Certificate of Analysis

Product name: **Amiloridi hydrochloridum dihyd**

Batch number / Weight: **22K26-B15-224543 / 5 G**

Analysed according to: **Ph.Eur.10.8**

Number of analysis / Inspection Code **22K26-B15 / INS-22-9857**

Reference Code / No.: **V01535 / 2001012203012**

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	0,00	ml	
Related substances	acc. to Ph. Eur.	Conform		
Impurity C	<= 0,2	<0,05	%	
Unspecified impurities	<=0,10	0,098	%	
Total impurities	<= 0,4	0,15	%	
Water (Karl Fischer)	11,0 - 13,0	12,20	%	
Sulphated ash	<=0,1	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	98,0 - 101,0	99,36	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents				
Methanol	<= 3000	<3000	ppm	
Acetonitrile	<= 410	<410	ppm	
Dimethylformamide	<= 880	<880	ppm	

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Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

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:
Agnieszka Pszczółka
Qualified Person

21-12-2022

Expiration: 28-02-2027

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl