

CERTIFICATE OF ANALYSIS

(Certificate No. KML060020-01)

Release Date: 21/03/2025

Re-test Date: 20/03/2028

Albuterol EP Impurity I

Identification

Chemical Name :

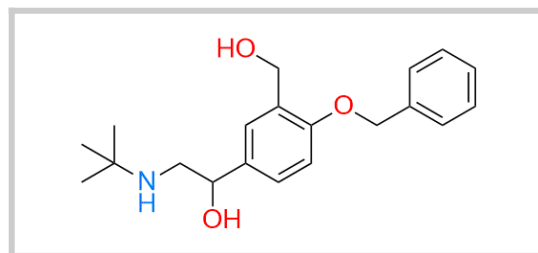
(RS)-1-(4-(Benzyloxy)-3-(hydroxymethyl)phenyl)-2-(tert-butylamino)ethan-1-ol

CAT No. : KML060020

CAS No. : 56796-66-8

Molecular Formula : C₂₀H₂₇NO₃

Molecular Weight : 329.4



Analytical Information

Batch No. : L060020-091-258

Description : White Solid

HPLC Purity : 99.92 %

Weight Loss By TGA : 0.50 %

% Potency : 99.42 %

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 - 0.50(Weight Loss By TGA)] x [99.92(HPLC Purity)]/100 = 99.42 %

-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