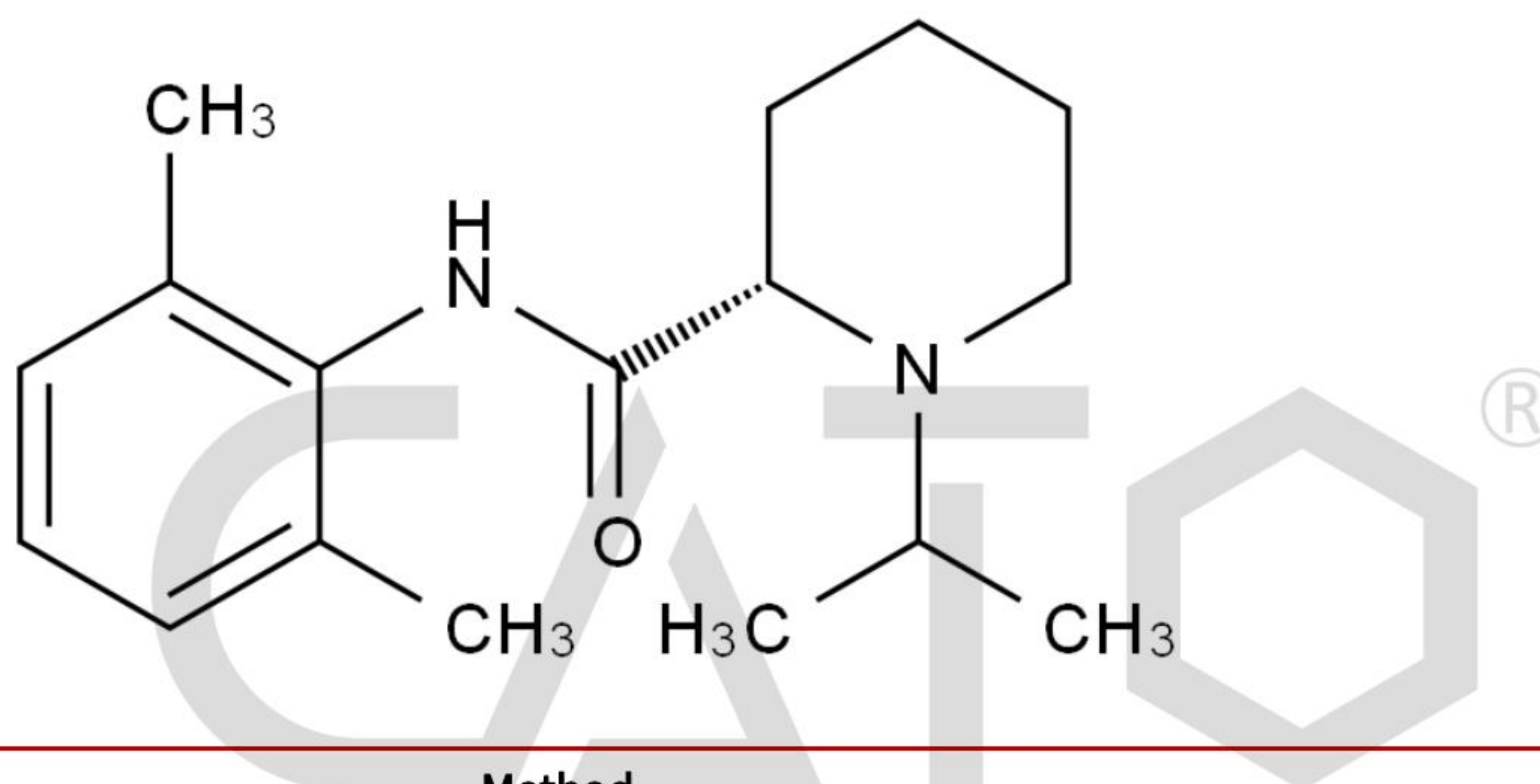


Certificate of Analysis

Reference Material & Standard

Product Name:	Ropivacaine EP Impurity E	Catalogue Number:	C4X-17533
Synonyms:	N/A	Lot Number:	0220-RG-0049
CAS Number:	265120-58-9	Expiry Date:	Feb 19, 2028
Molecular Formula:	C ₁₇ H ₂₆ N ₂ O	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	274.40		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.6882%
Residue on Ignition	TGA	0.614%
Loss On Drying	TGA	0.381%
Assay		98.7%

Comment:

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

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

Residue on Ignition and Loss On Drying are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Lily

Reviewed by:

Hinlam

Approved by General Manager:

David

Date: Feb 24, 2025

Date: Feb 24, 2025

Date: Feb 24, 2025

