CERTIFICATE OF ANALYSIS

(Certificate No. KMA078015-02)

Release Date: 11/10/2025 **Re-test Date:** 10/10/2028

Albuterol EP Impurity E

Identification

Chemical Name:

4-[(1RS)-2-[benzyl(tert-butyl)amino]-1-hydroxyethyl]-2-(hydroxymethyl)phenol (as per EP)

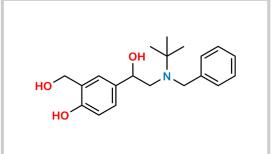
Alt. Name : Salbutamol BP Impurity E; N-Benzyl

Albuterol

CAT No. : KMA078015 CAS No. : 24085-03-8

Molecular Formula : C20H27NO3

Molecular Weight : 329.4



Analytical Information

Batch No. : A078015-102-314 **Solubility** : Methanol : Water

(1:1)

: Confirm

Description : Off White Solid

HPLC Purity : 99.29 %

Weight Loss By TGA : 3.51 %

% Potency : 95.8 %

Mass : Confirm

1H NMR : Confirm

IR

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 - 3.51(Weight Loss By TGA)] x [99.29(HPLC Purity)]/100 = 95.8 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		12/10/2025
Reviewed & Approved By	Quality Control	Jatin Patel		12/10/2025

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