

Certificate of Analysis

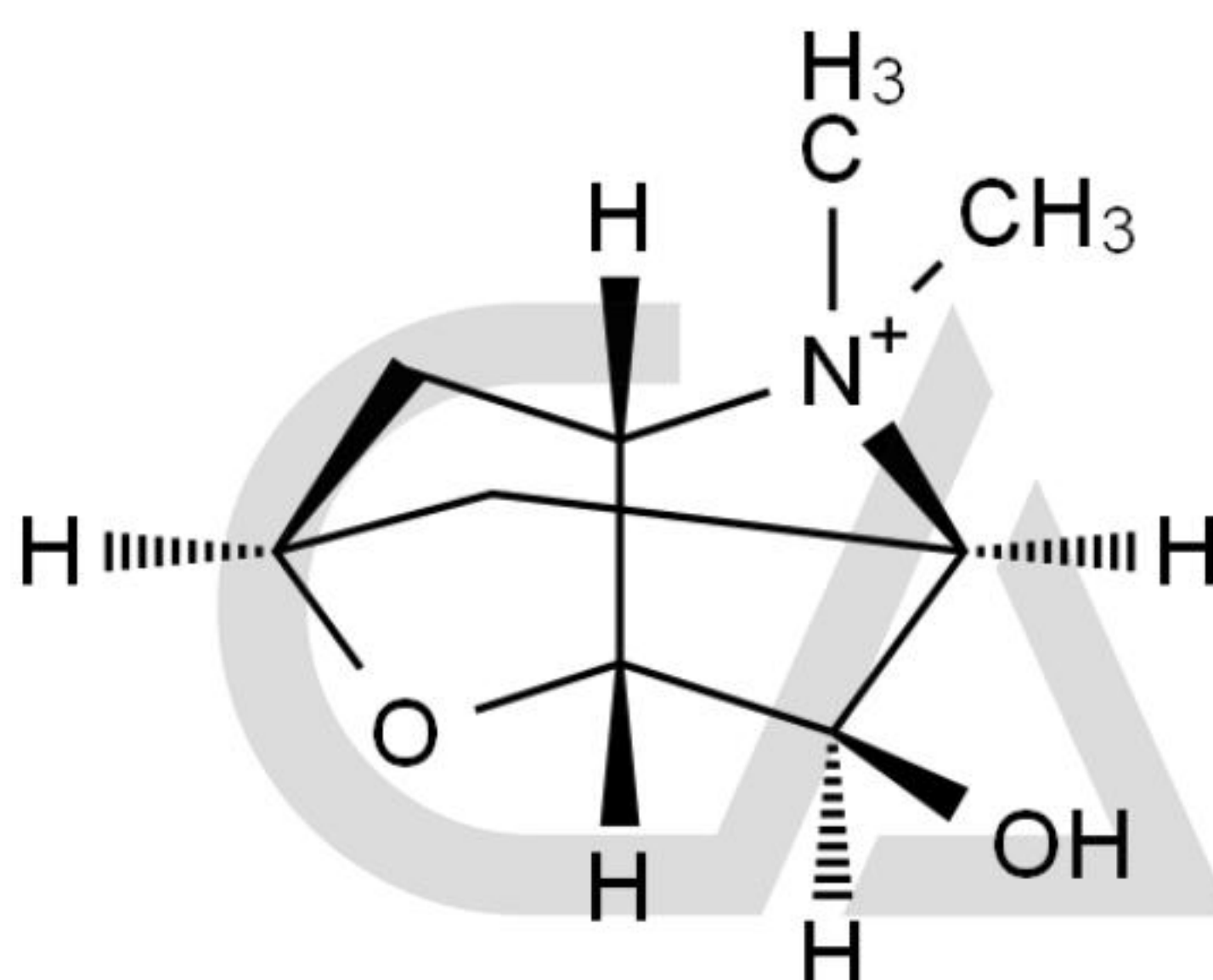
Reference Material & Standard

Product Name:	Tiotropium Bromide EP Impurity H (Mixture of Enantiomers)	Catalogue Number:	C4X-17648
Synonyms:	N/A	Lot Number:	1111-RF-0112
CAS Number:	1044148-31-3	Expiry Date:	Nov 05, 2027
Molecular Formula:	C ₉ H ₁₆ NO ₂ Br	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	170.23 79.90	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	ELSD	97.91%
Water Content	Karl Fischer	0.30%
Residual Solvents	NMR	Not detected in NMR
Assay		97.6%

Comment:

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

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

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

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Nov 15, 2024

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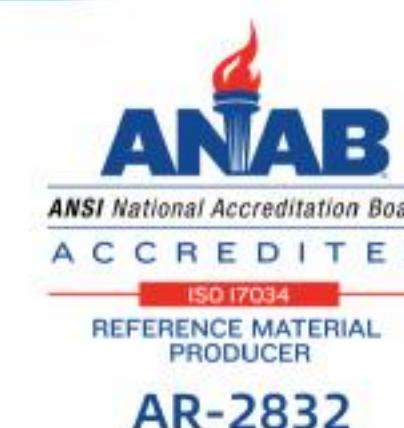
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