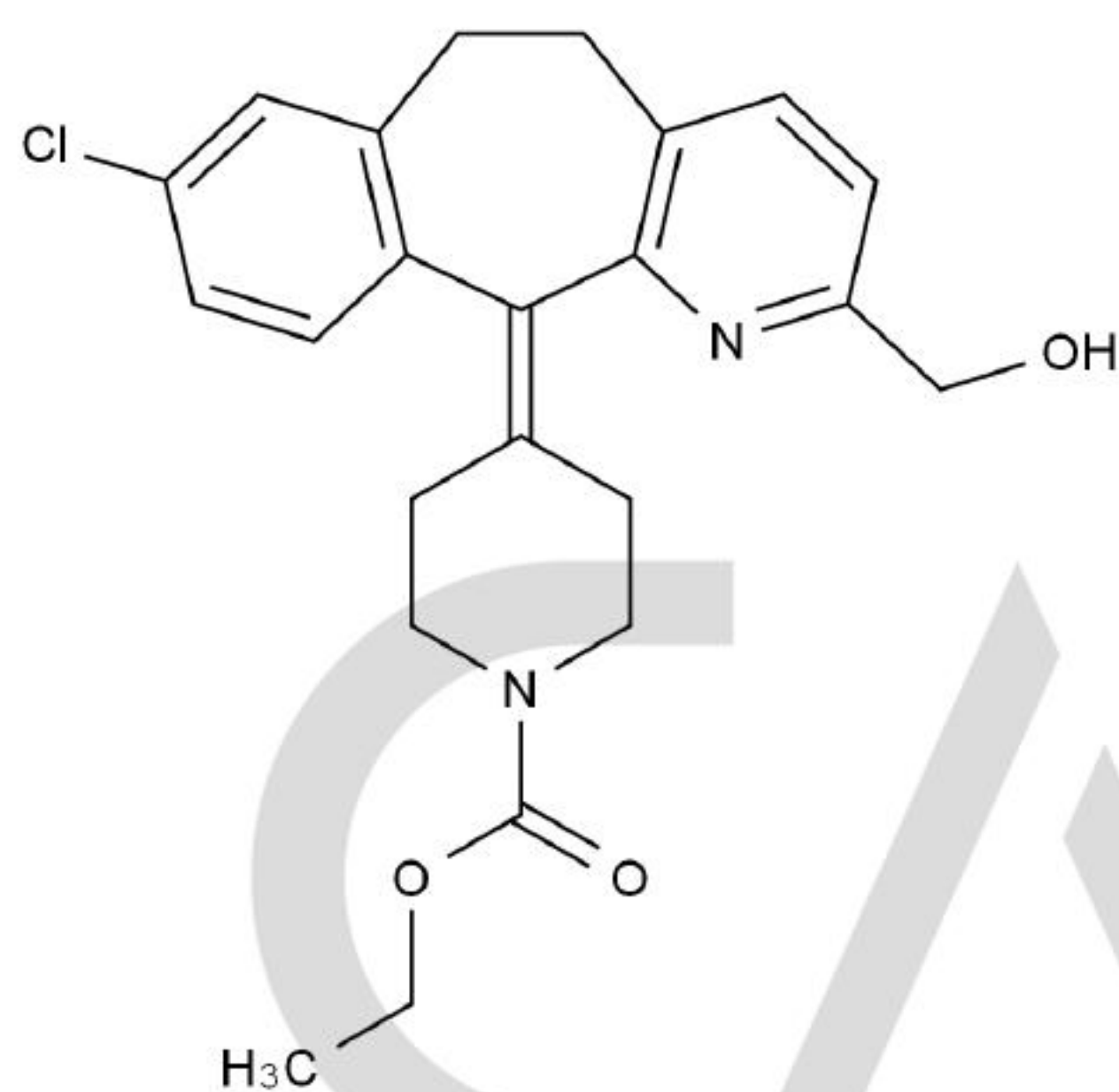


Certificate of Analysis

Reference Material & Standard

Product Name:	Loratadine 2-Hydroxymethyl Impurity (USP)	Catalogue Number:	C4X-14269
Synonyms:	N/A	Lot Number:	0630-RE-0002
CAS Number:	609806-39-5	Expiry Date:	Sep 13, 2027
Molecular Formula:	C ₂₃ H ₂₅ ClN ₂ O ₃	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	412.91		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White Crystalline Solid
Identification	LCMS&HNMR	Confirmed
Purity	HPLC	99.516%
Loss On Drying	TGA	0.2905%
Assay		99.2%

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: Sep 18, 2024

Date: Sep 18, 2024

Date: Sep 18, 2024

