

## Certificate of Analysis

**Product name:** **Metformini hydrochloridum**  
**Batch number / Weight:** **21G23-B01-215554 / 500 G**  
**Analysed according to:** **Ph. Eur.**

| Tests                          | Requirement                                  | Result    | Unit | Standard remark |
|--------------------------------|--|-----------|------|-----------------|
| Appearance                     | White, crystalline powder or white crystals  | Conform   |      |                 |
| Identification B               | Conform                                      | Conform   |      |                 |
| Identification E               | Conform                                      | Conform   |      |                 |
| Appearance of solution         | Clear / colourless                           | Conform   |      |                 |
| Impurity F                     | $\leq 0,05$                                  | $< 0,005$ | %    |                 |
| Related substances             | Conform                                      | Conform   |      |                 |
| Impurity A                     | $\leq 0,02$                                  | 0,001     | %    |                 |
| Unspecified impurities         | $\leq 0,05$                                  | $< 0,03$  | %    |                 |
| Total impurities               | $\leq 0,2$                                   | 0,00      | %    |                 |
| Loss on drying                 | $\leq 0,5$                                   | 0,05      | %    |                 |
| Sulphated ash                  | $\leq 0,1$                                   | 0,05      | %    |                 |
| Metallic residues              | CHMP/ICH/353369/2013                         | Conform   |      | Data producer   |
| Residual solvents              | CPMP/ICH/82 260/06                           | Conform   |      | Data producer   |
| Assay Metformine hydrochloride | 98,5 - 101,0                                 | 100,03    | %m/m |                 |
| TSE/BSE-statement:             | No contamination with TSE/BSE-risk materials | Conform   |      | Data producer   |

Analysis performed by the authorized lab.

Release:

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Qualified Person

29-11-2021

Expiration: 28-02-2026

Conclusion: APPROVED

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