

## CERTIFICATE OF ANALYSIS

Product: **FELIBIO PCHR, emulsie injectabilă**

Batch No.: **825230A**

Expiry: **01/2025**

Date of production: **2.2.2023**

### Results of analysis:

| Tests                       |      | Release limits                                                                                           | Shelf-life limits      | Results          |
|-----------------------------|------|----------------------------------------------------------------------------------------------------------|------------------------|------------------|
| Appearance                  |      | Pinkish liquid free of any sediment.                                                                     |                        | conforms         |
| Content of original package | 1 ml | Min. 1 ml                                                                                                |                        | 1.0 ml           |
|                             | 5 ml | Min. 5 ml                                                                                                |                        | ---              |
| Sterility                   |      | Vaccine must be sterile.                                                                                 |                        | sterile          |
| Identity                    |      | After immunization of animals the presence of antibodies against antigens declares must be demonstrated. |                        | conforms         |
| Efficacy                    |      | Vaccine must be efficient:                                                                               |                        | conforms         |
|                             |      | FPV                                                                                                      | RP $\geq 1$            | 1.11             |
|                             |      | FCV                                                                                                      | RP $\geq 1$            | 1.25             |
|                             |      | FHV                                                                                                      | RP $\geq 1$            | 1.18             |
|                             |      | RV***                                                                                                    | >1IU ( $p \leq 0,05$ ) | >1 IU, $p=0.002$ |
| Inactivation                |      | Vaccine must contain inactivated antigens.                                                               |                        | conforms         |
| pH                          |      | 6.5 – 7.5                                                                                                |                        | 7.5              |
| Thiomersal content*         |      | 0.01 % (0.0085 – 0.0115)                                                                                 |                        | --- %            |
| Air tightness               |      | The vials must be hermetically sealed.                                                                   |                        | conforms         |
| Viscosity                   |      | 1.0 – 2.0 mPa.s                                                                                          |                        | 1.39 mPa.s       |

\* Thiomersal as preservative is added only if the same batch is filled into single- and multi- dose packs.

\*\* Serum against rabies is obtained from the mice vaccinated with the test vaccine.

\*\*\* Antibody titers in mice after vaccination of batch of the preparation are statistically significantly higher than the titers obtained standard vaccine 1IU ( $p \leq 0,05$ ).

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. 154,V004.



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.....3/4/2023  
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