

Certificate of Analysis

Product name: **Hydralazini hydrochloridum**

Batch number / Weight: **22H25-B04-225089 / 25 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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