

CERTIFICATE OF ANALYSIS

(Certificate No. KMA078012-01)

Release Date: 10/01/2025

Re-test Date: 09/01/2028

Albuterol Impurity B

Identification

Chemical Name :

(1R)-2-[(1,1-Dimethylethyl)amino]-1-(4-hydroxyphenyl)ethanol (as per EP)

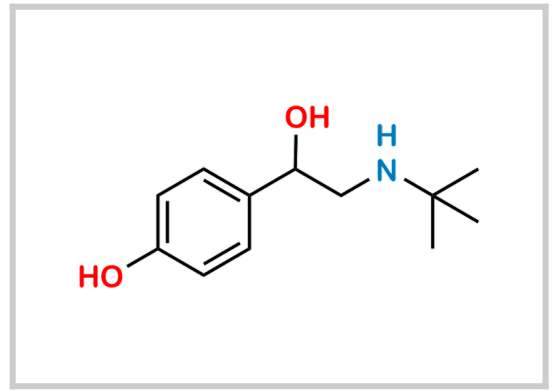
Alt. Name : Salbutamol BP Impurity C ; Albuterol
USP Related Compound I ;
Levalbuterol USP Related Compound B
; Buctopamine ; t-Butyl-norsynephrine

CAT No. : KMA078012

CAS No. : 96948-64-0

Molecular Formula : C₁₂H₁₉NO₂

Molecular Weight : 209.3



Analytical Information

Batch No. : A078012-091-127

Description : Light Brown Solid

HPLC Purity : 99.15 %

Weight Loss By TGA : 2.31 %

% Potency : 96.86 %

Solubility : ACN : Water (1:1)

Mass : Confirm

IR : Confirm

¹H 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 - 2.31(Weight Loss By TGA)] x [99.15(HPLC Purity)]/100 = 96.86 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Ravi Sakhiya		16/01/2025
Reviewed & Approved By	Quality Control	Jatin Patel		16/01/2025

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA