

# 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

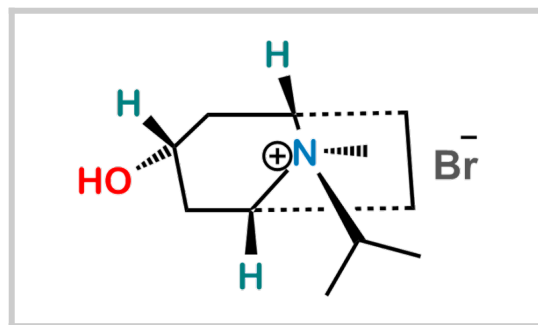
**Alt. Name** : Ipratropium Bromide USP Related Compound A

**CAT No.** : KMI054012

**CAS No.** : 58005-18-8

**Molecular Formula** : C<sub>11</sub>H<sub>22</sub>NO : Br

**Molecular Weight** : 184.3 : 79.9



### Analytical Information

**Batch No.** : I054012-102-122

**Description** : Off White Solid

**HPLC Purity** : 95.01 %

**Weight Loss By TGA** : 0.44 %

**% Potency** : 94.59 %

**Solubility** : DMSO

**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 - 0.44(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, <sup>1</sup>HNMR, <sup>13</sup>CNMR, IR and TGA