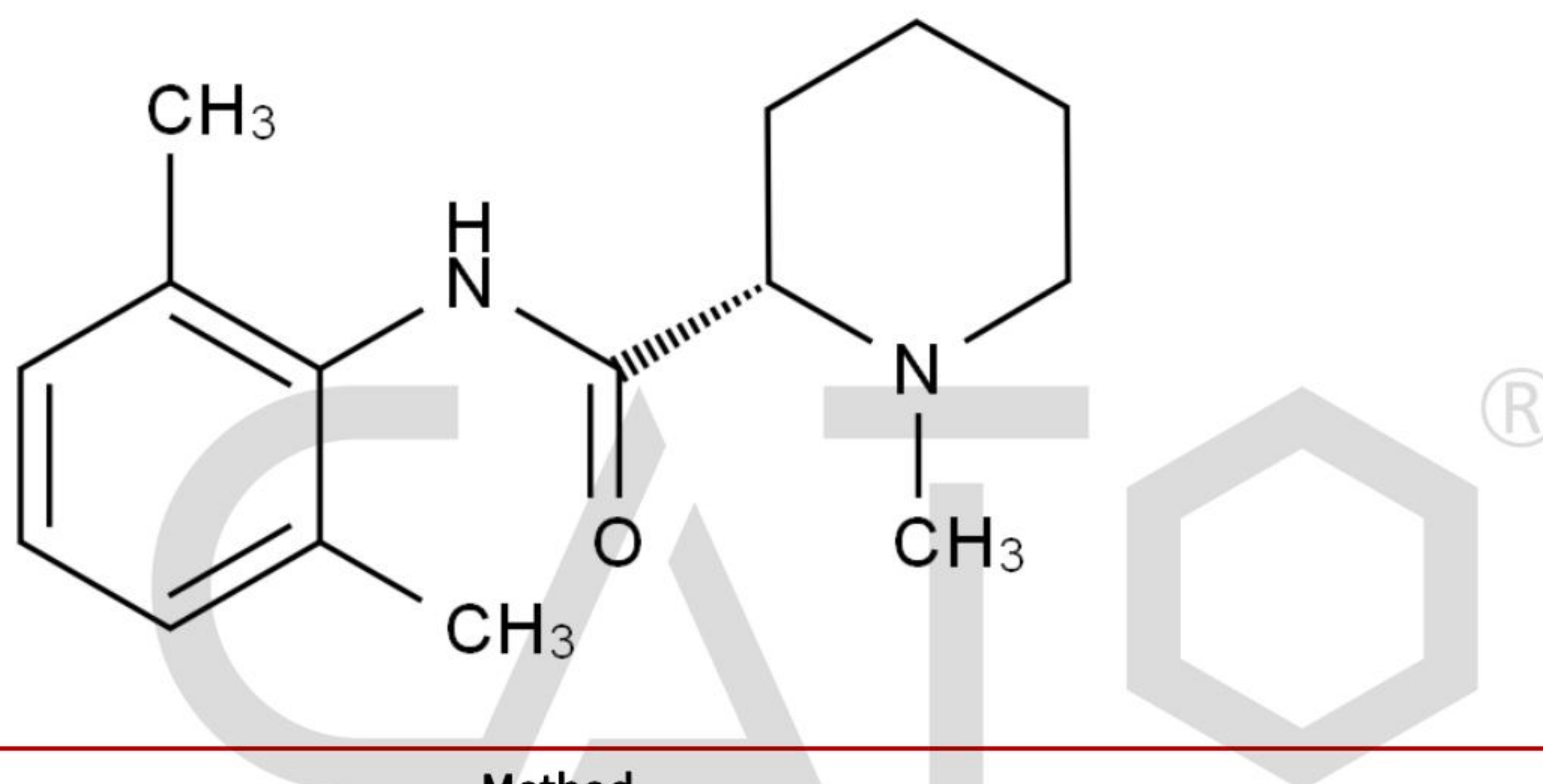


Certificate of Analysis

Reference Material & Standard

Product Name:	Ropivacaine EP Impurity C	Catalogue Number:	C4X-17536
Synonyms:	N/A	Lot Number:	0220-RG-0051
CAS Number:	24358-84-7	Expiry Date:	Feb 18, 2028
Molecular Formula:	C ₁₅ H ₂₂ N ₂ O	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	246.35		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.4604%
Residue on Ignition	TGA	0.533%
Loss On Drying	TGA	0.399%
Assay		98.5%

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 21, 2025

Date: Feb 24, 2025

Date: Feb 24, 2025

