

CERTIFICATE OF ANALYSIS

Product: **BioRabbit RHDV 1,2 suspensie injectabilă**

Batch No.: **035530A**

Expiry: **04/2025**

Date of production: **15.5.2023**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Liquid of white to grey-white colour with the presence of fine sediment, which disperses homogeneously after shaking. On prolonged standing, the contents split into a clear liquid and a milky white to grey-white sediment, which dispersed homogeneously after shaking.		conforms
Extractable volume test	min. 0.5 ml, 5 ml, 10 ml		0.53 ml
Sterility	Vaccine must be sterile		sterile
pH	6.8 – 7.5		7.13
Aluminium oxide content ¹	4 mg/ml (3.4 – 4.8 mg/ml)		3.45 mg/ml
Sodium thiomersal content ¹	0.1 mg/ml (0.085 – 0.115 mg/ml)		0.095 mg/ml
Airtightness	The vials must be airtight.		conforms
Identity ¹	The presence of specific antibodies must be demonstrated in the serum of vaccinated animals.		conforms
	RHDV2 subtype demonstrated RHDV1a subtype demonstrated		conforms
Potency ¹	The serum of vaccinated animals must show the presence of specific antibodies against RHDV2 in a titre of at least 80 ² and RHDV1a in a titre of at least 60 ² .		conforms
Residual live virus ³	The vaccine must not contain live virus.		conforms

¹ The test is performed on a vaccine bulk.

² Titer of haemagglutination inhibitory (HI) antibodies in rabbit serum after administration of 1 vaccination dose. The average antibody titer must be min. 80 and more for RHDV2 and min. 60 and more for RHDV 1a.

³ The test is performed on individual antigens before formulation.

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. 541,V001.



Mgr. Hana Nezvalová
HEAD of QC, QP

24/08/2023