

## Certificate of Analysis

**Product name:** **Haloperidolum**

**Batch number / Weight:** **22C03-B02-226294 / 1 G**

**Analysed according to:** **Ph. Eur. 10.8**

**Number of analysis / Inspection Code** **22C03-B02 / INS-22-3457**

**Reference Code / No.:** **V01877 / 03538400821**

| Tests                  | Requirement                                  | Result  | Unit | Standard remark |
|------------------------|--|---------|------|-----------------|
| Appearance             | (Almost) white powder                        | Conform |      |                 |
| Identification B       | Conform                                      | Conform |      |                 |
| Identification E       | White  | Conform | %    |                 |
| Appearance of solution | Clear ≤Y7                                    | Conform |      |                 |
| Related substances     | Conform                                      | Conform |      |                 |
| Impurity B             | ≤0,3   | 0,13    | %    |                 |
| Impurity D             | ≤0,5   | <0,05   | %    |                 |
| Impurity G             | ≤0,15  | 0,00    | %    |                 |
| Impurity H             | ≤0,15  | 0,00    | %    |                 |
| Unspecified impurities | ≤0,10  | <0,05   | %    |                 |
| Total impurities       | ≤1,0   | 0,13    | %    |                 |
| Loss on drying         | ≤0,5   | 0,02    | %    |                 |
| 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 Haloperidol      | 99,0 - 101,0                                 | 99,66   | %m/m |                 |
| TSE/BSE-statement:     | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |
| Residual solvents      |  | Conform |      |                 |
| Acetone                | <5000 ppm                                    | <5000   | ppm  |                 |

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:  
Ewelina Gadzinowska  
Qualified Person

22-12-2022

Expiration: 31-05-2026

Conclusion: APPROVED

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