# Certificate of Analysis

**Product name:** **Domperidonum**

**Batch number / Weight:** **23G13-B14-227824 / 5 G**

**Analysed according to:** **Ph.Eur.11.2**

**Number of analysis / Inspection Code** **23G13-B14 / INS-23-6002**

**Reference Code / No.:** **V02332 / DMP-10323**

| Tests | Requirement | Result | Unit | Standard remark |
|---|---|---|---|---|
| Appearance | (Almost) white powder | Conform | | |
| Identification | Conform | Conform | | |
| Appearance of solution | Clear <=Y6 | Conform | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,2 | 0,11 | % | |
| Sum of impurities D and E | <=0,25 | 0,154 | % | |
| Unspecified impurities | for each <=0,10 | <0,05 | % | |
| Total impurities | <=0,5 | 0,27 | % | |
| Loss on drying | <=0,5 | 0,15 | % | |
| Sulphated ash | <=0,1 | 0,06 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Assay | 99,0 - 101,0 | 99,65 | %m/m | |

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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

18-09-2023

Expiration: 30-04-2028

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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