

CERTIFICATE OF ANALYSIS

Product: **BIOSUIS APP 2,9,11 – emulsie injectabilă**
Batch No.: **44 52 25 B**
Expiry: **31.01.2020**
Date of production: **01.02.2018**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Milky liquid of light grey to white colour, small amount of sediment dispersing after shaking.		conforms
Content of original package	min. 10 ml, min. 50 ml, min. 100 ml, min. 250 ml		51 ml
Sterility	The vaccine must be sterile.		sterile
Residual toxicity	No pig shows notable signs of disease or dies from causes attributable to the vaccine; a transient temperature increase not exceeding 2.0°C may occur.		conforms
Potency and identity	Potency of each antigens must meet the following criteria:		conforms
<i>A pleuropneumoniae</i> s. 2	RP $\geq$ 1*		1.18
<i>A pleuropneumoniae</i> s. 9 and 11	RP $\geq$ 1*		1.14
Apx I toxoid	RP $\geq$ 1*		1.28
Apx II toxoid	RP $\geq$ 1*		1.23
Apx III toxoid	RP $\geq$ 1*		1.17
	Identity is confirmed by the formation of antibodies against antigens declared in healthy vaccinated animals without antibodies in the potency test.		conforms
* RP = Relative potency (ELISA) in comparison with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passes the challenge test in the target species.			
pH	6.5 – 7.5		7.5
Airtightness	The vials must be hermetically closed.		conforms
Thiomersal	0.1 mg/ml (0.085 – 0.115 mg/ml)		0.088 mg/ml
Formaldehyde	max. 1 mg/ml		0 mg/ml
Bacterial endotoxins	Max. 4.4 x 10 ⁵ EU/ml		6.6 x10 ⁴ EU/ml
Viscosity	1.5 – 3.0 mPa.s		2.67 mPa.s

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. 258.



Handwritten signature
30/04/2019
Mgr. Hana Nezvalová
HEAD of QC, QP