

CERTIFICATE OF ANALYSIS

(Certificate No. KMS009025-01)

Release Date: 29/07/2025

Re-test Date: 28/07/2028

Albuterol EP Impurity J

Identification

Chemical Name :

2-(tert-butylamino)-1-[4-hydroxy-3-(hydroxy-methyl)phenyl]ethan-1-one (as per EP)

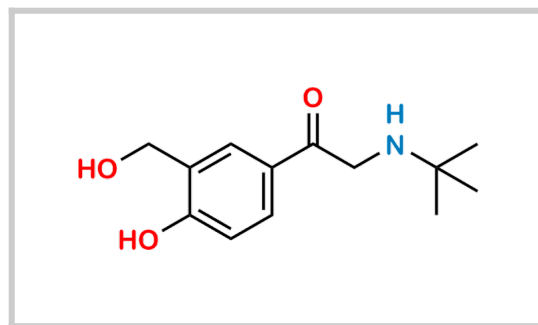
Alt. Name : Salbutamol BP Impurity J ;
Salbutamone HCl

CAT No. : KMS009025

CAS No. : 156547-62-5

Molecular Formula : C₁₃H₁₉NO₃

Molecular Weight : 237.3



Analytical Information

Batch No. : S009025-102-179

Description : Light Brown Solid

HPLC Purity : 96.83 %

Weight Loss By TGA : 3.49 %

% Potency : 93.45 %

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 - 3.49(Weight Loss By TGA)] x [96.83(HPLC Purity)]/100 = 93.45 %

*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