

Certificate of Analysis

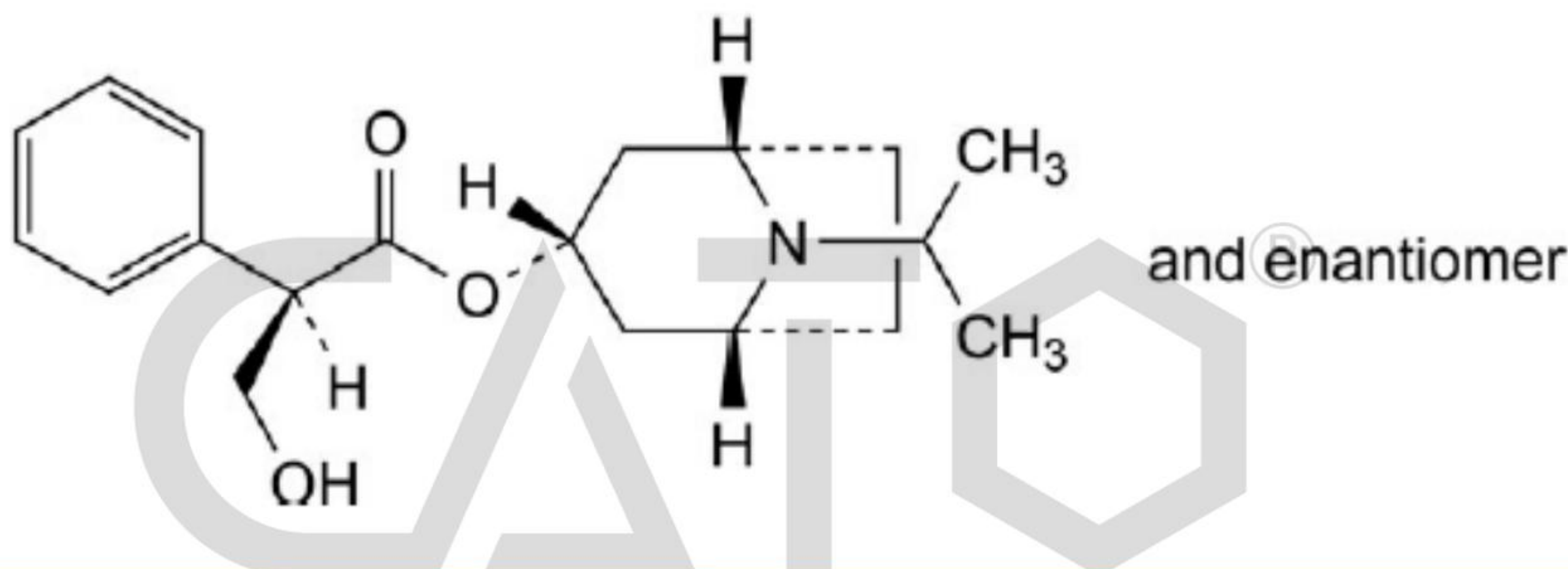
Reference Material & Standard

Product Name:	Ipratropium Bromide EP Impurity E	Catalogue Number:	C4X-16655
Synonyms:	Desmethyl ipratropium	Lot Number:	1014-RG-0073
CAS Number:	22235-81-0	Expiry Date:	Oct 19, 2029
Molecular Formula:	C ₁₉ H ₂₇ NO ₃	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	317.42		

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	100.000%
Loss On Drying	TGA	0.0283%
Assay		100.0%

Comment:

The calculation of the mass balance 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:

Nice

Reviewed by:

Koi

Approved by General Manager:

David

Date: Oct 20, 2025

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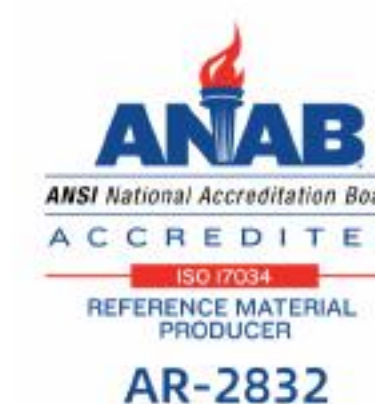
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