

Certificate of Analysis

Product name: **Isoniazidum**

Batch number / Weight: **21G27-B11-213395 / 100 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification A	170 - 174	171	°C	
Identification B	Conform	Conform		
Appearance of solution	Clear / <BY7	Conform		
pH	6,0 - 8,0	7,51		
Impurity E	<=15	9	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	<0,15	%	
Loss on drying	<=0,5	0,10	%	
Sulphated ash	<=0,1	0,05	%	
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	100,8	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Ethanol	not more than 2000 ppm	229	ppm	
Benzene	<=2	1,2	ppm	
Pyridine	<=200	<10	ppm	

Analysis performed by the authorized lab.

Release:
Dominika Soltysik
Qualified Person

21-12-2021

Expiration: 31-12-2025

Conclusion: APPROVED

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