CERTIFICATE OF ANALYSIS

(Certificate No. KMA078011-01)

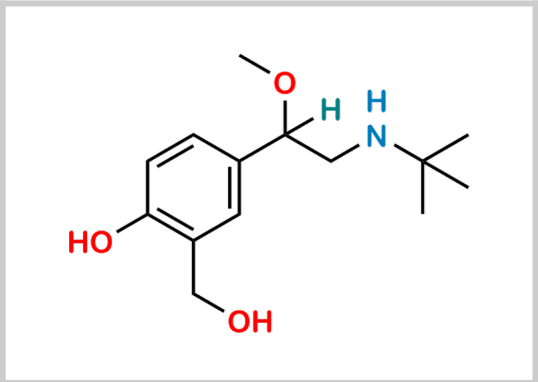
Release Date: 24/09/2025 **Re-test Date:** 23/09/2028

Albuterol EP Impurity A

Identification

Chemical Name :
4-[(1RS)-2-(tert-butylamino)-1-methoxyethyl]-2-(hydroxymethyl)phenol (as per EP)

Alt. Name	: Salbutamol BP Impurity A ; Levalbuterol USP Related Compound H ; Salbutamol Methyl Ether ; α-Methoxy Albuterol
CAT No.	: KMA078011
CAS No.	: 870076-72-5
Molecular Formula	: C14H23NO3
Molecular Weight	: 253.3



Analytical Information

Batch No.	: A078011-102-177	**Solubility**	: Water
Description	: Off white Hygroscopic Solid	**Mass**	: Confirm
HPLC Purity	: 97.82 %	**IR**	: Confirm
Weight Loss By TGA	: 2.18 %	**1H NMR**	: Confirm
% Potency	: 95.69 %	**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 - 2.18(Weight Loss By TGA)] x [97.82(HPLC Purity)]/100 = 95.69 %
*As per client request chemical name change as per EP monograph
-Re-tested 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