

CERTIFICATE OF ANALYSIS

Product: **FELIBIO PCHR, emulsie injectabilă**

Batch No.: **01 61 26 A**

Expiry: **04.11.2021**

Date of production: **05.11.2019**

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		1.1 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	1.05
		FCV	RP $\geq$ 1	1.08
		FHV	RP $\geq$ 1	1.18
		RV***	>1IU (p $\leq$ 0,05)	> 1 IU, p-0,000
Inactivation		Vaccine must contain inactivated antigens.		conforms
pH		6.5 – 7.5		7.3
Thiomersal content*		0.01 % (0.0085 – 0.0115)		--- %
Air tightness		The vials must be hermetically sealed.		conforms
Viscosity		1.0 – 2.0 mPa.s		1.61 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.



Nezvalová
.....12/12/2019
Mgr. Hana Nezvalová
HEAD of QC, QP