

Certificate of Analysis

Product name: **Cetirizini dihydrochloridum**

Batch number / Weight: **22J05-B02-222993 / 10 G**

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

Number of analysis / Inspection Code **22J05-B02 / INS-22-8528**

Reference Code / No.: **V01858 / BT00-22001**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	Clear / colour ≤BY7	Conform		
pH	1,2 - 1,8	1,48		
Related substances	Conform	Conform		
Impurity A	≤0,15	<0,05	%	
Impurity B	≤0,15	<0,05	%	
Impurity C	≤0,15	<0,05	%	
Impurity D	≤0,15	<0,05	%	
Impurity E	≤0,15	<0,05	%	
Impurity F	≤0,15	<0,05	%	
Unspecified impurities	≤0,10	0,09	%	
Total impurities	≤0,3	0,09	%	
Loss on drying	≤0,5	0,03	%	
Sulphated ash	≤0,2	0,10	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Cetirizine dihydrochloride	99,0 - 101,0	100,2	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	≤ 3000	<25	ppm	
Acetone	≤ 5000	1665	ppm	
Methylene chloride	≤ 600	<25	ppm	
Ethyl acetate	≤ 5000	<25	ppm	
Chloroform	≤ 60	<25	ppm	
Toluene	≤ 890	<25	ppm	

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Dimethylformamide	<880	<25	ppm
Benzene	<= 2	<2	ppm

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:

Agnieszka Pszczółka

Qualified Person

08-11-2022

Expiration: 03-04-2027

Conclusion: APPROVED

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