

CERTIFICATE OF ANALYSIS

(Certificate No. KMA078011-01)

Release Date: 29/07/2025

Re-test Date: 28/07/2028

Albuterol EP Impurity A

Identification

Chemical Name :

4-[(1RS)-2-(tert-butylamino)-1-methoxyethyl]-2-(hydroxymethyl)phenol (as per EP)

Alt. Name

: Salbutamol BP Impurity A ;
Levalbuterol USP Related Compound
H ; Salbutamol Methyl Ether ; α-
Methoxy Albuterol

CAT No.

: KMA078011

CAS No.

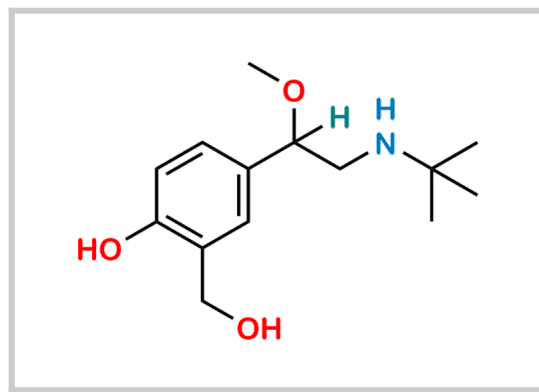
: 870076-72-5

Molecular Formula

: C₁₄H₂₃NO₃

Molecular Weight

: 253.3



Analytical Information

Batch No.

: A078011-102-177

Solubility

: Water

Description

: Off white Hygroscopic Solid

Mass

: Confirm

HPLC Purity

: 99.27 %

IR

: Confirm

Weight Loss By TGA

: 2.18 %

¹H NMR

: Confirm

% Potency

: 97.11 %

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 - 2.18(Weight Loss By TGA)] x [99.27(HPLC Purity)]/100 = 97.11 %

*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