

CERTIFICATE OF ANALYSIS

Product: **BIOSUIS Entero, emulsie injectabilă**
 Batch No.: **045731A**
 Expiry: **06/2026**
 Date of production: **3.7.2024**

Results of analysis:

Tests		Release limits	Shelf-life limits	Results
Appearance		White oily liquid containing a sediment that can be easily shaken.		conforms
Content of original packing		Min. 10 ml, 50 ml, 100 ml, 250 ml		53.0 ml
Concentration of hydrogen ions (pH)		6.5 – 7.5		7.28
Viscosity ¹		2.0 – 5.0 mPa.s		3.98 mPa.s
Airtightness		The vials shall be sealed airtight.		conforms
Identification of active substance: ¹		The vaccine shall comply with identity test.		conforms
Identification of PRV component		The vaccine contains porcine rotavirus.		conforms
Identification of <i>E. coli</i> component		The vaccine contains F4, F6, F5, F41 fimbria <i>E. coli</i> antigen.		conforms
Identification of <i>Clostridium perfringens</i> (toxoid β) component		The vaccine contains toxoid β produced by <i>Clostridium perfringens</i> .		conforms
Potency: ²		The vaccine shall be effective and should stimulate the specific antibodies formation against porcine rotavirus, against F4, F6, F5, F41 <i>E.coli</i> and toxoid β produced by <i>Clostridium perfringens</i> .		conforms
Potency test of PRV component		RP $\geq$ 1.49 – 2.82	RP $\geq$ 1	1.56
Potency test of <i>E. coli</i> component	<i>E. coli</i> (F4)	RP $\geq$ 1.21 – 2.93	RP $\geq$ 1	1.52
	<i>E. coli</i> (F6)	RP $\geq$ 1.30 – 3.25	RP $\geq$ 1	1.70
	<i>E. coli</i> (F5)	RP $\geq$ 1.27 – 3.16	RP $\geq$ 1	1.49
	<i>E. coli</i> (F41)	RP $\geq$ 1.19 – 2.83	RP $\geq$ 1	1.59
Potency test of <i>Clostridium perfringens</i> toxoid β		RP $\geq$ 1.20 – 2.70	RP $\geq$ 1	1.39
Identification and assay of adjuvants:				
Determination of formaldehyde ²		Maximum 0.05 % (0.5 mg/ml)		0.009 %
Thiomersal ²		0.1 mg/ml (0.085 – 0.115 mg/ml)		0.113 mg/ml
Content of adjuvant ²		0.442 – 0.598 ml/dose		0.597 ml/dose
Test of sterility and purity				
Sterility		The preparation shall be sterile.		sterile
Inactivation and detoxification: ³				
Residual live virus		The sample must not contain any living virus.		conforms
Residual live bacteria - <i>E. coli</i>		The sample must not contain any living germs, there must not be any turbidity in liquid culture medium and/or growth of culture on agar medium.		conforms
Residual live bacteria - <i>Clostridium perfringens</i>		The sample must not contain any living germs.		conforms
Residual toxicity (β -toxin)		It must comply the residual toxicity test.		conforms
Content of α -toxin		The vaccine should contain max. 16.26 IU / dose		2.13 IU/dose
Bacterial endotoxins ⁴		Max. 4.58 x 10 ⁵ EU/dose		8.85 x 10 ⁴ EU/d.

Used shortcut and notes: Ph.Eur. = European Pharmacopoeia / SOP = Standard Operation Procedure (in-house method)

¹Performed on bulk/ ²Performed on bulk/ ³ Performed as in-process control (IPC) immediately after the inactivation and /or detoxification

⁴ The test is performed as in process control immediately after mixing the required volume of all active substances and phosphate buffer (before adding thiomersal and adjuvants). This value is calculated per dose from the determined as IPC.

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. 564,V001.



.....27/09/2024

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 HEAD of QC, QP