

## CERTIFICATE OF ANALYSIS

Product: **OXYTOCIN BIOVETA, soluție injectabilă, 5 UI/ml**

Batch No.: **415230A**

Expiry: **01/2025**

Date of production: **16.2.2023**

### Results of analysis:

| Tests                                                         | Release limits                                        | Shelf-life limits | Results     |
|---------------------------------------------------------------|-------------------------------------------------------|-------------------|-------------|
| Appearance                                                    | Clear, colourless solution, without visible particles |                   | conforms    |
| Injection solution actual acidity                             | 3.6 – 4.0                                             | 3.2 – 4.3         | 4.0         |
| Injection solution volume                                     | min. 10 ml, min. 20 ml, min. 50 ml                    |                   | 51.0 ml     |
| Air-tightness                                                 | Hermetically closed vial.                             |                   | conforms    |
| Content of active substances and excipients                   |                                                       |                   |             |
| Oxytocin and chlorobutanol identity test                      | Conformity of RT peak of standard and sample          |                   | conforms    |
| Oxytocin content determination (HPLC method)                  | 4.75 – 5.25 IU/ml                                     | 4.5 – 5.5 IU/ml   | 4.847 IU/ml |
| Chlorobutanol hemihydrate content determination (HPLC method) | 3.8 – 4.2 mg/ml                                       | 3.6 – 4.4 mg/ml   | 4.01 mg/ml  |
| Microbiological tests                                         |                                                       |                   |             |
| Sterility test                                                | The product must be sterile.                          |                   | sterile     |

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. 333,V002.



*Nezvalová*  
.....28/03/2023  
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