

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA078014-03)

Release Date: 11/09/2025

Re-test Date: 10/09/2028

## Salbutamol EP Impurity D

### Identification

**Chemical Name :**

5-[(1RS)-2-(tert-butylamino)-1-hydroxyethyl]-2-hydroxybenzaldehyde (as per EP)

**Alt. Name**

: Salbutamol BP Impurity D ;  
Levalbuterol USP RC D ; Salbutamol  
Aldehyde Impurity

**CAT No.**

: KMA078014

**CAS No.**

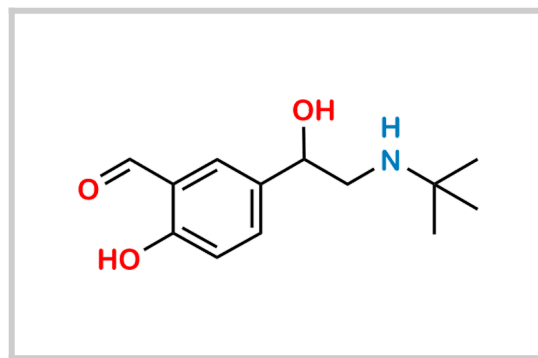
: 156339-88-7

**Molecular Formula**

: C<sub>13</sub>H<sub>19</sub>NO<sub>3</sub>

**Molecular Weight**

: 237.3



### Analytical Information

**Batch No.**

: A078014-102-178

**Solubility**

: Water

**Description**

: Yellow Solid

**Mass**

: Confirm

**HPLC Purity**

: 98.14 %

**IR**

: Confirm

**Weight Loss By TGA**

: 1.80 %

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

: Confirm

**% Potency**

: 96.37 %

### 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 - 1.80(Weight Loss By TGA)] x [98.14(HPLC Purity)]/100 = 96.37 %

**Recommendation**

: Released

|                        | Department      | Name        | Signature | Date       |
|------------------------|-----------------|-------------|-----------|------------|
| Prepared By            | Analytical      | Parag Patel |           | 11/09/2025 |
| Reviewed & Approved By | Quality Control | Jatin Patel |           | 11/09/2025 |

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