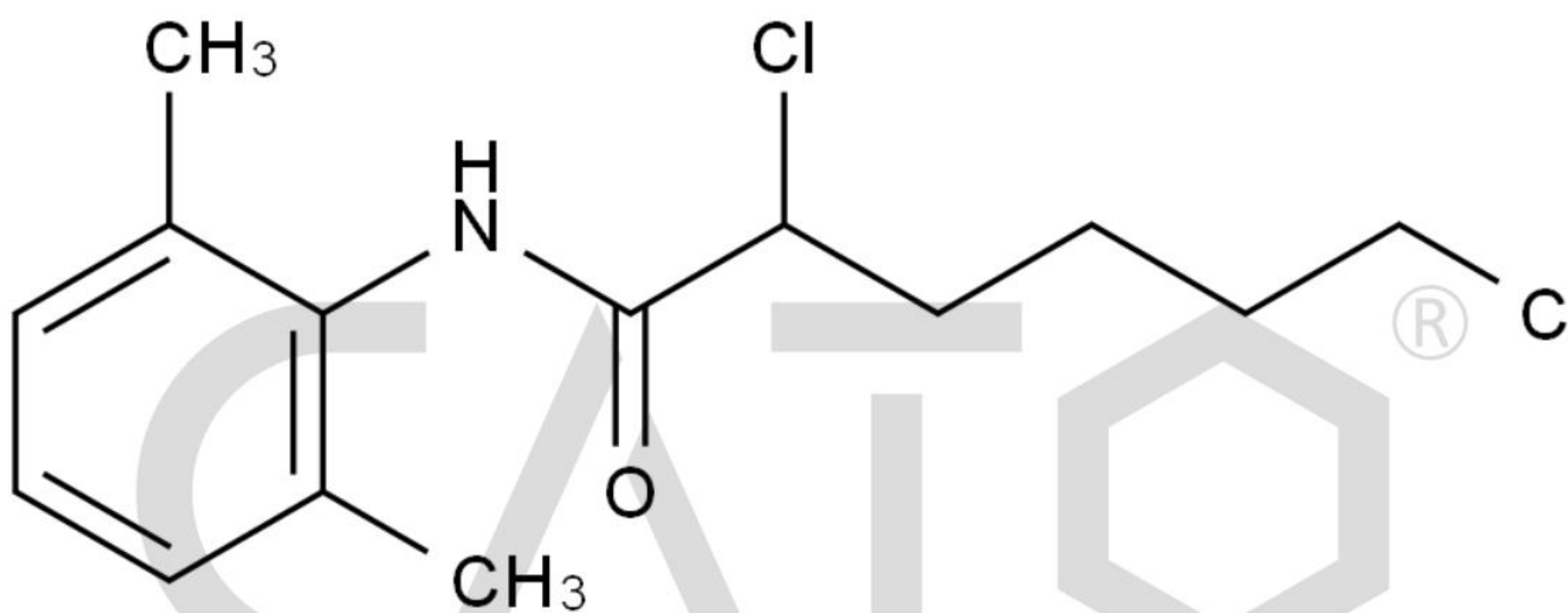


Certificate of Analysis

Reference Material & Standard

Product Name:	Bupivacaine EP Impurity D	Catalogue Number:	C4X-14824
Synonyms:	N/A	Lot Number:	0422-RG-0099
CAS Number:	1037184-07-8	Expiry Date:	Mar 26, 2027
Molecular Formula:	C ₁₄ H ₁₉ Cl ₂ NO	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	288.21	Warning:	 

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.442%
Loss On Drying	TGA	2.98%
Assay		95.5%

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:

Lily

Reviewed by:

Lisa

Approved by General Manager:

David

Date: Apr 27, 2025

Date: Apr 28, 2025

Date: Apr 28, 2025

