

# CERTIFICATE OF ANALYSIS

(Certificate No. KMA078013-01)

Release Date: 23/10/2023

Re-test Date: 22/10/2026

## Albuterol Impurity C

### Identification

**Chemical Name :**

(1RS)-2-[(1,1-Dimethylethyl)amino]-1-(4-hydroxy-3-methylphenyl)ethanol (as per EP)

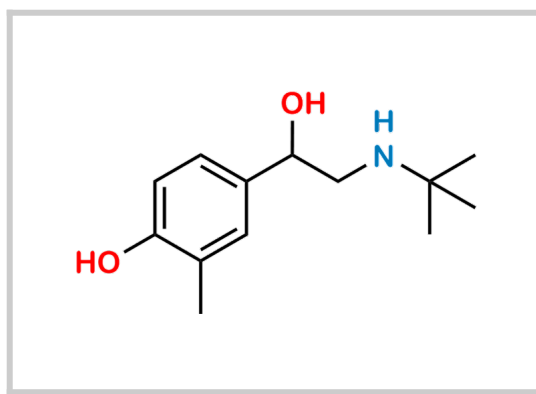
**Alt. Name** : Albuterol USP Related Compound A ;  
Levalbuterol USP Related Compound B  
; Salbutamol Deshydroxy Impurity ; 3-  
Dehydroxy Salbutamol

**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.** : SAL-IMP-C-019-219

**Description** : White Solid

**HPLC Purity** : 99.70 %

**Weight Loss By TGA** : 0.30 %

**% Potency** : 99.4 %

**Solubility** : Methanol

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H 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 - 0.30(Weight Loss By TGA)] x [99.70(HPLC Purity)]/100 = 99.4 %

Remarks : COA Re-generated on 03.01.2025

-Re-tested on 23.10.2023

**Recommendation** : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		03/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		03/01/2025

**Attachments** : COA, HPLC, MASS, 1HNMR, IR and TGA