

Certificate of Analysis

Product name: Loratadinum
Batch number / Weight: 21E19-B04-215585 / 5 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	Conform	Conform		
Appearance of solution	Clear <=BY5	Conform		
Impurity H	Conform	Conform		
Related substances	Conform	Conform		
Impurity F	<=0,2	<0,05	%	
Impurity A	<=0,1	<0,05	%	
Impurity B	<=0,1	<0,05	%	
Impurity C	<=0,1	<0,05	%	
Impurity D	<=0,1	<0,05	%	
Impurity E	<=0,1	<0,05	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=0,5	0,05	%	
Sulphates	<=150	Conform	ppm	
Loss on drying	<=0,5	0,05	%	
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Loratadine	98,5 - 101,5	100,4	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

09-12-2021

Expiration: 31-01-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.