CERTIFICATE OF ANALYSIS

(Certificate No. KMS009025-02)

Release Date: 10/10/2025 **Re-test Date:** 09/10/2028

Albuterol EP Impurity J

Identification

Chemical Name:

2-(tert-butylamino)-1-[4-hydroxy-3-(hydroxy-methyl)phenyl]ethan-1-one formate salt

Alt. Name : Salbutamol BP Impurity J ;

Salbutamone HCl

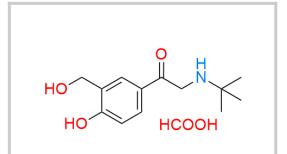
CAT No. : KMS009025

CAS No. : Not Available ; 156547-62-5 (Free

base)

Molecular Formula : C13H19NO3 : CH2O2

Molecular Weight : 237.3:46.0



Analytical Information

Description

: Light Brown Solid (1:1)

HPLC Purity : 99.84 %

Weight Loss By TGA : 5.63 %

Mass : Confirm

IR : 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 - 5.63(Weight Loss By TGA)] x [99.84(HPLC Purity)]/100 = 94.22 %

Recommendation: Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		11/10/2025
Reviewed & Approved By	Quality Control	Jatin Patel		11/10/2025

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