

CERTIFICATE OF ANALYSIS

(Certificate No. KMI054014-01)

Release Date: 25/09/2025

Re-test Date: 24/09/2028

Ipratropium EP Impurity C

Identification

Chemical Name :
3-Hydroxy-2-phenylpropanoic acid

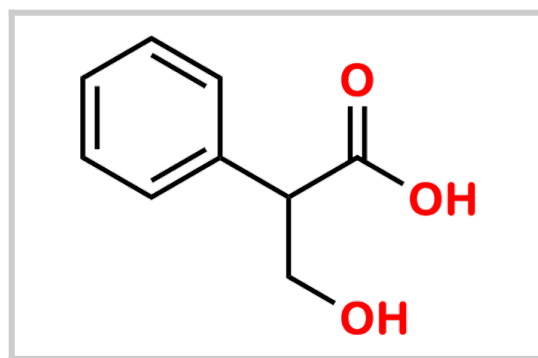
Alt. Name : Ipratropium Bromide USP Related
Compound C ; DL-Tropic Acid

CAT No. : KMI054014

CAS No. : 552-63-6

Molecular Formula : C₉H₁₀O₃

Molecular Weight : 166.2



Analytical Information

Batch No. : I054014-102-120

Description : Off White Solid

HPLC Purity : 99.16 %

Weight Loss By TGA : 0.40 %

% Potency : 98.76 %

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 - 0.40(Weight Loss By TGA)] x [99.16(HPLC Purity)]/100 = 98.76 %

-Re-tested in client method on 25.09.2025

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