

Certificate of Analysis

Product name: **Histamini dihydrochloridum**

Batch number / Weight: **23D04-B02-229330 / 5 G**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **23D04-B02 / INS-23-3307**

Reference Code / No.: **V02110 / 002072022**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals, hygroscopic	Conform		
Identification A	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	Clear / $\leq Y7$	Conform		
pH	2,85 - 3,60	3,42		
Histidine	Conform	Conform	%	
Sulphates	$\leq 0,1$	$<0,1$	%	
Loss on drying	$\leq 0,5$	0,17	%	
Sulphated ash	$\leq 0,1$	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Histamine dihydrochloride	98,5 - 101,0	100,63	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
2-Propanol	$\leq 0,5\%$ (LOD)	Conform		

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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:
Dominika Soltysik
Qualified Person

13-06-2023

Expiration: 31-07-2027

Conclusion: APPROVED

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