

CERTIFICATE OF ANALYSIS

(Certificate No. KMS009023-01)

Release Date: 24/09/2025

Re-test Date: 23/09/2028

Albuterol EP Impurity H

Identification

Chemical Name :

4-[2-(tert-butylamino)ethyl]-2-methylphenol (as per EP)

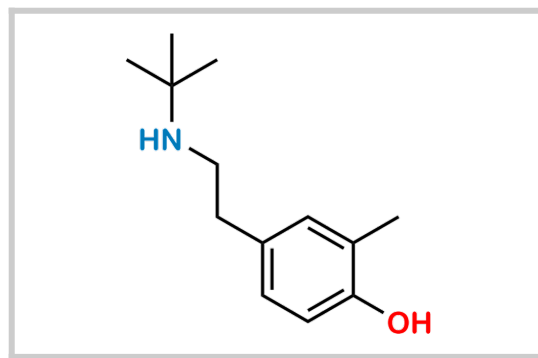
Alt. Name : Salbutamol BP Impurity H ;
Salbutamol Dideshydroxy Impurity

CAT No. : KMS009023

CAS No. : 132183-64-3

Molecular Formula : C₁₃H₂₁NO

Molecular Weight : 207.3



Analytical Information

Batch No. : S009023-102-245

Description : Off White Solid

HPLC Purity : 97.74 %

Weight Loss By TGA : 0.51 %

% Potency : 97.24 %

Solubility : Methanol : Water
(1:1)

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 - 0.51(Weight Loss By TGA)] x [97.74(HPLC Purity)]/100 = 97.24 %

-Retested in client method on 24.09.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		06/10/2025
Reviewed & Approved By	Quality Control	Jatin Patel		06/10/2025

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