

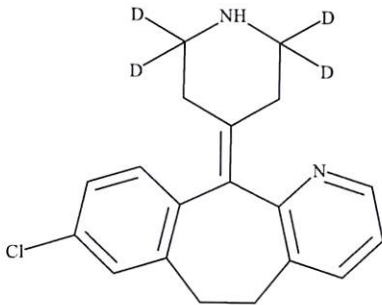
Certificate of Analysis

Certificate No.: **20260609020**



Date: June 9, 2026

Retest date: June 2, 2029

Compound Name: Loratadine EP Impurity D-d ₄ (Loratadine USP Related Compound A-d ₄ , Rupatadine EP Impurity B-d ₄ , Desloratadine-d ₄)	
Synonyms:	8-chloro-11-(piperidin-4-ylidene-2,2,6,6-d ₄)-6,11-dihydro-5H-benzo[5,6]cyclohepta[1,2-b]pyridine
TLC Catalogue Number:	L-10100
CAS Number:	381727-29-3
Alternate CAS Number:	100643-71-8 (non-labelled)
Molecular Weight:	314.85
Molecular Formula:	C ₁₉ H ₁₅ D ₄ ClN ₂
Source:	TLC Pharmaceutical Standards
Source Lot No.:	7295-059A3
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO, Acidic solution, Acetonitrile



Test Description	Specifications	Results
Visual Description	Off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.6%
Impurity (HPLC)	N/A	
Isotopic Enrichment	Not less than 98.0%	99.4%
Water Content (KF)	N/A	0.4%
Residual Solvents (NMR)	0.4% isopropyl ether	
Assay (%)	Not less than 90.0%	98.8%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		06/09/2026
Approved by:	Quality Assurance		06/09/2026

Attachments: Peak Attribution Table, Assay Calculation, HPLC, IR, MS and NMR spectra.