

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 :

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

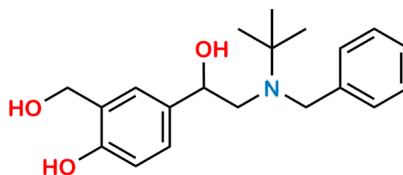
Alt. Name : Salbutamol BP Impurity E ; N-Benzyl Albuterol

CAT No. : KMA078015

CAS No. : 24085-03-8

Molecular Formula : C₂₀H₂₇NO₃

Molecular Weight : 329.4



Analytical Information

Batch No. : A078015-091-178

Description : Off White Solid

HPLC Purity : 98.89 %

Weight Loss By TGA : 0.70 %

% Potency : 98.2 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

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

*As per client request chemical name change as per EP monograph

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		22/08/2025
Reviewed & Approved By	Quality Control	Jatin Patel		22/08/2025

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