

## CERTIFICATE OF ANALYSIS

Product: **SELIVERM 45 mg, soluție spot-on pentru pisici M**

Batch No.: **0725A01**

Expiry: **01/2027**

Date of production: **8.2.2025**

### Results of analysis:

| Tests                                              | Release limits                                                                                                                                                                                                                                                                                             | Shelf-life limits | Results                  |
|----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------------------|
| Appearance                                         | A clear, colourless to yellow solution or yellow-green. The solution is clear like water R. The yellow colour of the solution is not more intense than the colour of the reference solution Y1. The green-yellow colour of the solution is not more intense than the colour of the reference solution GY1. |                   | complies                 |
| Microbiological quality:                           |                                                                                                                                                                                                                                                                                                            |                   |                          |
| TAMC                                               | < 10 <sup>2</sup> (CFU/g or CFU/ml)                                                                                                                                                                                                                                                                        |                   | <10 CFU/ml               |
| TYMC                                               | < 10 <sup>1</sup> (CFU/g or CFU/ml)                                                                                                                                                                                                                                                                        |                   | <10 CFU/ml               |
| <i>Staphylococcus aureus</i>                       | absent (in 1 g or 1 ml)                                                                                                                                                                                                                                                                                    |                   | absent                   |
| <i>Pseudomonas aeruginosa</i>                      | absent (in 1 g or 1 ml)                                                                                                                                                                                                                                                                                    |                   | absent                   |
| Water content                                      | Max. 2.0 %                                                                                                                                                                                                                                                                                                 |                   | 0.13 %                   |
| Density                                            | 0.8050 – 0.8300 g/cm <sup>3</sup>                                                                                                                                                                                                                                                                          |                   | 0.8158 g/cm <sup>3</sup> |
| Refractive index                                   | 1.36 – 1.42                                                                                                                                                                                                                                                                                                |                   | 1.389                    |
| Selamectin identity test                           | RT and UV spectrum match with standard                                                                                                                                                                                                                                                                     |                   | complies                 |
| Selamectin assay                                   | 42.75 – 47.25 mg/tube                                                                                                                                                                                                                                                                                      |                   | 45.351 mg/tube           |
| Butylhydroxytoluene identity test                  | Rt and UV spectrum match with standard                                                                                                                                                                                                                                                                     |                   | complies                 |
| BHT assay                                          | 0.72 – 0.88 mg/ml                                                                                                                                                                                                                                                                                          | Max. 0.88 mg/ml   | 0.828 mg/ml              |
| Purity test                                        | Impurity A – max. 2.0 %                                                                                                                                                                                                                                                                                    |                   | 0.17 %                   |
|                                                    | Impurity B – max. 2.0 %                                                                                                                                                                                                                                                                                    |                   | 0.03 %                   |
|                                                    | Impurity C – max. 1.5 %                                                                                                                                                                                                                                                                                    |                   | 0.04 %                   |
|                                                    | Impurity D – max. 1.5 %                                                                                                                                                                                                                                                                                    |                   | 0.05 %                   |
|                                                    | Any individual undefined impurity - max. 1.0 %                                                                                                                                                                                                                                                             |                   | <1.0 %                   |
|                                                    | Sum of impurities – max. 4.0 %                                                                                                                                                                                                                                                                             |                   | 0.75 %                   |
| Uniformity of dosage units<br>(Weight variability) | Must comply.                                                                                                                                                                                                                                                                                               |                   | complies                 |
| Average extractable volume                         | 0.6750 - 0.8250 ml                                                                                                                                                                                                                                                                                         |                   | 0.7300 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. 555b,V001.



.....26/02/2025  
Mgr. Hana Nezvalová  
HEAD of QC, QP