CERTIFICATE OF ANALYSIS

(Certificate No. KMI054016-01)

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

Ipratropium EP Impurity E

Identification

Chemical Name :
(1R,3r,5S)-8-(1-methylethyl)-8-azabicyclo[3.2.1]oct-3-yl (2RS)-3-hydroxy-2-phenylpropanoate (as per EP)

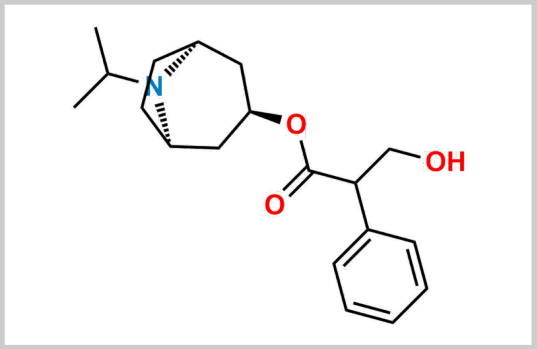
Alt. Name : N-Isopropyl Noratropine

CAT No. : KMI054016

CAS No. : 22235-81-0

Molecular Formula : C19H27NO3

Molecular Weight : 317.4



Analytical Information

Batch No. : I054016-102-201

Description : Off White Solid

HPLC Purity : 97.57 %

Weight Loss By TGA : 0.91 %

% Potency : 96.68 %

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 - 0.91(Weight Loss By TGA)] x [97.57(HPLC Purity)]/100 = 96.68 %
-Re-purified and Re-tested on 07.10.2025

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