

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA078014-03)

Release Date: 29/07/2025

Re-test Date: 28/07/2028

## Albuterol 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.**

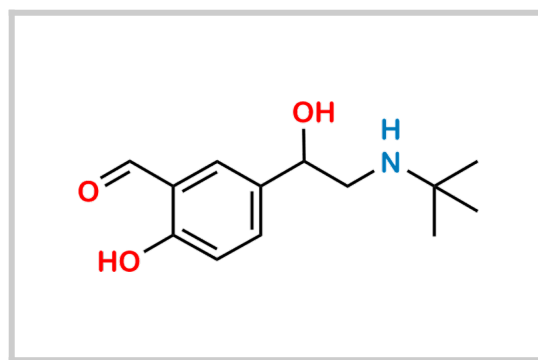
: 156339-88-7

**Molecular Formula**

: C13H19NO3

**Molecular Weight**

: 237.3



### Analytical Information

**Batch No.**

: A078014-102-178

**Solubility**

: Water

**Description**

: Yellow Solid

**Mass**

: Confirm

**HPLC Purity**

: 95.25 %

**IR**

: Confirm

**Weight Loss By TGA**

: 1.80 %

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

: Confirm

**% Potency**

: 93.54 %

**<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 - 1.80(Weight Loss By TGA)] x [95.25(HPLC Purity)]/100 = 93.54 %

\*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>H NMR, <sup>13</sup>C NMR, IR and TGA