

Certificate of Analysis

Productname: Hydralazini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-187341B
Batchnumber: 20I02-F04-375165
Reference code / No.: 4386 / HH20060120
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification E	White	Conform		Chloride
Appearance of solution	Clear <=GY6	Conform		0.4% m/V
pH	3,5 - 4,2	3,8		2%m/V
Hydrazine	<=10	Conform	ppm	TLC
Related substances	Conform	Conform		HPLC
Any impurity	<=0,2	0,1	%	
Loss on drying	<=0,5	0,3	%	In vacuo
Sulphated ash	<=0,1	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Hydralazine hydrochloride	98,5 - 101,0	99,4	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP beschikbaar	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

11/26/20

Expiration: 05-2025

Conclusion: APPROVED

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