CERTIFICATE OF ANALYSIS

(Certificate No. KMA078023-01)

Release Date: 08/11/2025 **Re-test Date:** 07/11/2028

Albuterol EP Impurity M

Identification

Chemical Name :
4-[(1RS)-2-(tert-butylamino)-1-hydroxyethyl]-2-(methoxymethyl)phenol formate salt

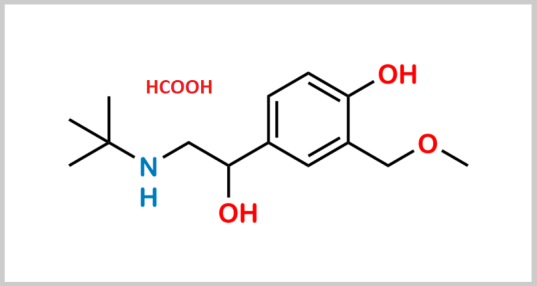
Alt. Name : Salbutamol BP Impurity M

CAT No. : KMA078023

CAS No. : Not Available ; 18910-70-8 (free base)

Molecular Formula : C14H23NO3 : CH2O2

Molecular Weight : 253.3 : 46.0



Analytical Information

Batch No. : A078023-102-368

Description : White Solid

HPLC Purity : 99.18 %

Weight Loss By TGA : 0.13 %

% Potency : 99.05 %

Solubility : Water : Methanol (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 - 0.13(Weight Loss By TGA)] x [99.18(HPLC Purity)]/100 = 99.05 %

Recommendation : Released

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

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