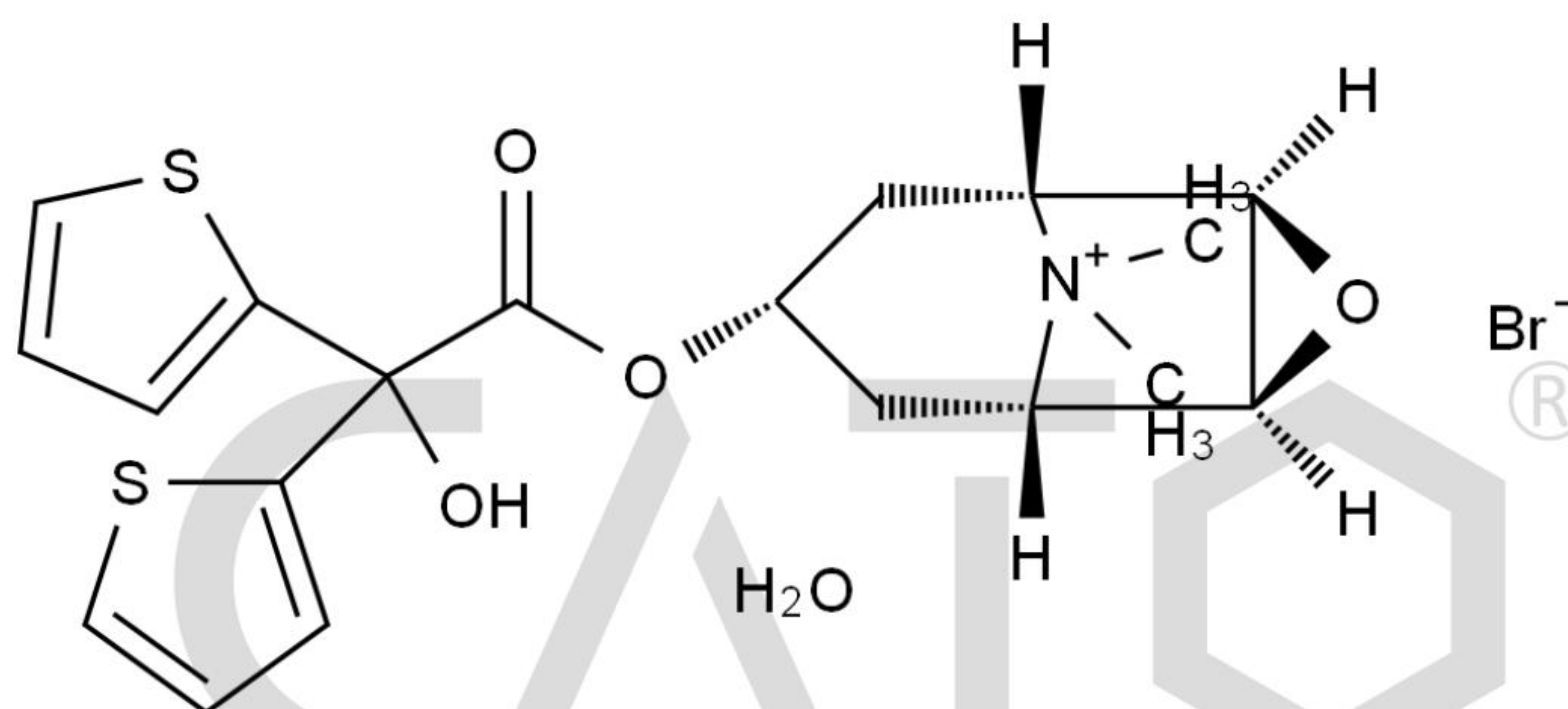


Certificate of Analysis

Reference Material & Standard

Product Name:	Tiotropium Bromide Monohydrate	Catalogue Number:	C4X-1764
Synonyms:	N/A	Lot Number:	1015-RG-0052
CAS Number:	139404-48-1	Expiry Date:	Oct 15, 2029
Molecular Formula:	C ₁₉ H ₂₂ NO ₄ S ₂ Br H ₂ O	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	392.51 79.90 18.02	Shipping Condition:	Shipping at Room Temperature

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	100.000%
Water Content	Karl Fischer	3.68%
Water Content(Free Water)		0.0060%
Residue on Ignition	TGA	0.0225%
Assay		99.97%

Comment:

- The content of crystal water is 3.6740%.
- The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

$$\text{Assay (\%)} = (100\% - \text{Water Content(Free Water)} - \text{Residue on Ignition}) * \text{Purity HPLC (\%)} / 100\%$$

Water Content(Free Water) and Residue on Ignition are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Mar 17, 2026

Date: Mar 17, 2026

Date: Mar 17, 2026

