

CERTIFICATE OF ANALYSIS

(Certificate No. SZ-L002004-2357-2)

Analysis Date: 12/08/2019

Re-test Date: 28/07/2021

Loratadine EP Impurity C

Identification

Chemical Name : Ethyl 4-(4,8-dichloro-5,6-dihydro-1H-benzo[5,6]cyclohepta[1,2-b]pyridin-11-ylidene)piperidine-1-carboxylate

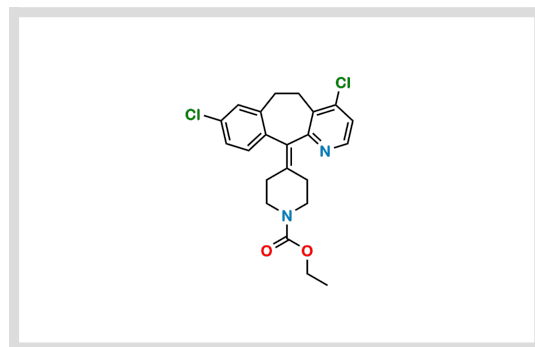
CAT No. : SZ-L002004

CAS No. : 165739-83-3

Molecular Formula : C₂₂H₂₂Cl₂N₂O₂

Molecular Weight : 417.3

Synonyms : Loratadine USP Related Compound G ; 4-Chloro Loratadine



Analytical Information

Batch Code : SRL-147-74-B

HPLC Purity : 98.72 %

Solubility : CN:Water(8:2)

Mass : Confirm

Appearance of product : Off White Solid

IR Analysis : Confirm

Long Term Storage : 2-8 °C for long term storage

¹H NMR : Confirm

Weight Loss By TGA : 0.51 %

Additional Information

% Potency = [100 - 0.51 (Wt loss by TGA)] X [98.72 (HPLC Purity)] / 100 = 98.22 %

Recommendation : Released



	Department	Signature	Date
Prepared by	Quality Assurance		
Checked by	Quality Assurance		
Approved By	Quality Assurance		

Attachments : HPLC, Mass, NMR, IR, TGA