

CERTIFICATE OF ANALYSIS

(Certificate No. KML095023-01)

Release Date: 19/08/2025

Re-test Date: 18/08/2028

Loratadine Impurity D

Identification

Chemical Name :

8-Chloro-11-(piperidin-4-ylidene)-6,11-dihydro-5H-benzo[5,6]cyclohepta[1,2-b]pyridine (as per EP)

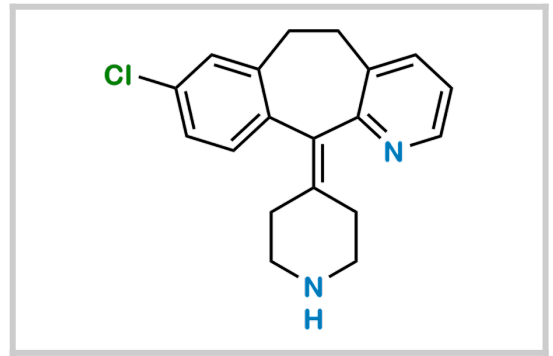
Alt. Name : Desloratadine ; Loratadine USP
Related Compound A

CAT No. : KML095023

CAS No. : 100643-71-8

Molecular Formula : C₁₉H₁₉ClN₂

Molecular Weight : 310.8



Analytical Information

Batch No. : L095023-102-221

Description : Off White Solid

HPLC Purity : 99.80 %

Weight Loss By TGA : 0.45 %

% Potency : 99.35 %

Solubility : ACN : Water (1:1)

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 0.45(Weight Loss By TGA)] x [99.80(HPLC Purity)]/100 = 99.35 %

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		25/08/2025
Reviewed & Approved By	Quality Control	Jatin Patel		25/08/2025

Attachments : COA, HPLC, MASS, ¹H NMR, IR and TGA