

Certificate of Analysis

Product name: **Hydralazini hydrochloridum**

Batch number / Weight: **22H25-B04-223815 / 5 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22H25-B04 / INS-22-8042**

Reference Code / No.: **V01726 / HH21060109**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Identification B	Conform	Conform		
Identification E	White	Conform		
Melting point	About 275	272,8	°C	
Appearance of solution	Clear ≤GY6	Conform		
pH	3,5 - 4,2	3,81		
Hydrazine	≤10	Conform	ppm	
Related substances	Conform	Conform		
Any impurity	≤0,2	0,08	%	
Loss on drying	≤0,5	0,18	%	
Sulphated ash	≤0,1	0,06	%	
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	98,82	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Ethanol	<5000	<5000	ppm	
Tetrahydrofurane	<720	<720	ppm	
Propan-2-ol	<5000	0,0	ppm	
Cyclohexane	<3880	<3880	ppm	
Toluene	<890	<890	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 FAGRON PL lab

Release:
Ewelina Gadzinowska
Qualified Person

28-10-2022

Expiration: 31-05-2026

Conclusion: APPROVED

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