

## CERTIFICATE OF ANALYSIS

Product: **PESTORIN MORMYX, liofilizat ,i solvent pentru suspensie injectabili**

Batch No.: **715831**  
Expiry: **06/2026**  
Date of production: **16.7.2024**

### Results of analysis:

| Tests                                   | Release limits                                                                                                                              | Shelf-life limits                                                                                                                                                | Results                             |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| <b>Liquid component</b>                 |                                                                                                                                             |                                                                                                                                                                  |                                     |
| Appearance                              | White or greyish white liquid containing fine sediment.                                                                                     |                                                                                                                                                                  | conforms                            |
| Extractable volume                      | min. 1 ml, min. 5 ml, min. 10 ml, min. 20 ml                                                                                                |                                                                                                                                                                  | 1.0 ml                              |
| Sterility                               | The preparation shall be sterile.                                                                                                           |                                                                                                                                                                  | sterile                             |
| pH                                      | 6.5 – 7.5                                                                                                                                   |                                                                                                                                                                  | 7.4                                 |
| Content of aluminium oxide              | 0.2 – 0.6 %                                                                                                                                 |                                                                                                                                                                  | 0.31 %                              |
| Thiomersalum content                    | 0.0085 – 0.0115 %                                                                                                                           |                                                                                                                                                                  | 0.0091 %                            |
| Airtightness                            | The vials shall be hermetically sealed.                                                                                                     |                                                                                                                                                                  | conforms                            |
| Identity test                           | The presence of the specific antibodies against RHDV having the titre of at least 80 shall be proved in the serum of the vaccinated animals |                                                                                                                                                                  | conforms                            |
| <b>Freeze-dried component:</b>          |                                                                                                                                             |                                                                                                                                                                  |                                     |
| Appearance                              | Lyophilized vaccine is yellowish colour and spongy structure.                                                                               |                                                                                                                                                                  | conforms                            |
| Sterility                               | Vaccine must be sterile.                                                                                                                    |                                                                                                                                                                  | Sterile                             |
| Mycoplasma test                         | Free from mycoplasma.                                                                                                                       |                                                                                                                                                                  | conforms                            |
| Proof of extraneous agents              | Free from antibodies against rabbit haemorrhagic disease virus.                                                                             |                                                                                                                                                                  | conforms                            |
| Identity test                           | The positive control shall exhibit the apparent positive reaction, the negative control shall exhibit absence of the specific fluorescence. |                                                                                                                                                                  | conforms                            |
| Titre of myxomatosis virus              | MXT virus attenuated strain CAMP V-219: vaccine titre $10^{3.3}$ TCID <sub>50</sub> /1 ml - $10^{5.8}$ TCID <sub>50</sub> /1 ml             |                                                                                                                                                                  | $10^{5.5}$ TCID <sub>50</sub> /1 ml |
| Residual humidity                       | Max. 3 %                                                                                                                                    |                                                                                                                                                                  | 1.0 %                               |
| Vacuum                                  | The vials shall be evacuated to the residual pressure lower than 2.66 Pa                                                                    |                                                                                                                                                                  | conforms                            |
| <b>Diluted vaccine:</b>                 |                                                                                                                                             |                                                                                                                                                                  |                                     |
| Appearance                              | Reconstituted vaccine is white or greyish white liquid or slightly pinkish containing fine sediment.                                        |                                                                                                                                                                  | conforms                            |
| Sterility                               | Vaccine shall be sterile.                                                                                                                   |                                                                                                                                                                  | sterile                             |
| pH                                      | 6.5 – 7.5                                                                                                                                   |                                                                                                                                                                  | 7.0                                 |
| Residual live virus /previously safety/ | The vaccine complies with the test if no rabbit shows notable signs of disease or dies from causes attributable to the vaccine.             |                                                                                                                                                                  | safe                                |
| Potency                                 | RHD component                                                                                                                               | The vaccine meets the requirements specified for the efficacy testing if at least 90 % of vaccinated animals survive during the specified monitoring period.     | conforms                            |
|                                         |                                                                                                                                             | The vaccine meets the requirements specified for efficacy testing if the average titre of HI antibodies of at least 1:80 is found out in the vaccinated rabbits. | conforms                            |
|                                         |                                                                                                                                             | RHD virus inactivated strain CAMP V-351: Min. 128 – max. 1024 HAU *                                                                                              | 819.0 HAU                           |
|                                         | MXT component                                                                                                                               | The result of the test is acceptable if during the 21-day monitoring period at least 90 % of vaccinates resist to the infection by myxoma virus.**               | conforms                            |

Note: \* The test is carried out as the in-process control /\*\*The efficacy test by challenge is always performed with the first batch of the vaccine produced from the new batch of the working seed lot, but at least once per year

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. 195,V004.

v2  23/09/2024  
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HEAD of QC, QP

