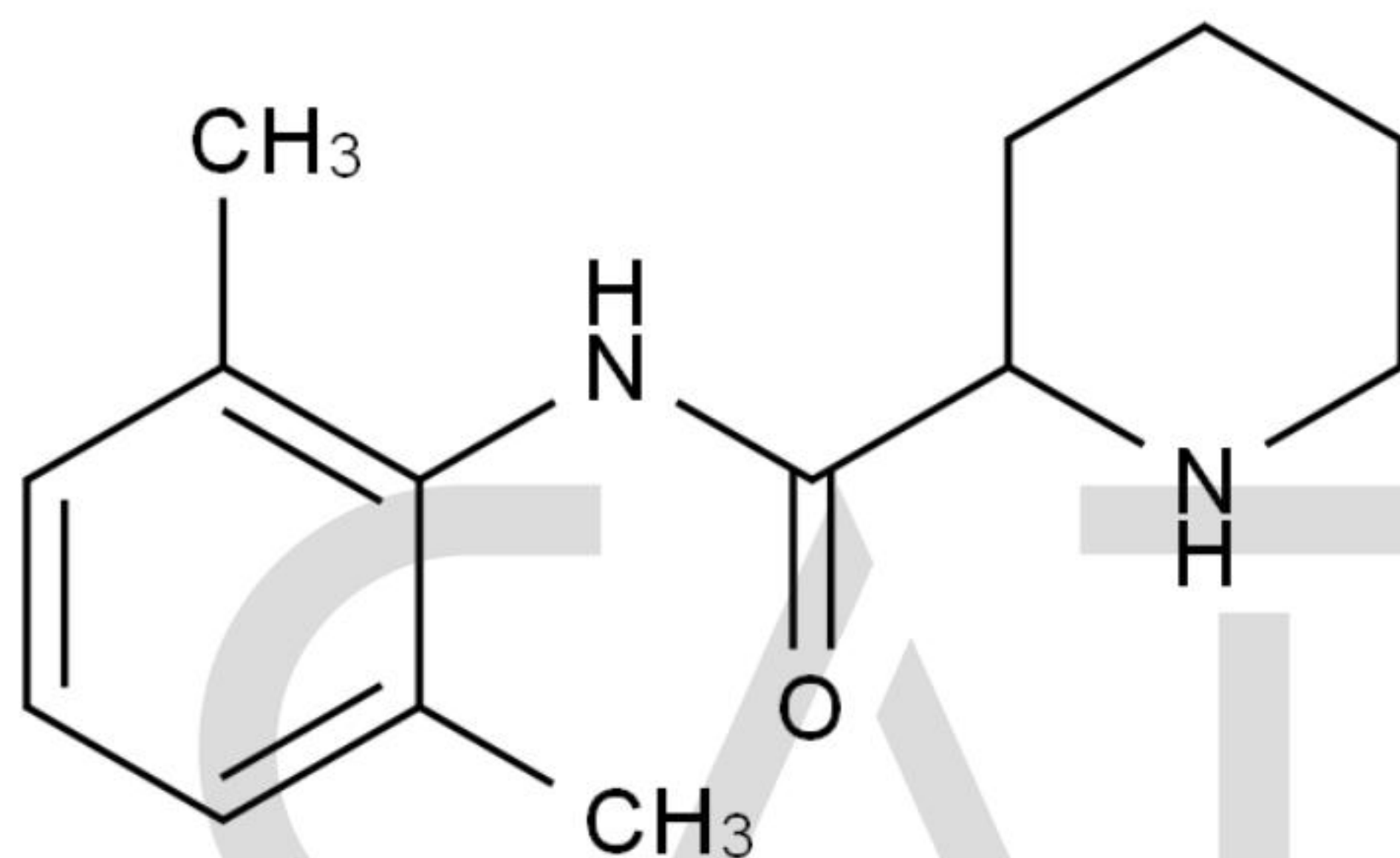


Certificate of Analysis

Reference Material & Standard

Product Name:	Bupivacaine EP Impurity B	Catalogue Number:	C4X-14822
Synonyms:	N/A	Lot Number:	0330-RD-0044
CAS Number:	15883-20-2	Expiry Date:	Oct 24, 2027
Molecular Formula:	C ₁₄ H ₂₀ N ₂ O	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	232.32	Warning:	

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	100.000%
Loss On Drying	TGA	0.0579%
Assay		99.9%

Comment:

The calculation of the 100% 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:

Koi

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Oct 25, 2024

Date: Oct 25, 2024

Date: Oct 25, 2024

