

Certificate of Analysis

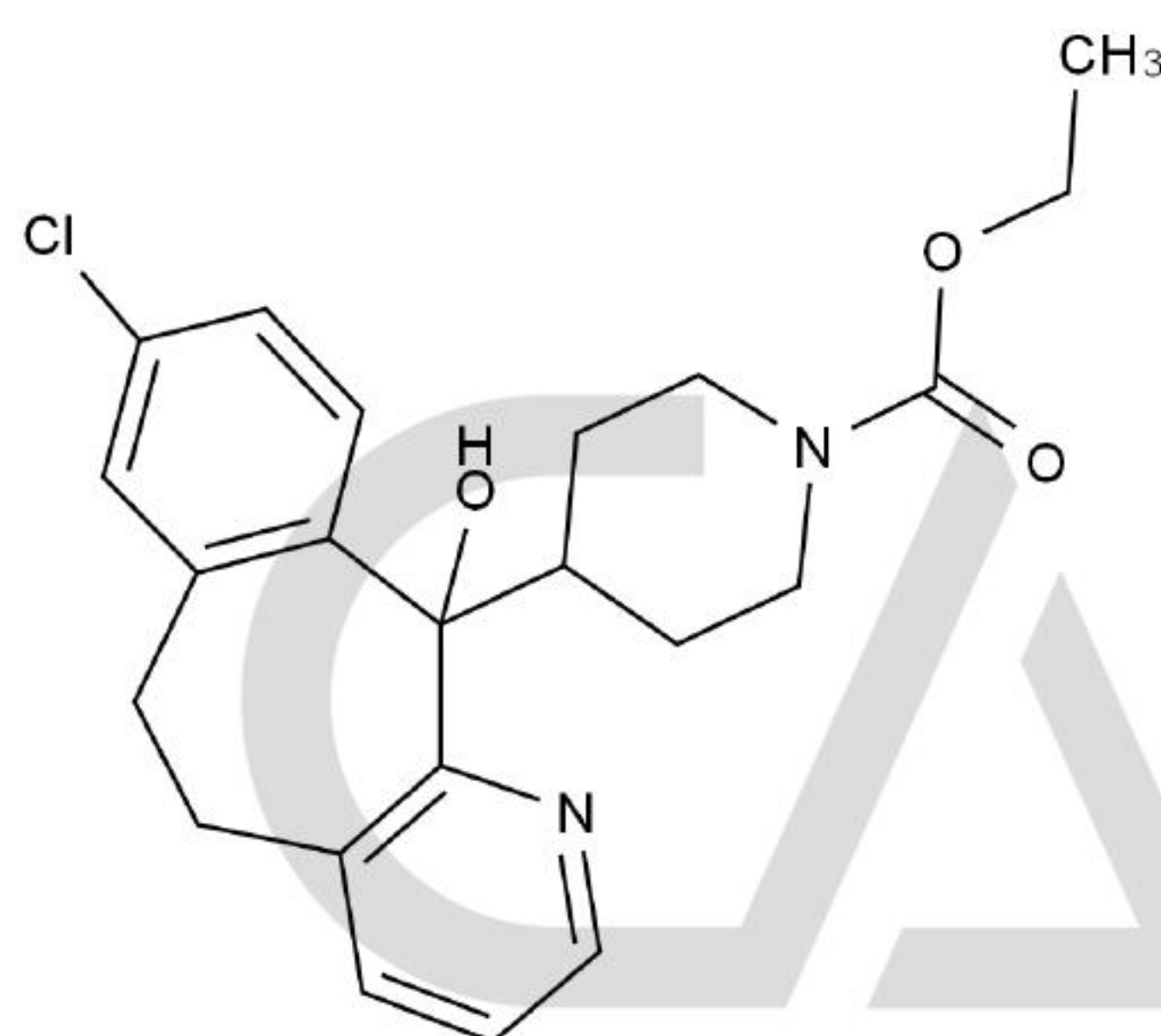
Reference Material & Standard

Product Name:	Loratadine EP Impurity A	Catalogue Number:	C4X-14261
Synonyms:	Hydroxyloratadine	Lot Number:	0506-RH-0041
CAS Number:	133284-74-9	Expiry Date:	Apr 26, 2030
Molecular Formula:	C ₂₂ H ₂₅ ClN ₂ O ₃	Storage:	-20°C±5°C Protected from light and Sealed
Molecular Weight:	400.90	Shipping Condition:	Shipping with Ice Packs

Warning:



Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	Off-White Solid
Identification	LCMS&UV&HNMR	Confirmed
Purity	HPLC	99.828%
Water Content	Karl Fischer	0.04%
Residual Solvents	NMR	0.04% acetonitrile
Assay		99.7%

Comment:

The calculation of the mass balance method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Reviewed by:

Approved by General Manager:

Date: May 06, 2026

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