

Certificate of Analysis

Product name: Hydralazini hydrochloridum
Batch number / Weight: 21J07-B01-213739 / 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:
Ewelina Gadzinowska
Qualified Person

29-10-2021

Expiration: 30-06-2026

Conclusion: APPROVED

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