

## CERTIFICATE OF ANALYSIS

Product: **OVIVERM 25 mg/ml, suspensie orală**

Batch No.: **385533A**

Expiry: **04/2028**

Date of production: **8.5.2026**

### Results of analysis:

| Tests                      | Release limits                                                                                                                                                                     | Shelf-life limits | Results                          |
|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------------------------|
| Appearance                 | White suspension.                                                                                                                                                                  |                   | conforms                         |
| Microbiological quality:   |                                                                                                                                                                                    |                   |                                  |
| TAMC                       | $< 10^2$ (CFU/g or CFU/ml)                                                                                                                                                         |                   | <10 CFU/g                        |
| TYMC                       | $< 10^1$ (CFU/g or CFU/ml)                                                                                                                                                         |                   | <10 CFU/g                        |
| <i>Escherichia coli</i>    | absent (in 1 g or 1 ml)                                                                                                                                                            |                   | absent                           |
| Density                    | 0.9850 – 1.0450 g/cm <sup>3</sup>                                                                                                                                                  |                   | 1.0139 g/cm <sup>3</sup>         |
| pH                         | 4.50 – 5.70                                                                                                                                                                        |                   | 5.10                             |
| Praziquantel identity      | Rt and UV spectrum match with standard                                                                                                                                             |                   | conforms                         |
| Praziquantel content       | 23.75 – 26.25 mg/ml                                                                                                                                                                |                   | 25.006 mg/ml                     |
| Sodium benzoate identity   | Rt and UV spectrum match with standard                                                                                                                                             |                   | conforms                         |
| Sodium benzoate content    | 1.80 – 2.20 mg/ml                                                                                                                                                                  |                   | 1.912 mg/ml                      |
| Sodium propionate identity | Rt and UV spectrum match with standard                                                                                                                                             |                   | conforms                         |
| Sodium propionate content  | 1.80 – 2.20 mg/ml                                                                                                                                                                  |                   | 1.967 mg/ml                      |
| Purity test                | Praziquantel impurities:<br>Impurity A – max. 0.5 %<br>Impurity B – max. 0.5 %<br>Any individual undefined impurity - max. 1.0 %<br>Sum of impurities – max. 1.5 %                 |                   | 0.04 %<br>0.00 %<br>ND<br>0.04 % |
| Particle size              | Min. 10% of particles ( $Dv_{10}$ ) $\leq 5 \mu\text{m}$<br>Min. 50% of particles ( $Dv_{50}$ ) $\leq 10 \mu\text{m}$<br>Min. 90% of particles ( $Dv_{90}$ ) $\leq 30 \mu\text{m}$ |                   | conforms<br>conforms<br>conforms |
| Viscosity                  | 100 - 550 mPas                                                                                                                                                                     |                   | 410.0 mPas                       |
| Dispersibility             | Must pass the test.                                                                                                                                                                |                   | conforms                         |
| Sedimentation              | Must pass the test.                                                                                                                                                                |                   | conforms                         |
| Package extractable volume | min. 950 ml                                                                                                                                                                        |                   | 969.0 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. 566, V001.



V.2. L1 .....04/09/2026

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HEAD of QC, QP