

Certificate of Analysis

Product name: **Aminopyridinum (4-)**
Batch number / Weight: **22K17-B03-228624 / 1 G**
Analysed according to: **Monograph**

Number of analysis / Inspection Code **22K17-B03 / INS-22-10308**

Reference Code / No.: **V01521 / 33-22-I-19P4870**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or pale brown, crystalline powder	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear / <=BY5	Conform		
Related substances	Conform	Conform		
4-Cyanopyridine (=A)	<=0,1	<0,01	%	
Isonicotinamide (=B)	<=0,1	<0,01	%	
Any unknown impurities	<=0,10	0,07	%	
Total impurities	<=0,5	0,09	%	
Water (Karl Fischer)	<=0,5	0,31	%	
Sulphated ash	<=0,1	0,05	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Aminopyridine 4-	99,0 - 101,0	99,8	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents				
Methanol	<= 3000 ppm	<25	ppm	
Ethyl acetate	<= 5000 ppm	<25	ppm	

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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 EL Spol

Release:
Dominika Soltysik
Qualified Person

14-04-2023

Expiration: 20-09-2025

Conclusion: APPROVED

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