

Certificate of Analysis

Productname: **Prasteronum**
Number of analysis/Inspection Code: 1 / KEUR-193467B
Batchnumber: **21K30-F03-380900**
Reference code / No.: 4509 / DHEAH210602W
Analysed according to: **PH.FR.2017**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------|--|---------|--------------|---|
| Appearance | (Yellow-)white, crystalline powder | Conform | | |
| Identification B | Conform | Conform | | IR-spectrum |
| Spezifische Drehung | +11,0 - +14,0 | +12,6 | | 2% <i>m/V</i> in EtOH; water and solvent free |
| Related substances | Conform | Conform | | HPLC |
| Impurity A | <=0,1 | 0,0 | % | |
| Impurity B | <=0,1 | 0,0 | % | |
| Impurity D | <=0,1 | 0,0 | % | |
| Impurity E | <=0,1 | 0,0 | % | |
| Impurity C | <=0,02 | 0,00 | % | |
| Impurity F | <=0,08 | 0,00 | % | |
| Any other impurity | <=0,10 | <0,025 | % | |
| Total impurities | <=0,5 | 0,0 | % | |
| Hydroxylamine | <=5 | Conform | ppm | |
| Sulphated ash | <=0,1 | 0,1 | % | |
| Water | <=1,0 | 0,0 | % | Karl Fischer |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | |
| Assay Prasterone | 97,5 - 102,0 | 99,1 | % <i>m/m</i> | Anhydrous and solvent-free |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized laboratory Proxylabs.

Release:
 Anthony Amoureux
 Qualified Person

01/25/22

Expiration: 06-2023

Conclusion: APPROVED

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