

Certificate of Analysis

Product name: Loratadinum
Batch number / Weight: 23I27-B03-235702 / 5 G
Analysed according to: Ph.Eur.11.2
Number of analysis / Inspection Code 23I27-B03 / INS-23-8718
Reference Code / No.: V01498 / BLRDE/2307055

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	Conform	Conform		
Appearance of solution	Clear <=BY5	Conform		
Impurity H	Conform	<0,1	%	
Related substances	Conform	Conform		
Impurity F	<=0,2	0,00	%	
Impurity A	<=0,1	0,00	%	
Impurity B	<=0,1	<0,05	%	
Impurity C	<=0,1	0,00	%	
Impurity D	<=0,1	0,00	%	
Impurity E	<=0,1	0,00	%	
Unspecified impurities	<=0,10	0,052	%	
Total impurities	<=0,5	0,05	%	
Sulphates	<=150	<150	ppm	
Loss on drying	<=0,5	0,02	%	
Sulphated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Loratadine	98,5 - 101,5	99,79	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:
Ewelina Gadzinowska
Qualified Person

10-01-2024

Expiration: 30-06-2028

Conclusion: APPROVED

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