

CERTIFICATE OF ANALYSIS

(Certificate No. KMA078012-01)

Release Date: 10/01/2025

Re-test Date: 09/01/2028

Salbutamol EP Impurity B

Identification

Chemical Name :

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

Alt. Name

: Salbutamol BP Impurity C ; Albuterol
USP Related Compound I ;
Levalbuterol USP Related Compound B
; Buctopamine ; t-Butylorsynephrine

CAT No.

: KMA078012

CAS No.

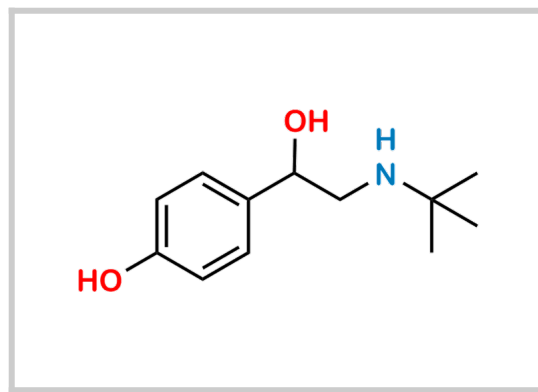
: 96948-64-0

Molecular Formula

: C₁₂H₁₉NO₂

Molecular Weight

: 209.3



Analytical Information

Batch No.

: A078012-091-127

Solubility

: ACN : Water (1:1)

Description

: Light Brown Solid

Mass

: Confirm

HPLC Purity

: 99.15 %

IR

: Confirm

Weight Loss By TGA

: 2.31 %

¹H NMR

: Confirm

% Potency

: 96.86 %

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 - 2.31(Weight Loss By TGA)] x [99.15(HPLC Purity)]/100 = 96.86 %

Recommendation

: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Parag Patel		11/09/2025
Reviewed & Approved By	Quality Control	Jatin Patel		11/09/2025

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