CERTIFICATE OF ANALYSIS

(Certificate No. KMI054017-01)

Release Date: 07/10/2025 **Re-test Date:** 06/10/2028

Ipratropium EP Impurity F

Identification

Chemical Name :
(1R,3r,5S,8r)-8-Methyl-8-(1-methylethyl)-3-[(2-phenylpropenoyl)oxy]-8-azoniabicyclo[3.2.1]octane (as per EP)

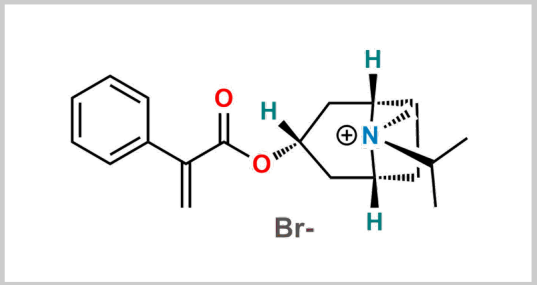
Alt. Name : Ipratropium atropic analog (USP)

CAT No. : KMI054017

CAS No. : 17812-46-3

Molecular Formula : C20H28NO2 : Br

Molecular Weight : 314.4 : 79.9



Analytical Information

Batch No. : I054017-102-183

Description : Off White Solid

HPLC Purity : 98.06 %

Weight Loss By TGA : 0.72 %

% Potency : 97.35 %

Solubility : Methanol : Water (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 - 0.72(Weight Loss By TGA)] x [98.06(HPLC Purity)]/100 = 97.35 %
-Re-purified and Re-tested on 02.10.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		07/10/2025
Reviewed & Approved By	Quality Control	Jatin Patel		07/10/2025

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