

## Certificate of Analysis

**Product name:** Estriolum  
**Batch number / Weight:** 25L03-B04-017965 / 5 g  
**Producer / Producer Batch Number:** Qinhuangdao Zizhu Pharmaceutical Co., Ltd. / 818008802506002  
**Analyzed according to:** Ph.Eur.12.1  
**Number of Analysis / Certificate no.:** 25L03-B04 / QO0026076

|                           | Requirement                                      | Result  | Unit  | Standard remark |
|---------------------------|--------------------------------------------------|---------|-------|-----------------|
| Appearance                | (Almost) white, crystalline powder               | Conform |       |                 |
| Identification            | A,B                                              | Conform |       |                 |
| Specific optical rotation | (+60) - (+65)                                    | +62,0   |       |                 |
| Related substances        | Conform                                          | Conform |       |                 |
| Impurity A                | <=0,2                                            | < 0,05  | %     |                 |
| Impurity D                | <=0,2                                            | 0,06    | %     |                 |
| Impurity E                | <=0,3                                            | 0,05    | %     |                 |
| Impurity F                | <=0,5                                            | <0,05   | %     |                 |
| Unspecified impurities    | <=0,10                                           | <0,05   | %     |                 |
| Sum of impurities         | <=1,0                                            | 0,00    | %     |                 |
| Loss on drying            | <=0,5                                            | 0,12    | %     |                 |
| Metallic residues         | CHMP/ICH/353369/2013                             | Conform |       | DP              |
| Residual solvents         | CPMP/ICH/82 260/06                               | Conform |       | DP              |
| Assay                     | 97,5 - 102,0                                     | 99,22   | % m/m |                 |
| TSE/BSE-statement:        | EMA/410/01 guidance compliant – no contamination | Conform |       | DP              |

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 FSNE LAB

**Release:**

12-1-2026  
 Agnieszka Pszczółka  
 Qualified Person

**Expiration:** 18-6-2028

**Conclusion:** APPROVED

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