

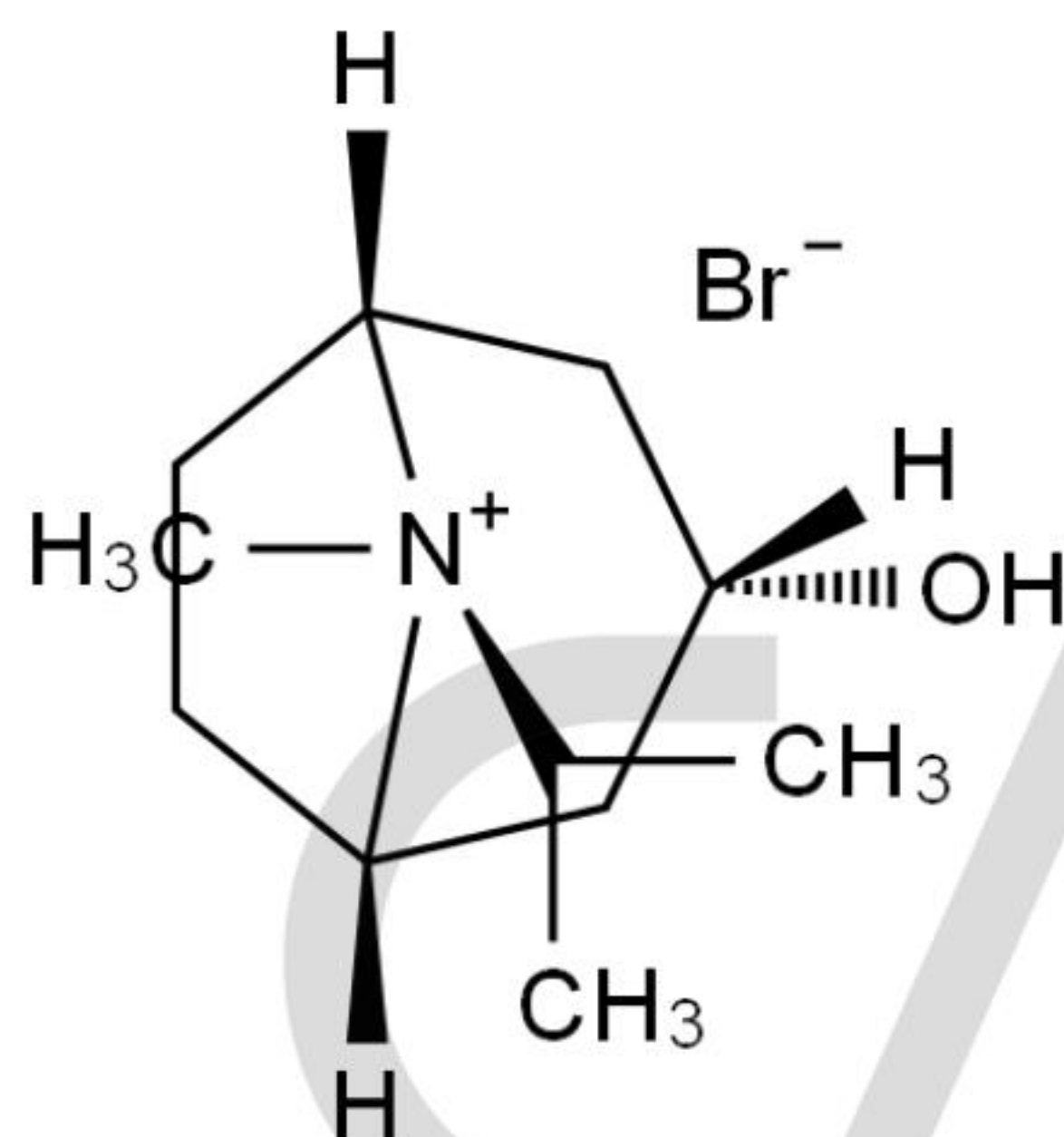
# Certificate of Analysis

## Reference Material & Standard

|                           |                                       |                          |                                           |
|---------------------------|---------------------------------------|--------------------------|-------------------------------------------|
| <b>Product Name:</b>      | Ipratropium Bromide EP Impurity A     | <b>Catalogue Number:</b> | C4X-16657                                 |
| <b>Synonyms:</b>          | N/A                                   | <b>Lot Number:</b>       | 0318-RG-0071                              |
| <b>CAS Number:</b>        | 58005-18-8                            | <b>Expiry Date:</b>      | Mar 23, 2028                              |
| <b>Molecular Formula:</b> | C <sub>11</sub> H <sub>22</sub> NO Br | <b>Storage:</b>          | 2°C ~ 8°C Protected from light and Sealed |
| <b>Molecular Weight:</b>  | 184.30 79.90                          | <b>Warning:</b>          |                                           |



Chemical Structure:



| Test Items          | Method            | Results     |
|---------------------|-------------------|-------------|
| Appearance          | Visual inspection | White Solid |
| Identification      | LCMS&IR&CNMR&HNMR | Confirmed   |
| Purity              | ELSD              | 98.235%     |
| Residue on Ignition | TGA               | 0.2700%     |
| Loss On Drying      | TGA               | 0.0012%     |
| Assay               |                   | 98.0%       |

## Comment:

The calculation of the 100% method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Residue on Ignition - Loss On Drying) \* Purity ELSD (%) / 100%

Residue on Ignition and Loss On Drying are considered as absolute effect, ELSD purity is considered as relative effect.

## Signature:

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Approved by General Manager:

*David*

Date: Mar 24, 2025

Date: Mar 24, 2025

Date: Mar 24, 2025

