

Certificate of Analysis

Product name: **Promethazini hydrochloridum**
Batch number / Weight: **21E13-B02-215561 / 10 G**
Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------------|--|---------|------|-----------------|
| Appearance | White or faintly yellowish, crystalline powder | Conform | | |
| Melting point | about 222 | 222,8 | °C | |
| Identification A | Conform | Conform | | |
| Identification D | Conform | Conform | | |
| pH | 4,0 - 5,0 | 4,5 | | |
| Related substances | Conform | Conform | | |
| Impurity B | <=0,8 | 0,24 | % | |
| Impurity C | <=0,2 | 0,08 | % | |
| Impurity A | <=0,1 | <0,05 | % | |
| Impurity D | <=0,1 | <0,05 | % | |
| Unspecified impurities | <=0,10 | <0,05 | % | |
| Total impurities | <=1,2 | 0,32 | % | |
| Loss on drying | <=0,5 | 0,04 | % | |
| Sulphated ash | <=0,1 | 0,04 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Promethazine hydrochlori | 99,0 - 101,0 (dried substance) | 99,7 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

25-01-2022

Expiration: 31-01-2026

Conclusion: APPROVED

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