

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.

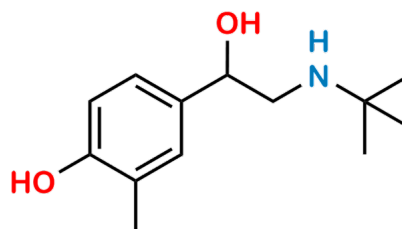
: 18910-68-4

Molecular Formula

: C₁₃H₂₁NO₂

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 %

¹H NMR

: Confirm

% Potency

: 98.72 %

¹³C 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, ¹HNMR, ¹³CNMR, IR and TGA