



CERTIFICATE OF ANALYSIS

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1. Identification

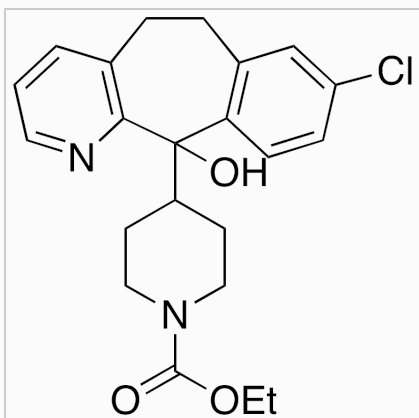
Catalogue Number: H941370

CAS Number: 133284-74-9

Product: 11-Hydroxy Dihydro Loratadine

Synonym: 4-(8-Chloro-6,11-dihydro-11-hydroxy-5H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-yl)-1-piperidinecarboxylic Acid Ethyl Ester; Loratadine EP Impurity A; Loratadine USP Related Compound F

Structure:



Molecular Formula:

C₂₂H₂₅ClN₂O₃

Molecular weight:

400.9

Source of Product:

Synthetic

Solubility:

Chloroform (Slightly),
Dichloromethane (Slightly),
DMSO (Slightly), Ethanol (Slightly)

Lot Number: 58-GHZ-70-1

Purity: 98%

Shipping Condition: This Product Is Stable To Be Shipped At Room Temperature

Storage Condition: -20°C

2. Warning

Warning 1:

Warning 2:

Warning 3:

3. Analytical Information

Tests:	Specifications:	Results:
Appearance	White to Pale Yellow Solid	White to Off-White Solid
NMR	Conforms to Structure	Conforms
Elemental Analysis	Conforms	%C: 65.59, %H: 6.21, %N: 6.91
MS	Conforms to Structure	Conforms
Specific Rotation	Report Result	-0.4° (c = 0.5, Chloroform)
HPLC Purity	Report Result	99.53% (210 nm)

Additional Information: N/A

Purity is based on the analytical results of the tests performed. NMR and Elemental Analysis (if available) may have an accuracy of ± 2%. Isotopic purity is based on mass distribution observed. The contents of the specifications are subject to change without advance notice, and the specification values displayed here are the most up to date values.

4. Signatures

Reviewed By	Reviewed By	C of A Approved By	Test Date	Retest Date
Swathi Reddy	Toni Rantanen	Chanell Chu	7/26/2021	7/24/2025

R. Lewis