

Certificate of Analysis

Productname: Isoniazidum
Number of analysis/Inspection Code: 1 / KEUR-182960B
Batchnumber: 19L24-F02-370170
Reference code / No.: 4111 / 19420/INH
Analysed according to: PH.EUR10.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder or colourless crystals	Conform		
Identification A	170 - 174	172	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / <BY7	Conform		5% m/V
pH	6,0 - 8,0	6,8		5%m/V
Impurity E	<=15	8	ppm	HPLC
Related substances	Conform	Conform		HPLC
Impurity A, B	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	0,0	%	
Loss on drying	<=0,5	0,1	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Isoniazide	99,0 - 101,0	100,8	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

05/27/20

Expiration: 11-2024

Conclusion: APPROVED

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