

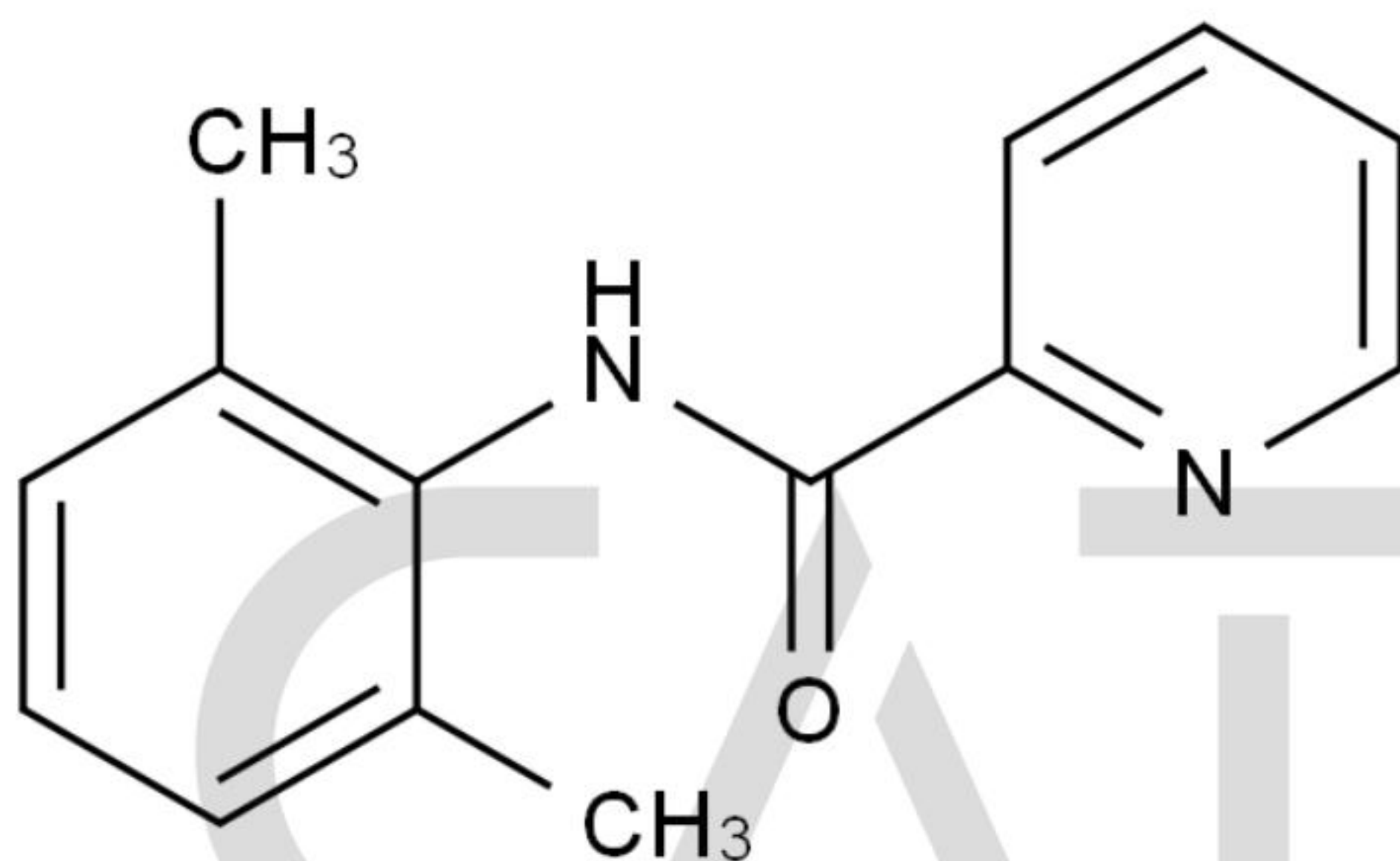
Certificate of Analysis

Reference Material & Standard

Product Name:	Bupivacaine EP Impurity A	Catalogue Number:	C4X-14821
Synonyms:	N/A	Lot Number:	0514-RG-0097
CAS Number:	39627-98-0	Expiry Date:	May 15, 2028
Molecular Formula:	C ₁₄ H ₁₄ N ₂ O	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	226.27	Warning:	



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&IR&UV&HNMR	Confirmed
Purity	HPLC	100.000%
Loss On Drying	TGA	0.0574%
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:

Nice

Reviewed by:

Koi

Approved by General Manager:

David

Date: May 16, 2025

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