

Certificate of Analysis

Product name: **Isoniazidum**
Batch number / Weight: **22C03-B06-221619 / 100 G**
Analysed according to: **Ph. Eur. 10.8**
Number of analysis / Inspection Code **22C03-B06 / INS-22-5029**
Reference Code / No.: **V01780 / 21303/INH**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification A	170 - 174	172	°C	
Identification B	Conform	Conform		
Appearance of solution	Clear / <BY7	Conform		
pH	6,0 - 8,0	7,35		
Impurity E	<=15	14,7	ppm	
Related substances	Conform	Conform		
Impurity A	<=0,15	<0,05	%	
Impurity B	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total	<=0,5	<0,05	%	
Loss on drying	<=0,5	0,03	%	
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 Isoniazide	99,0 - 101,0	99,2	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<=3000	<25	ppm	
Benzene	<=2	<2	ppm	
Pyridine	<=200	<45	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

24-08-2022

Expiration: 16-10-2026

Conclusion: APPROVED

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