

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA078013-02)

Release Date: 29/07/2025

Re-test Date: 28/07/2028

## Albuterol EP Impurity C

### Identification

**Chemical Name :**

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

**Alt. Name**

: Albuterol USP Related Compound A ;  
Levalbuterol USP Related Compound B  
; Salbutamol Deshydroxy Impurity ; 3-  
Dehydroxy Salbutamol

**CAT No.**

: KMA078013

**CAS No.**

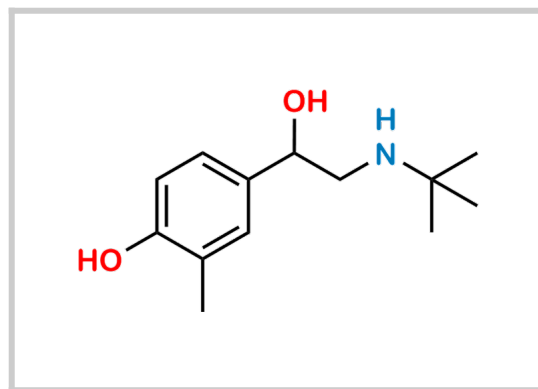
: 18910-68-4

**Molecular Formula**

: C<sub>13</sub>H<sub>21</sub>NO<sub>2</sub>

**Molecular Weight**

: 223.3



### Analytical Information

**Batch No.**

: A078013-102-176

**Solubility**

: Acetonitrile

**Description**

: Off White Solid

**Mass**

: Confirm

**HPLC Purity**

: 99.14 %

**IR**

: Confirm

**Weight Loss By TGA**

: 0.42 %

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

: Confirm

**% Potency**

: 98.72 %

**<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 - 0.42(Weight Loss By TGA)] x [99.14(HPLC Purity)]/100 = 98.72 %

\*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