

CERTIFICATE OF ANALYSIS

(Certificate No. KML060017-01)

Release Date: 21/03/2025

Re-test Date: 20/03/2028

Albuterol EP Impurity M

Identification

Chemical Name :

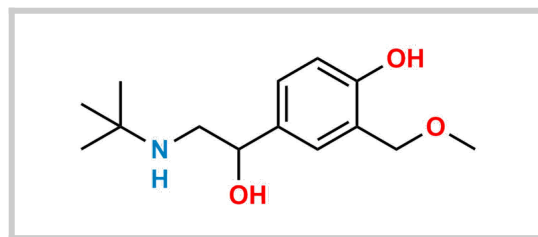
4-[(1RS)-2-(tert-butylamino)-1-hydroxyethyl]-2-(methoxymethyl)phenol (as per EP)

CAT No. : KML060017

CAS No. : 18910-70-8

Molecular Formula : C₁₄H₂₃NO₃

Molecular Weight : 253.3



Analytical Information

Batch No. : L060017-091-278

Description : White Solid

HPLC Purity : 99.85 %

Weight Loss By TGA : 0.32 %

% Potency : 99.53 %

Solubility : Water

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 - 0.32(Weight Loss By TGA)] x [99.85(HPLC Purity)]/100 = 99.53 %

-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, ¹H NMR, ¹³C NMR, IR and TGA