

# 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

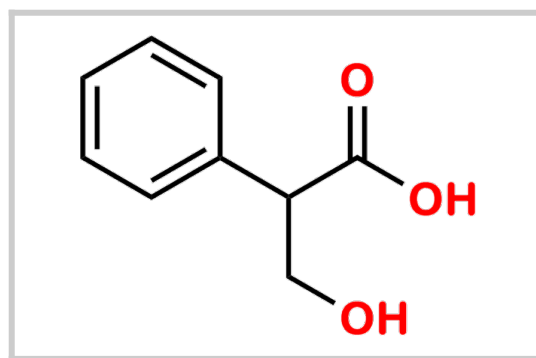
**Alt. Name** : Ipratropium Bromide USP Related  
Compound C ; DL-Tropic Acid

**CAT No.** : KMI054014

**CAS No.** : 552-63-6

**Molecular Formula** : C<sub>9</sub>H<sub>10</sub>O<sub>3</sub>

**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

**<sup>1</sup>H NMR** : Confirm

**<sup>13</sup>C 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
<b>Prepared By</b>	Analytical	Jignesh Patel		06/10/2025
<b>Reviewed &amp; Approved By</b>	Quality Control	Jatin Patel		06/10/2025

**Attachments** : COA, HPLC, MASS, <sup>1</sup>H NMR, <sup>13</sup>C NMR, IR and TGA