

## CERTIFICATE OF ANALYSIS

Product: **TULATHROMYCIN Bioveta 100 mg/ml, soluție injectabilă**

Batch No.: **015232A**  
Expiry: **01/2027**  
Date of production: **24.2.2025**

### Results of analysis:

| Tests                                                                                                                     | Release limits                                                                                   | Shelf-life limits | Results                                |
|---------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-------------------|----------------------------------------|
| Appearance                                                                                                                | Clear (like water R), colourless to slightly yellow solution (NMT Y6) free of visible particles. |                   | complies                               |
| Extractable volume                                                                                                        | min. 50.0 ml; 100.0 ml                                                                           |                   | 50.50 ml                               |
| pH                                                                                                                        | 5.1 – 5.7                                                                                        |                   | 5.54                                   |
| Tulathromycin A identity test                                                                                             | Retention time and UV spectrum must comply.                                                      |                   | complies                               |
| Tulathromycin B identity test                                                                                             | Retention time and UV spectrum must comply.                                                      |                   | complies                               |
| Monothioglycerol identity test                                                                                            | Retention time and UV spectrum must comply.                                                      |                   | complies                               |
| Tulathromycin content<br>(Σ tulathromycin A and B)                                                                        | 95.0 – 105.0 mg/ml                                                                               |                   | 97.90 mg/ml                            |
| Tulathromycin B content<br>(% - referred to Σ tulathromycin A and B)                                                      | 8.0 – 13.0 %                                                                                     | 6.0 – 14.0 %      | 10.17 %                                |
| Monothioglycerol content                                                                                                  | 4.5 – 5.5 mg/ml                                                                                  | max. 5.5 mg/ml    | 5.41 mg/ml                             |
| Purity test<br>- impurity C<br>- impurity D<br>- impurity E<br>- any individual undefined impurity<br>- sum of impurities | max. 1.0 %<br>max. 1.0 %<br>max. 1.0 %<br>max. 1.0 %<br>max. 3.0 %                               |                   | 0.12 %<br>ND<br>ND<br><1.0 %<br>0.46 % |
| Sterility                                                                                                                 | The product must be sterile.                                                                     |                   | sterile                                |
| Airtightness                                                                                                              | Must comply.                                                                                     |                   | complies                               |

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. 563,V001.



Mgr. Hana Nezvalová  
HEAD of QC, QP