

Certificate of Analysis

Product name: **Hydralazini hydrochloridum**

Batch number / Weight: **21J07-B01-217418 / 5 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Identification B	Conform	Conform		
Identification E	White	Conform	%	
Appearance of solution	Clear ≤GY6	Conform		
pH	3,5 - 4,2	3,80		
Hydrazine	≤10	Conform	ppm	
Related substances	Conform	Conform		
Any impurity	≤0,2	0,09	%	
Loss on drying	≤0,5	0,37	%	
Sulphated ash	≤0,1	0,07	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Hydralazine hydrochloride	98,5 - 101,0	100,60	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

19-03-2022

Expiration: 30-06-2026

Conclusion: APPROVED

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