

CERTIFICATE OF ANALYSIS

(Certificate No. KMA078015-01)

Release Date: 25/01/2025

Re-test Date: 24/01/2028

Albuterol EP Impurity E

Identification

Chemical Name :

(1RS)-2-[Benzyl(1,1-dimethylethyl)amino]-1-[4-hydroxy-3-(hydroxymethyl)phenyl]ethanol (as per EP)

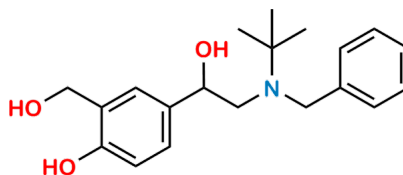
Alt. Name : Salbutamol BP Impurity E ; N-Benzyl
Albuterol

CAT No. : KMA078015

CAS No. : 24085-03-8

Molecular Formula : C₂₀H₂₇NO₃

Molecular Weight : 329.4



Analytical Information

Batch No. : A078015-091-178

Solubility : Acetonitrile

Description : Off White Solid

Mass : Confirm

HPLC Purity : 98.89 %

IR : Confirm

Weight Loss By TGA : 0.70 %

¹H NMR : Confirm

% Potency : 98.2 %

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 - 0.70(Weight Loss By TGA)] x [98.89(HPLC Purity)]/100 = 98.2 %

-¹³C NMR Analysis added on 01.07.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		10/07/2025
Reviewed & Approved By	Quality Control	Jatin Patel		10/07/2025

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