

Certificate of Analysis

Product name: **Histamini dihydrochloridum**
Batch number / Weight: **21J01-B02-213531 / 5 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder, hygroscopic !	Conform		
Identification A	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	Clear / <= Y7	Conform		
pH	2,85 - 3,60	3,41		
Histidine	Conform	Conform	%	
Sulphates	<= 0,1	<0,1	%	
Loss on drying	<= 0,5	0,2	%	
Sulphated ash	<= 0,1	0,05	%	
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	100,23	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

11-03-2022

Expiration: 31-08-2024

Conclusion: APPROVED

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