

Certificate of Analysis

Product name: **Amiloridi hydrochloridum dihyd**
Batch number / Weight: **21J26-B19-216092 / 5 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	pale yellow or greenish-yellow powder	Conform		
Identification A	Conform	Conform		
Identification C	Conform	Conform		
Identification D	11,0 - 13,0 %	Conform		
Free acid	Conform	Conform		
Related substances	acc. to Ph. Eur.	Conform		
Impurity C	<= 0,2	0,07	%	
Unspecified impurities	<=0,10	0,10	%	
Total impurities	<= 0,4	0,23	%	
Water (Karl Fischer)	11,0 - 13,0	12,09	%	
Sulphated ash	<=0,1	0,05	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	98,0 - 101,0	100,08	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

19-05-2022

Expiration: 28-02-2026

Conclusion: APPROVED

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