

CERTIFICATE OF ANALYSIS

Product: **BORRELYM 3 – suspensie injectabilă**Batch No.: **55 55 25 A**Expiry: **03.05.2020**Date of production: **04.05.2018**

Results of analysis:

Tests	Limit		Results
	Release limits	Shelf-life limits	
Appearance	Pinkish up to white fluid containing white sediment that disperses easily when the content is shaken.		conforms
Content of the original package	min. 1.00 ml		1.07 ml
Sterility	Free from bacteria and fungi.		sterile
Identity	Presence of <i>OspA B afzelii</i> , <i>OspA B. garinii</i> , <i>OspA B. burgdorferi</i>		conforms
Potency	<i>Borrelia afzelii</i> RP > 1.04	<i>Borrelia afzelii</i> RP ≥ 1	2.78
	<i>Borrelia garinii</i> RP > 1.08	<i>Borrelia garinii</i> RP ≥ 1	2.20
	<i>Borrelia burgdorferi</i> sensu stricto RP > 1.05	<i>Borrelia burgdorferi</i> sensu stricto RP ≥ 1	1.77
	RP = Relative potency (ELISA) in comparison to reference serum acquired from animals vaccinated with batch complying in challenge test on target animals.		
pH value	7.0 – 8.2		7.9
Content of aluminum oxide	2 mg/ml (1.8 – 2.2 mg/ml) (expressed as Al ₂ O ₃)		2.0 mg/ml
Formaldehyde	max. 0.5 mg/ml		0.0 mg/ml
Air tightness	The vial shall be airtight sealed.		conforms

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. 157.



.....08/01/2019
Mgr. Hana Nezvalová
HEAD of QC, QP