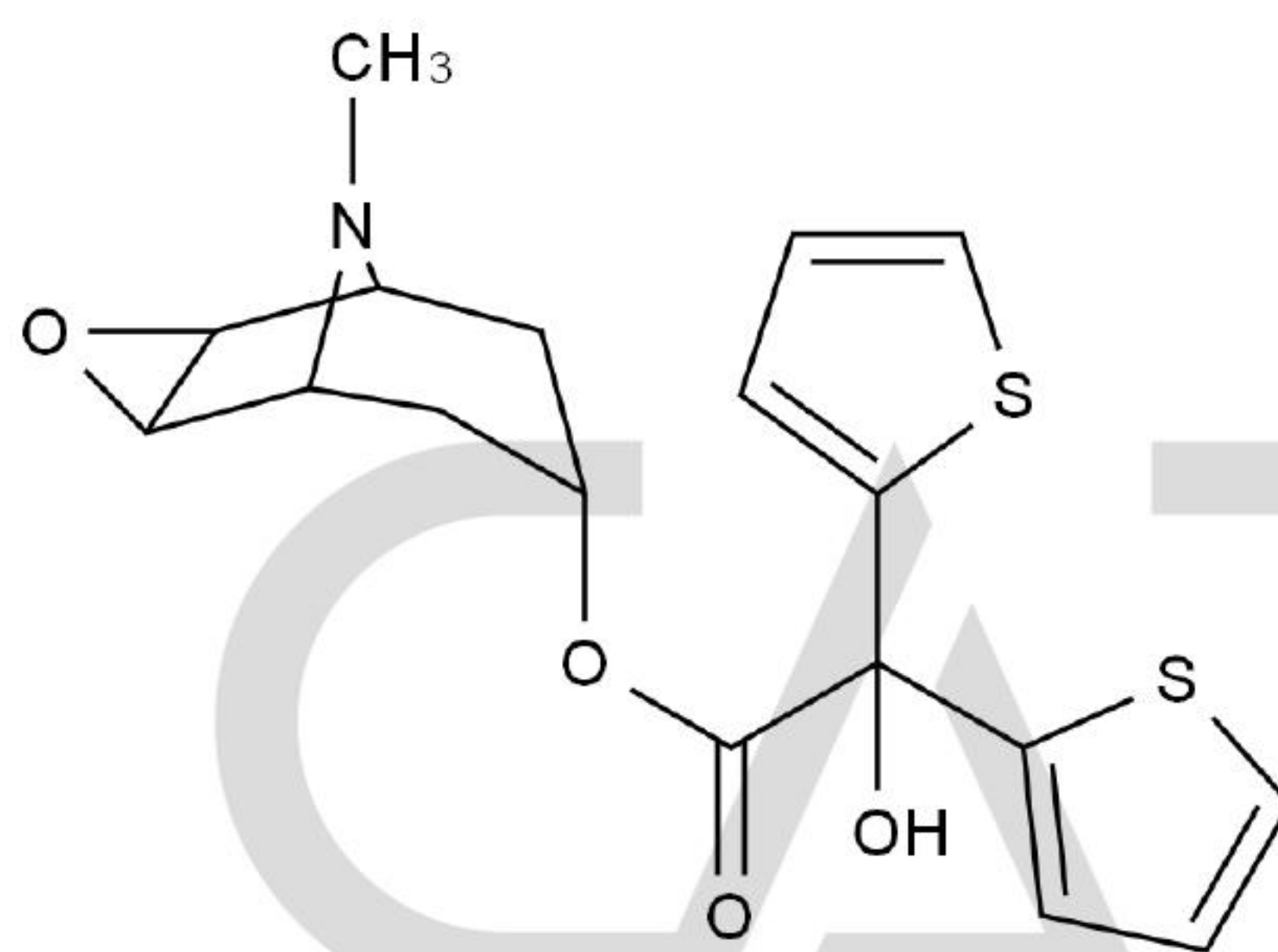


Certificate of Analysis

Reference Material & Standard

Product Name:	Tiotropium Bromide EP Impurity B	Catalogue Number:	C4X-17642
Synonyms:	N/A	Lot Number:	0209-RH-0042
CAS Number:	136310-64-0	Expiry Date:	Feb 10, 2030
Molecular Formula:	C ₁₈ H ₁₉ NO ₄ S ₂	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	377.48	Shipping Condition:	Shipping with Ice Packs
Solubility:	Acetonitrile		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.948%
Loss On Drying	TGA	0.0293%
Assay		99.9%

Comment:

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

$\text{Assay (\%)} = (100\% - \text{Loss On Drying}) * \text{Purity HPLC (\%)} / 100\%$

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

Signature:

Prepared by:

Nice

Reviewed by:

Koi

Approved by General Manager:

David

Date: Feb 11, 2026

Date: Feb 11, 2026

Date: Feb 11, 2026



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