potency**

: 96.86 %

**<sup>13</sup>C 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 - 2.31(Weight Loss By TGA)] x [99.15(HPLC Purity)]/100 = 96.86 %

-<sup>13</sup>C NMR Analysis added on 01.07.2025

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

**Recommendation**

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		22/08/2025
Reviewed & Approved By	Quality Control	Jatin Patel		22/08/2025

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA