

## Certificate of Analysis

**Product name:** **Histamini dihydrochloridum**

**Batch number / Weight:** **22C03-B07-218258 / 5 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	hygroscopic ! (Almost) white, crystalline powder,	Conform		
Identification A	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	Clear / <= Y7	Conform		
pH	2,85 - 3,60	3,06		
Histidine	Conform	Conform	%	
Sulphates	<= 0,1	<0,1	%	
Loss on drying	<= 0,5	0,25	%	
Sulphated ash	<= 0,1	0,03	%	
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	99,2	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
2-Propanol		<25	ppm	
Acetone	not more than 3000 ppm	229	ppm	
Methanol		103	ppm	

Analysis performed by the authorized lab.

Release:  
Ewelina Gadzinowska  
Qualified Person

21-07-2022

Expiration: 31-01-2026

Conclusion: APPROVED

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