

## Certificate of Analysis

**Product name:** **Lidocaini hydrochloridum x1H2O**

**Batch number / Weight:** **21C05-B05-211209 / 5 G**

**Analysed according to:** **Ph. Eur.**

| Tests                         | Requirement                                  | Result  | Unit | Standard remark |
|-------------------------------|--|---------|------|-----------------|
| Appearance                    | (Almost) white, crystalline powder           | Conform |      |                 |
| Identification B              | Conform                                      | Conform |      |                 |
| Identification D              | White  | Conform |      |                 |
| Appearance of solution        | Clear and colourless                         | Conform |      |                 |
| pH                            | 4,0 - 5,5                                    | 5,01    |      |                 |
| Related substances            | Conform                                      | Conform |      |                 |
| Impurity A                    | <=0,01                                       | <0,005  | %    |                 |
| Unspecified impurities        | <=0,10                                       | <0,05   | %    |                 |
| Total impurities              | <=0,5  | <0,05   | %    |                 |
| Water (Karl Fischer)          | 5,5 - 7,0                                    | 6,3     | %    |                 |
| Sulphated ash                 | <= 0,1                                       | <0,01   | %    |                 |
| Metallic residues             | CHMP/ICH/353369/2013                         | Conform |      |                 |
| Residual solvents             | CPMP/ICH/82 260/06                           | Conform |      |                 |
| Assay Lidocaine hydrochloride | 99,0 - 101,0 (anhydrous substance)           | 100,5   | %m/m |                 |
| TSE/BSE-statement:            | No contamination with TSE/BSE-risk materials | Conform |      |                 |

Analysis performed by the authorized lab.

Release:  
Agnieszka Pszczółka  
Qualified Person

19-05-2021

Expiration: 31-10-2025

Conclusion: APPROVED

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