

CERTIFICATE OF ANALYSIS

Product: **POLYPLEUROSIN APX PLUS IM emulsie injectabilă**

Batch No.: **506027A**

Expiry: **21.4.2022**

Date of production: **22.10.2020**

Results of analysis:

Tests	Specification	Results
Appearance	Grey-to-white turbid liquid with sediment which homogeneously disperses after shaking.	complies
Content of original package	min. 50, min. 100, min. 250ml	102.0 ml
Sterility	The vaccine must be sterile.	sterile
Residual toxicity	The vaccine can not cause any excessive local or systemic reaction.	complies
Efficacy and identity	Must be effective and identity must complies. Potency of each antigens must meet the following criteria: <i>A pleuropneumoniae</i> s. 2 RP>1* <i>A pleuropneumoniae</i> s. 9 RP>1* <i>Pasteurella multocida</i> serotype A RP>1* <i>Pasteurella multocida</i> serotype D RP>1* <i>Bordetella bronchiseptica</i> RP>1* Apx I toxoid RP>1* Apx II toxoid RP>1* Apx III toxoid RP>1* Identity is confirmed by the formation of antibodies against antigens declared in healthy vaccinated animals without antibodies in the efficiency test <i>* RP = relative potency compared with the reference serum obtained after vaccination of mouse batches of vaccine that has passed the challenge test on the target species.</i>	complies 1.23 1.16 1.27 1.25 1.15 1.19 1.11 1.17
Bacterial endotoxins	max. 9.82×10^5 EU/ml	5.23×10^5 EU/ml
Thiomersal	0.1 mg/ml (0.085 – 0.115 mg/ml)	0.104 mg/ml
Viscosity	1.0 – 3.0 mPa.s	2.1 mPa.s
Air tightness	Must be hermetically sealed.	complies
pH	6.5 – 7.5	7.0

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. 349,spec.04.




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HEAD of QC, QP