

Certificate of Analysis

Product name: **Mebeverini hydrochloridum**
Batch number / Weight: **20L22-B01-203350 / 25 G**
Analysed according to: **BP**

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance | (Almost) white, crystalline powder | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | White | Conform | | |
| pH | 4,5 – 6,5 | 5,46 | | |
| Related substances | Conform | Conform | | |
| Impurity J | <=0,2 | 0,00 | % | |
| Unspecified impurities | <=0,10 | 0,06 | % | |
| Total impurities | <=0,3 | 0,06 | % | |
| Loss on drying | <=0,5 | 0,08 | % | |
| 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 | 99,0 - 101,0 | 99,8 | %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

16-02-2021

Expiration: 30-06-2024

Conclusion: APPROVED

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