

## CERTIFICATE OF ANALYSIS

Product: **BIOMEK, 10 mg/ml, soluție injectabilă pentru bovine, suine, ovine**

Batch No.: **505730A**

Expiry: **06/2025**

Date of production: **10.7.2023**

### Results of analysis:

| Tests                                                                                                                                     | Release limits                           | Shelf-life limits | Results                           |
|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|-------------------|-----------------------------------|
| Appearance                                                                                                                                | Clear, colourless or yellowish solution. |                   | conforms                          |
| Content of the original package                                                                                                           | min. 20 ml, 50 ml, 100 ml, 250 ml, 500ml |                   | 51.0 ml                           |
| Ivermectin identity test                                                                                                                  | It must be proved.                       |                   | conforms                          |
| Ivermectin B <sub>1a</sub> + B <sub>1b</sub> content                                                                                      | 0.95 – 1.05 g/100 ml                     |                   | 1.00 g/100 ml                     |
| Ivermectin impurities<br>- impurities with a relative retention of 1.2 -1.5<br>- any individual undefined impurity<br>- sum of impurities | max. 2.5%<br>max. 1.0 %<br>max. 5.0 %    |                   | 0.35 %/2.03 %<br><1.0 %<br>3.61 % |
| Density at 20 °C                                                                                                                          | 1.08 – 1.20 g/cm <sup>3</sup>            |                   | 1.10 g/cm <sup>3</sup>            |
| Airtightness                                                                                                                              | The vials must be closed hermetically.   |                   | conforms                          |
| Sterility                                                                                                                                 | The preparation 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. 380,V002.



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HEAD of QC, QP

08/08/2023