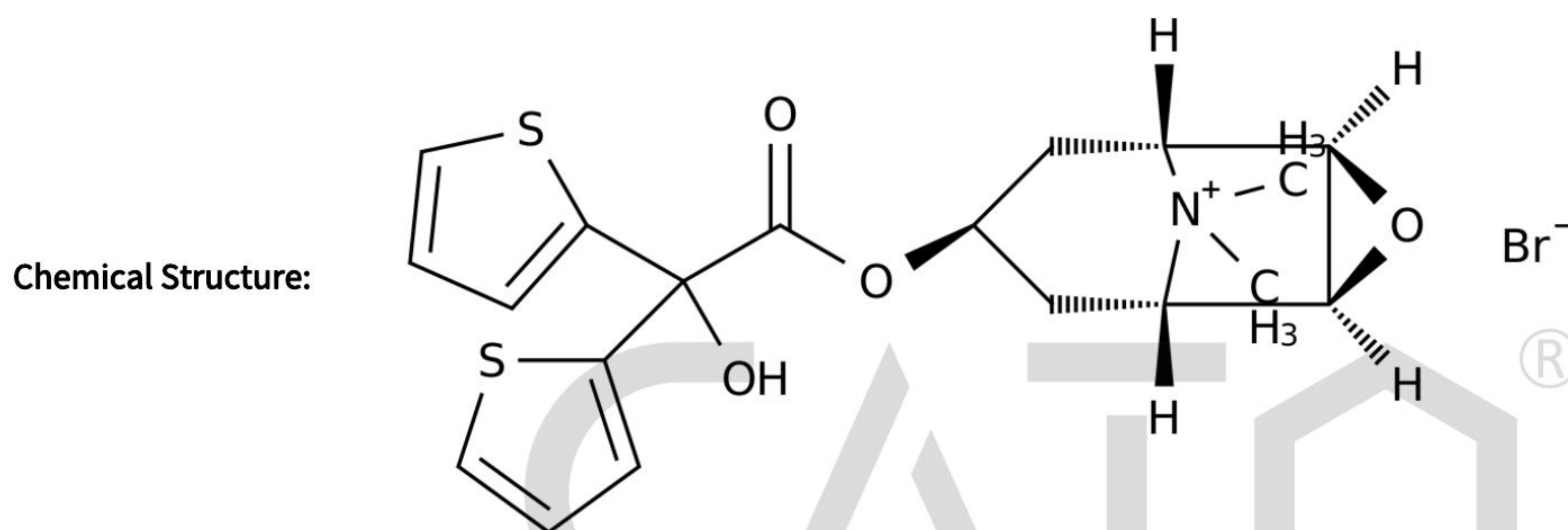


Certificate of Analysis

Reference Material & Standard

Product Name:	Tiotropium Bromide EP Impurity I	Catalogue Number:	C4X-176410
Synonyms:	N/A	Lot Number:	0711-RG-0037
CAS Number:	136521-48-7	Expiry Date:	Jun 17, 2027
Molecular Formula:	C ₁₉ H ₂₂ NO ₄ S ₂ Br	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	392.51 79.90		



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.6592%
Loss On Drying	TGA	0.196%
Assay		99.5%

Comment:

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

Assay (%) = (100% - Loss On Drying) * Purity HPLC (%) / 100%

Loss On Drying is considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Jul 11, 2025

Date: Jul 11, 2025

Date: Jul 11, 2025

