

Certificate of Analysis

Product name: **Loratadinum**

Batch number / Weight: **21K09-B04-218696 / 5 G**

Analysed according to: **Ph.Eur.10**

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	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Loratadine	98,5 - 101,5	99,5	%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

29-04-2022

Expiration: 31-05-2026

Conclusion: APPROVED

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