



## CERTIFICATE OF ANALYSIS

Product: OTIBIOVIN, soluție pentru aplicare topică

Batch No.: 895730A

Expiry: 06/2025

Date of production: 18.7.2023

## Results of analysis:

| Tests                                     | Release limits                                                                                                                                                                                                                            | Shelf-life limits     | Results      |
|-------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|--------------|
| Appearance                                | Colourless, faintly turbid solution, mildly opalescent. Faint turbidity can be observed, or sediment that disperses when being shaken can be formed, during storage. The turbidity mentioned does not affect efficacy of the preparation. |                       | conforms     |
| Content of original package               | min. 15 ml, min. 20 ml                                                                                                                                                                                                                    |                       | 21.0 ml      |
| pH value (Concentration of hydrogen ions) | 3 - 6                                                                                                                                                                                                                                     |                       | 4.3          |
| Microbiological harmlessness              | It shall comply with Ph. Eur., Article 5.1.4. - Category 2                                                                                                                                                                                |                       | conforms     |
| Triamcinolone content                     | 0.475 – 0.525 mg/ml                                                                                                                                                                                                                       | 0.45 – 0.525 mg/ml    | 0.507 mg/ml  |
| Triamcinolone identity                    | It shall be proved.                                                                                                                                                                                                                       |                       | conforms     |
| Gentamycin content                        | 1.9 – 2.1 mg/ml                                                                                                                                                                                                                           | 1.8 – 2.1 mg/ml       | 2.0 mg/ml    |
| Gentamycin identity                       | It shall be proved.                                                                                                                                                                                                                       |                       | conforms     |
| Salicylic acid content                    | 4.75 – 5.25 mg/ml                                                                                                                                                                                                                         | 4.5 – 5.25 mg/ml      | 5.002 mg/ml  |
| Salicylic acid identity                   | It shall be proved.                                                                                                                                                                                                                       |                       | conforms     |
| Carbethopendecinii bromidum content       | (0.118 - 0.131) mg/ml                                                                                                                                                                                                                     | (0.112 - 0.131) mg/ml | 0.1300 mg/ml |
| Carbethopendecinii bromidum identity      | It shall be proved.                                                                                                                                                                                                                       |                       | conforms     |

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. 340, V002.



*Handwritten signature*  
08/08/2023  
Mgr. Hana Nezvalová  
HEAD of QC, QP