

Certificate of Analysis

Productname: Estradiolum (17 alfa-)
Number of analysis/Inspection Code: 1 / KEUR-195344B
Batchnumber: 22A10-F02-381422
Reference code / No.: 1317 / 5122244
Analysed according to: DAC 2021/2

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------|--|---------|-----------------------|---------------------------------|
| Appearance | (Almost) white powder | Conform | | |
| Identification B | Conform | Conform | | IR-spectrum |
| Specific optical rotation | +51 - +56 | +55 | | 10% <i>m</i> /V EtOH 96%; dried |
| Related substances | Conform | Conform | | HPLC |
| Impurity A | <=0,2 | 0,1 | % | |
| Impurity B | <=0,15 | n.d. | % | |
| Impurity C | <=0,2 | n.d. | % | |
| Impurity D | <=0,3 | 0,1 | % | |
| Any other impurity | <=0,10 | <0,05 | % | |
| Total impurities | <=1,0 | 0,2 | % | |
| Loss on drying | <=0,5 | 0,0 | % | 105°C |
| Sulphated ash | <=0,1 | 0,0 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | |
| Assay 17-alfa-Estradiol | 97,0 - 102,0 | 100,2 | % <i>m</i> / <i>m</i> | Dried |
| 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

08/10/22

Expiration: 10-2024

Conclusion: APPROVED

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