

## Certificate of Analysis

**Product name:** **Hydralazini hydrochloridum**

**Batch number / Weight:** **21J07-B01-215521 / 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                                    | 3,80    |      |                 |
| Hydrazine                       | <=10   | Conform | ppm  |                 |
| Related substances              | Conform                                      | Conform |      |                 |
| Any impurity                    | <=0,2  | 0,09    | %    |                 |
| Loss on drying                  | <=0,5  | 0,37    | %    |                 |
| Sulphated ash                   | <=0,1  | 0,07    | %    |                 |
| 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                                 | 100,60  | %m/m |                 |
| TSE/BSE-statement:              | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |

Analysis performed by the authorized lab.

Release:  
Agnieszka Pszczółka  
Qualified Person

22-12-2021

Expiration: 30-06-2026

Conclusion: APPROVED

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