

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)

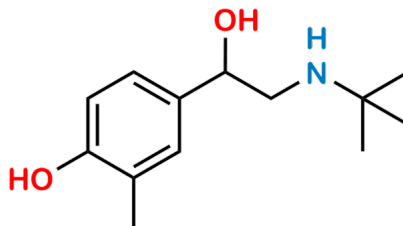
Alt. Name : Albuterol USP Related Compound A ;
Levalbuterol USP Related Compound B
; Salbutamol Deshydroxy Impurity ; 3-
Dehydroxy Salbutamol

CAT No. : KMA078013

CAS No. : 18910-68-4

Molecular Formula : C₁₃H₂₁NO₂

Molecular Weight : 223.3



Analytical Information

Batch No. : SAL-IMP-C-019-219

Solubility : Methanol

Description : White Solid

Mass : Confirm

HPLC Purity : 99.70 %

IR : Confirm

Weight Loss By TGA : 0.30 %

¹H NMR : Confirm

% Potency : 99.4 %

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