

## CERTIFICATE OF ANALYSIS

Product: **OESTROPHAN, soluție injectabilă, 0,25 mg/ml**

Batch No.: **645128A**

Expiry: **4.1.2024**

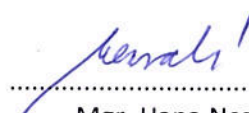
Date of production: **5.1.2021**

### Results of analysis:

| Tests                                   | Release limits                                                            | Shelf-life limits   | Results      |
|-----------------------------------------|---------------------------------------------------------------------------|---------------------|--------------|
| Appearance                              | Clear, almost colourless solution without visible particles.              |                     | conforms     |
| Injection solution capacity available   | min. 2 ml, min. 10 ml                                                     |                     | 2.1 ml       |
| Sterility                               | The preparation must be sterile.                                          |                     | sterile      |
| pH                                      | 5.5 – 6.5                                                                 |                     | 6.0          |
| Cloprostenol identity test              | Identical position of peaks in the sample and standard HPLC chromatograms |                     | conforms     |
| Cloprostenol active 15 S epimer content | 0.2375 – 0.2625 mg/ml                                                     | 0.225 – 0.275 mg/ml | 0.2403 mg/ml |
| Inactive 15-epimer content              | max. 3 %                                                                  |                     | 0.0 %        |
| 5,6-trans isomer content                | max. 4 %                                                                  |                     | 0.0 %        |
| Chlorcresol                             | 0.9 – 1.1. mg/ml                                                          |                     | 1.0 mg/ml    |

I certify that this product has been tested in the laboratories of Bioveta a.s. and has been found to meet specification requirements. Preparation is suitable with control regulations of the valid PN No. 301.



  
.....11/2/2021  
Mgr. Hana Nezvalová  
HEAD of QC, QP