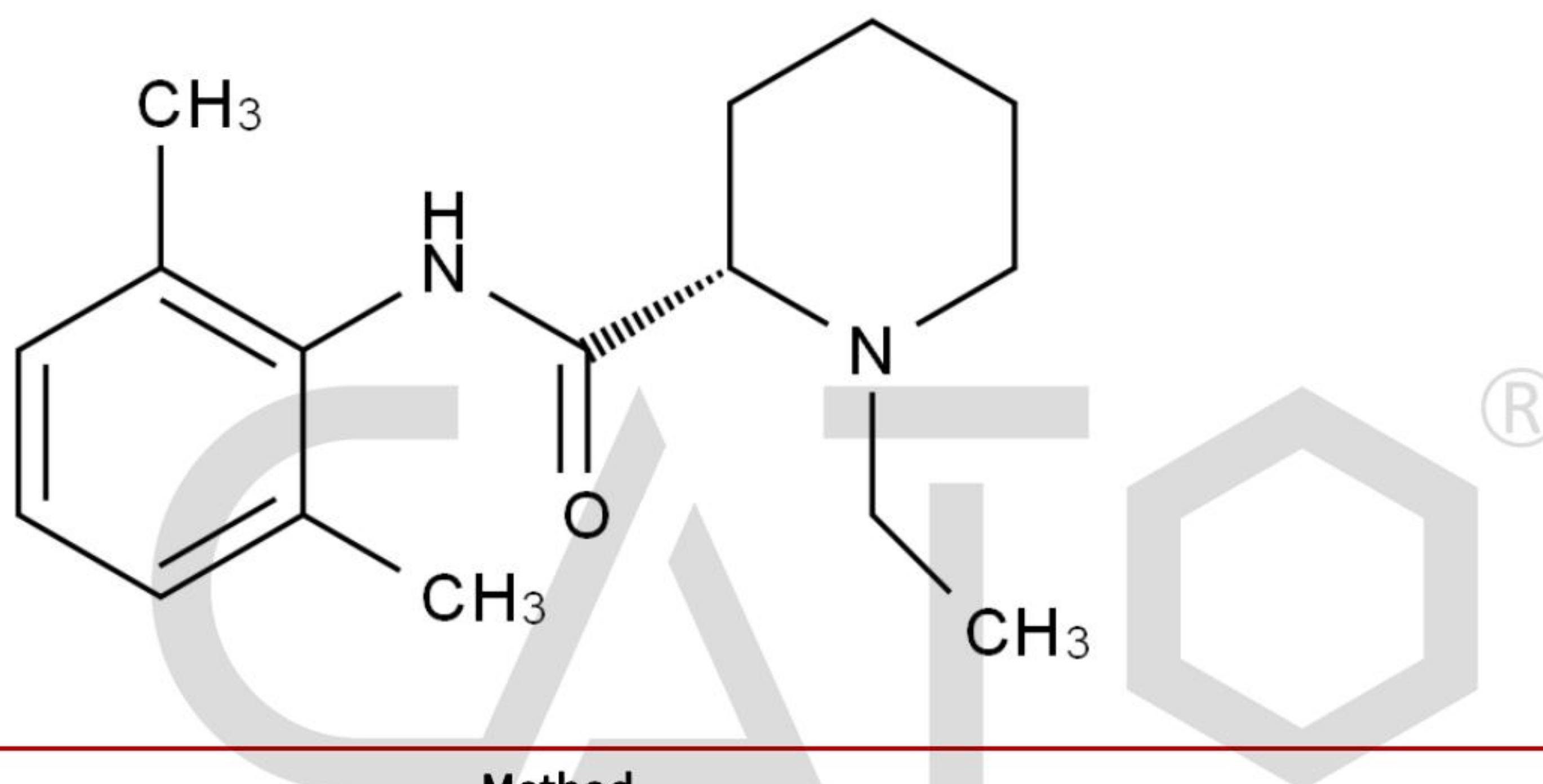


Certificate of Analysis

Reference Material & Standard

Product Name:	Ropivacaine EP Impurity D	Catalogue Number:	C4X-17532
Synonyms:	N/A	Lot Number:	0220-RG-0048
CAS Number:	98626-59-6	Expiry Date:	Feb 18, 2028
Molecular Formula:	C ₁₆ H ₂₄ N ₂ O	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	260.37		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.2914%
Residue on Ignition	TGA	1.800%
Loss On Drying	TGA	0.269%
Assay		97.2%

Comment:

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

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

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

