Certificate of Analysis

Product name: **Loratadinum**

Batch number / Weight: **22D29-B04-222983 / 5 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22D29-B04 / INS-22-7834**

Reference Code / No.: **V01498 / BLRDE/2111020**

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	<0,05	%	
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	<150	ppm	
Loss on drying	<=0,5	0,11	%	
Sulphated ash	<=0,1	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Loratadine	98,5 - 101,5	99,9	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Di-isopropyl ether	<=500	44	ppm	
Toluene	<=500	<12,5	ppm	
Triethylamine	<=50	<10	ppm	
Tetrahydrofurane		<25	ppm	

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Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

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 EL Spol

Release:
Ewelina Gadzinowska
Qualified Person

13-10-2022

Expiration: 31-10-2026

Conclusion: APPROVED

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Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl