

CERTIFICATE OF ANALYSIS

(Certificate No. KMS009034-01)

Release Date: 22/03/2025

Re-test Date: 21/03/2028

Albuterol EP Impurity O

Identification

Chemical Name :

4-(2-(Tert-butylamino)-1-hydroxyethyl)-2-(ethoxymethyl)phenol

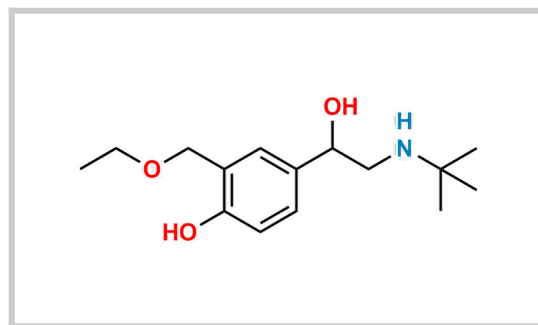
Alt. Name : Levalbuterol USP Related Compound E

CAT No. : KMS009034

CAS No. : 754926-25-5

Molecular Formula : C₁₅H₂₅NO₃

Molecular Weight : 267.4



Analytical Information

Batch No. : S009034-091-277

Solubility : Water

Description : White Solid

Mass : Confirm

HPLC Purity : 99.56 %

IR : Confirm

Weight Loss By TGA : 0.41 %

¹H NMR : Confirm

% Potency : 99.15 %

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 - 0.41(Weight Loss By TGA)] x [99.56(HPLC Purity)]/100 = 99.15 %
-¹³C NMR Analysis added on 01.07.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		12/07/2025
Reviewed & Approved By	Quality Control	Jatin Patel		12/07/2025

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