

Certificate of Analysis

Product name: Promethazini hydrochloridum
Batch number / Weight: 20B17-B06-197572 / 10 G
Analysed according to: Ph. Eur.

| Tests | Requirement | Result | Unit | Standard remark |
|--------------------------------|--|---------|------|-----------------|
| Appearance | White or faintly yellowish, crystalline powder | Conform | | |
| Identification | Conform | Conform | °C | |
| Melting point | about 222 | 223 | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | |
| Identification D | Conform | Conform | | |
| pH | 4,0 - 5,0 | 4,23 | | |
| Related substances | Conform | Conform | | |
| Impurity B | <=0,8 | 0,33 | % | |
| Impurity C | <=0,2 | 0,12 | % | |
| Impurity A | <=0,1 | <0,05 | % | |
| Impurity D | <=0,1 | 0,00 | % | |
| Unspecified impurities | <=0,10 | 0,05 | % | |
| Total impurities | <=1,2 | 0,50 | % | |
| Loss on drying | <=0,5 | 0,20 | % | |
| Sulphated ash | <=0,1 | 0,01 | % | |
| 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 | 100,62 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:
Dorota Sutkowska
Qualified Person

31-03-2020

Expiration: 31-10-2024

Conclusion: APPROVED

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