

CERTIFICATE OF ANALYSIS

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

Batch No.: **636129A**

Expiry: **04/2024**

Date of production: **3.11.2022**

Results of analysis:

Tests	Release limits	Shelf-life limits	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		100.0 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: <table><tr><td><i>A pleuropneumoniae</i> s. 2</td><td>RP>1*</td><td>1.27</td></tr><tr><td><i>A pleuropneumoniae</i> s. 9</td><td>RP>1*</td><td>1.23</td></tr><tr><td><i>Pasteurella multocida</i> serotype A</td><td>RP>1*</td><td>1.29</td></tr><tr><td><i>Pasteurella multocida</i> serotype D</td><td>RP>1*</td><td>1.22</td></tr><tr><td><i>Bordetella bronchiseptica</i></td><td>RP>1*</td><td>1.13</td></tr><tr><td>Apx I toxoid</td><td>RP>1*</td><td>1.25</td></tr><tr><td>Apx II toxoid</td><td>RP>1*</td><td>1.12</td></tr><tr><td>Apx III toxoid</td><td>RP>1*</td><td>1.08</td></tr></table> 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>		<i>A pleuropneumoniae</i> s. 2	RP>1*	1.27	<i>A pleuropneumoniae</i> s. 9	RP>1*	1.23	<i>Pasteurella multocida</i> serotype A	RP>1*	1.29	<i>Pasteurella multocida</i> serotype D	RP>1*	1.22	<i>Bordetella bronchiseptica</i>	RP>1*	1.13	Apx I toxoid	RP>1*	1.25	Apx II toxoid	RP>1*	1.12	Apx III toxoid	RP>1*	1.08	complies
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Bacterial endotoxins	max. 9.82×10 ⁵ EU/ml		6.14×10 ⁵ EU/ml																								
Thiomersal	0.1 mg/ml (0.085 – 0.115 mg/ml)		0.101 mg/ml																								
Viscosity	1.0 – 3.0 mPa.s		1.9 mPa.s																								
Air tightness	Must be hermetically sealed.		complies																								
pH	6.5 – 7.5		6.8																								

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,V004.




15/12/2022
 Mgr. Haňa Nezvalová
 HEAD of QC, QP