

## Certificate of Analysis

**Productname:** Domperidonum  
**Number of analysis/Inspection Code:** 1 / KEUR-179390B  
**Batchnumber:** 18I19-B10-365871  
**Reference code / No.:** 4207 / 013DN18-19  
**Analysed according to:** PH.EUR 9.5

| Tests                  | Requirement                                  | Result  | Unit         | Standard remark                    |
|------------------------|----------------------------------------------|---------|--------------|------------------------------------|
| Appearance             | (Almost) white powder                        | Conform |              |                                    |
| Identification A       | 244 - 248                                    | 245     | °C           | Melting point                      |
| Identification B       | Conform                                      | Conform |              | IR-spectrum                        |
| Appearance of solution | Clear <=Y6                                   | Conform |              | 1% <i>m/V</i> in dimethylformamide |
| Related substances     | Conform                                      | Conform |              | HPLC                               |
| Impurity A             | <=0,25                                       | <0,05   | %            |                                    |
| Impurity B             | <=0,25                                       | <0,05   | %            |                                    |
| Impurity C             | <=0,25                                       | <0,05   | %            |                                    |
| Impurity D             | <=0,25                                       | 0,14    | %            |                                    |
| Impurity E             | <=0,25                                       | <0,05   | %            |                                    |
| Impurity F             | <=0,25                                       | <0,05   | %            |                                    |
| Unspecified impurities | <=0,10                                       | <0,05   | %            |                                    |
| Total impurities       | <=0,5                                        | <0,5    | %            |                                    |
| Loss on drying         | <=0,5                                        | 0,1     | %            | 105°C                              |
| Sulphated ash          | <=0,1                                        | Conform | %            |                                    |
| Metallic residues      | CHMP/ICH/353369/2013                         | Conform |              | Data producer                      |
| Residual solvents      | CHMP/ICH/82260/2006                          | Conform |              | Data producer                      |
| Assay Domperidon       | 99,0 - 101,0                                 | 100,8   | % <i>m/m</i> | Dried                              |
| TSE/BSE-statement:     | No contamination with TSE/BSE-risk materials | Conform |              | Data producer                      |

Analysis performed by the authorized laboratory Eurofins.

Release:  
dr. M.J. Vincenten - van Maanen  
Pharmacist - Qualified Person

01/08/20

Expiration: 06-2023

Conclusion: APPROVED

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