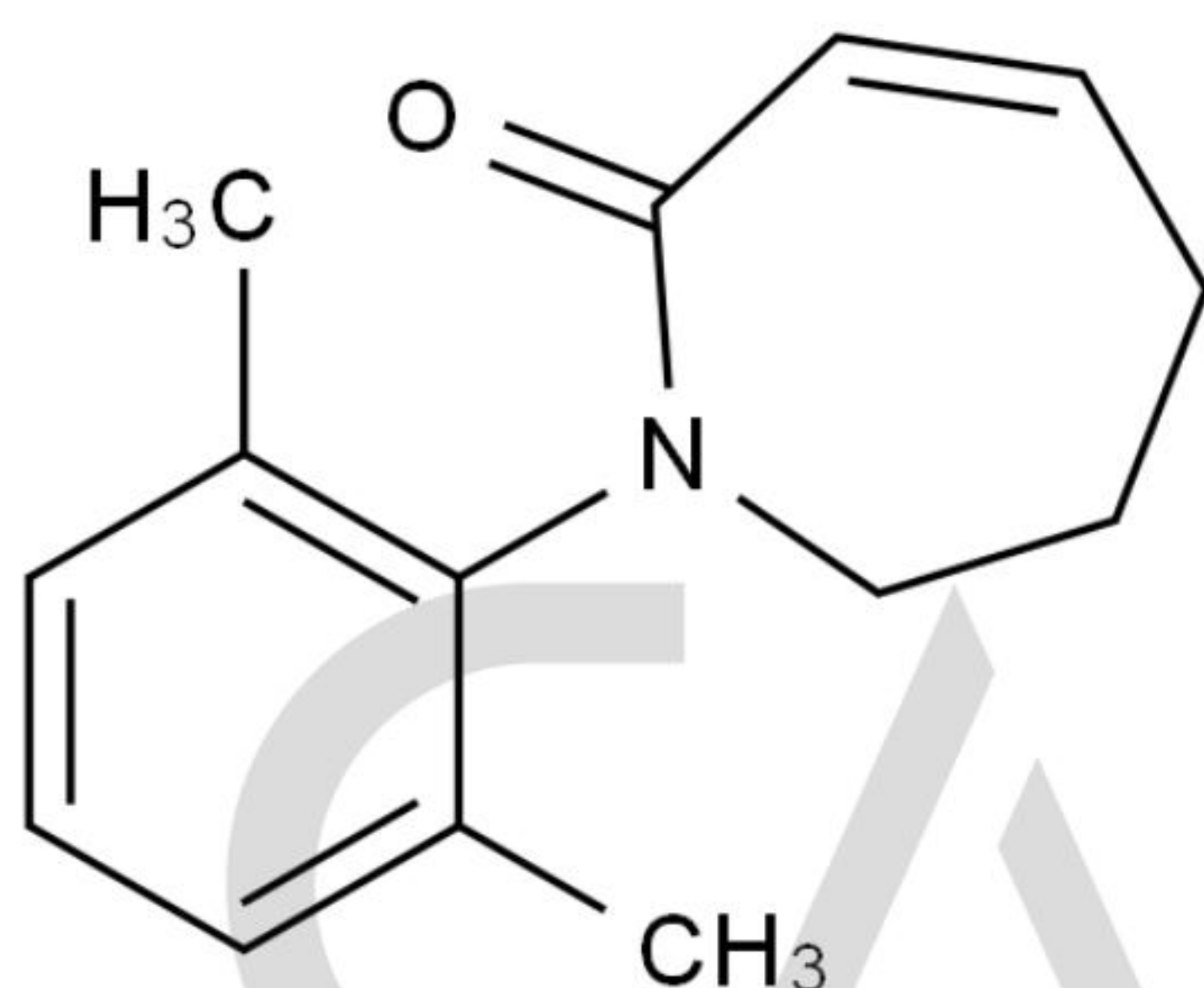


Certificate of Analysis

Reference Material & Standard

Product Name:	Bupivacaine EP Impurity C	Catalogue Number:	C4X-14823
Synonyms:	N/A	Lot Number:	0729-RG-0013
CAS Number:	1797894-80-4	Expiry Date:	Jun 26, 2027
Molecular Formula:	C ₁₄ H ₁₇ NO	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	215.29		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	98.3553%
Loss On Drying	TGA	0.52%
Assay		97.8%

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: Jul 30, 2025

Date: Jul 30, 2025

Date: Jul 30, 2025

