CERTIFICATE OF ANALYSIS

(Certificate No. KMI054012-01)

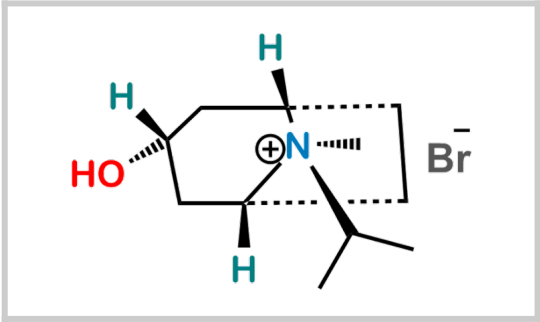
Release Date: 26/07/2025 **Re-test Date:** 25/07/2028

Ipratropium EP Impurity A

Identification

Chemical Name :
(1R,3r,5S,8r)-3-Hydroxy-8-isopropyl-8-methyl-8-azabicyclo[3.2.1]octan-8-ium bromide

Alt. Name	: Ipratropium Bromide USP Related Compound A
CAT No.	: KMI054012
CAS No.	: 58005-18-8
Molecular Formula	: C11H22NO : Br
Molecular Weight	: 184.3 : 79.9



Analytical Information

Batch No.	: I054012-102-122	**Solubility**	: DMSO
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 95.01 %	**IR**	: Confirm
Weight Loss By TGA	: 0.44 %	**1H NMR**	: Confirm
% Potency	: 94.59 %	**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 - 0.44(Weight Loss By TGA)] x [95.01(HPLC Purity)]/100 = 94.59 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		28/07/2025
Reviewed & Approved By	Quality Control	Jatin Patel		28/07/2025

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