

## Certificate of Analysis

**Productname:** Hydralazini hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-183793B  
**Batchnumber:** 20F04-F06-371385  
**Reference code / No.:** 4386 / HH18110165  
**Analysed according to:** PH.EUR10.1

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	<0,05	%	
Loss on drying	<=0,5	0,2	%	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	100,1	%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

06/29/20

Expiration: 10-2023

Conclusion: APPROVED

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