

Certificate of Analysis

Product name: **Cetirizini dihydrochloridum**

Batch number / Weight: **21J05-B02-215695 / 50 G**

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

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	1,33		
Related substances	Conform	Conform		
Impurity A	≤0,15	0,00	%	
Impurity B	≤0,15	<0,05	%	
Impurity C	≤0,15	0,077	%	
Impurity D	≤0,15	0,00	%	
Impurity E	≤0,15	<0,05	%	
Impurity F	≤0,15	0,00	%	
Unspecified impurities	≤0,10	0,097	%	
Total impurities	≤0,3	0,17	%	
Loss on drying	≤0,5	0,04	%	
Sulphated ash	≤0,2	0,03	%	
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	99,99	%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

18-05-2022

Expiration: 25-08-2026

Conclusion: APPROVED

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