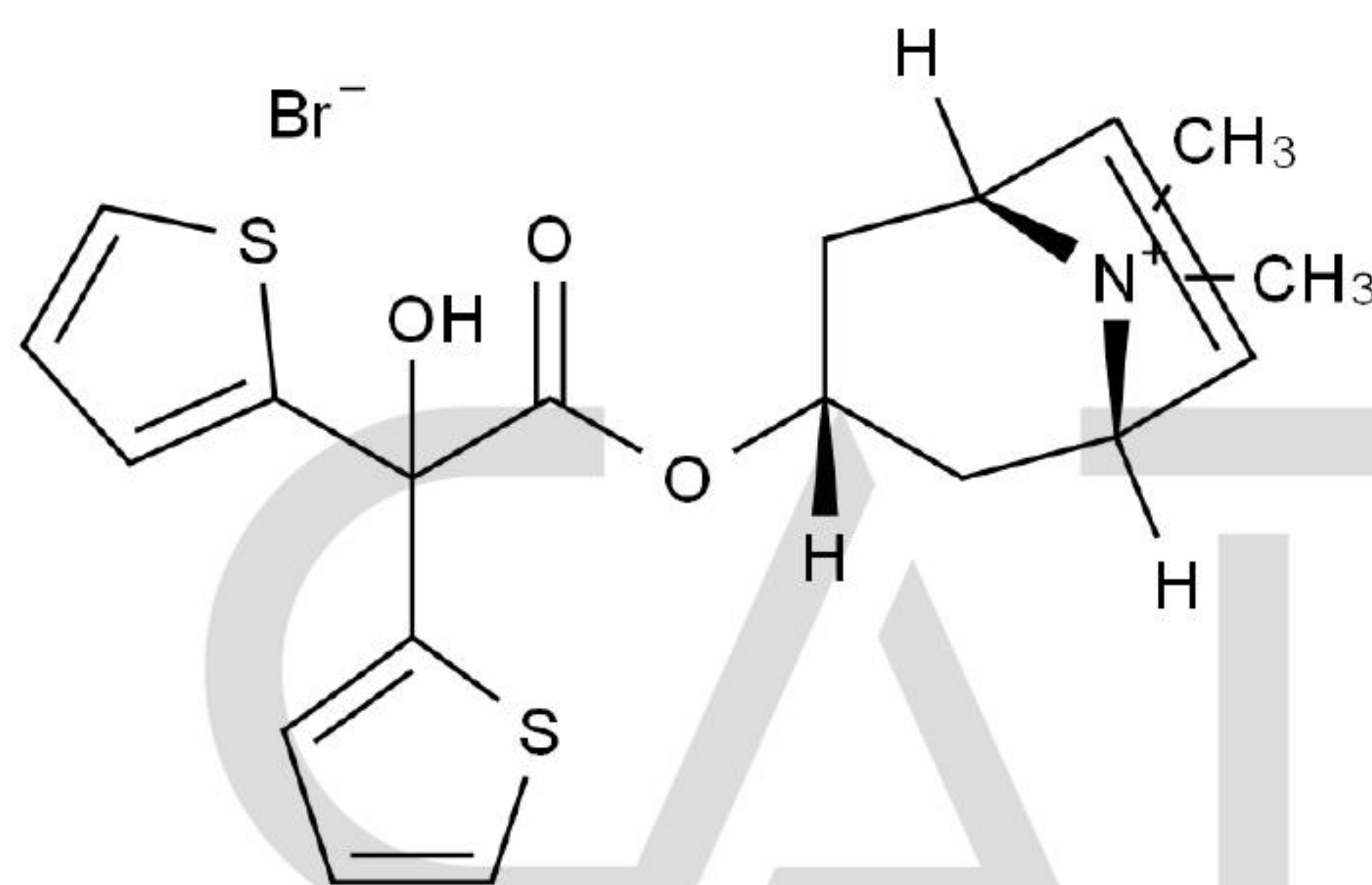


Certificate of Analysis

Reference Material & Standard

Product Name:	Tiotropium Bromide EP Impurity C	Catalogue Number:	C4X-17643
Synonyms:	N/A	Lot Number:	0725-RE-0107
CAS Number:	136310-95-7	Expiry Date:	Sep 09, 2028
Molecular Formula:	C ₁₉ H ₂₂ NO ₃ S ₂ Br	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	376.51 79.90	Shipping Condition:	Shipping with Ice Packs

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&IR&CNMR&HNMR	Confirmed
Purity	HPLC	99.532%
Water Content	Karl Fischer	4.73%
Residual Solvents	NMR	Not detected in NMR
Assay		94.8%

Comment:

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

Assay (%) = (100%-Water Content-Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Reviewed by:

Approved by General Manager:

Date: Mar 26, 2026

Date: Mar 26, 2026

Date: Mar 26, 2026



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