

Certificate of Analysis

Product name: **Aminopyridinum (4-)**
Batch number / Weight: **22I21-B07-223821 / 10 G**
Analysed according to: **Monograph**
Number of analysis / Inspection Code **22I21-B07 / INS-22-8018**
Reference Code / No.: **V01682 / 0000353033**

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	0,01	%	
Total impurities	<=0,5	0,01	%	
Water (Karl Fischer)	<=0,5	0,08	%	
Sulphated ash	<=0,1	0,06	%	
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				
Isobutyl alcohol	<= 5000 ppm	<5000	ppm	
Methyl isobutyl ketone	<= 4500 ppm	<4500	ppm	
Acetone	<= 5000 ppm	<5000	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:
Ewelina Gadzinowska
Qualified Person

24-10-2022

Expiration: 01-03-2027

Conclusion: APPROVED

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