CERTIFICATE OF ANALYSIS

(Certificate No. KMA078012-01)

Release Date: 24/09/2025 **Re-test Date:** 23/09/2028

Albuterol EP Impurity B

Identification

Chemical Name:

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

Alt. Name : Salbutamol BP Impurity C ; Albuterol

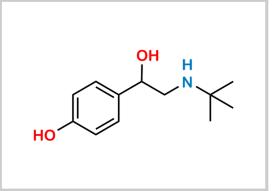
: C12H19NO2

USP Related Compound I;

Levalbuterol USP Related Compound B; Buctopamine; t-Butylnorsynephrine

CAT No. : KMA078012 **CAS No.** : 96948-64-0

Molecular Weight : 209.3



Analytical Information

Molecular Formula

(1:1)

: Confirm

: Confirm

Description : Light Brown Solid

HPLC Purity : 95.27 %

Weight Loss By TGA : 2.31 %

% Potency : 93.07 % 1H NMR : Confirm

13C NMR : Confirm

IR

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 [95.27(HPLC Purity)]/100 = 93.07 %

-13C NMR Analysis added on 01.07.2025 -Retested in client method on 24.09.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/10/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/10/2025

Attachments : COA, HPLC, MASS, 1HNMR, 13C NMR, IR and TGA