

Certificate of Analysis

Product name: **Hydralazini hydrochloridum**

Batch number / Weight: **20I02-F03-217188 / 10 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 | 3,8 | | |
| Hydrazine | ≤10 | Conform | ppm | |
| Related substances | Conform | Conform | | |
| Any impurity | ≤0,2 | 0,1 | % | |
| Loss on drying | ≤0,5 | 0,3 | % | |
| Sulphated ash | ≤0,1 | 0,1 | % | |
| 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 | 99,4 | %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

14-01-2022

Expiration: 31-05-2025

Conclusion: APPROVED

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