

## CERTIFICATE OF ANALYSIS

Product: **BORRELYM 3 – suspensie injectabilă**

Batch No.: **60 52 27 A**

Expiry: **04.02.2022**

Date of production: **05.02.2020**

### Results of analysis:

| Tests                           | Release limits                                                                                                                                            | Shelf-life limits                                | Results   |
|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|-----------|
| 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                                                                                                                                              |                                                  | 1.09 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                   | 2.56      |
|                                 | <i>Borrelia garinii</i> RP > 1.08                                                                                                                         | <i>Borrelia garinii</i> RP ≥ 1                   | 2.14      |
|                                 | <i>Borrelia burgdorferi</i> sensu stricto RP > 1.05                                                                                                       | <i>Borrelia burgdorferi</i> sensu stricto RP ≥ 1 | 1.93      |
|                                 | 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                                                                                                                                                 |                                                  | 7.2       |
| Content of aluminum oxide       | 2 mg/ml (1.8 – 2.2 mg/ml) (expressed as Al <sub>2</sub> O <sub>3</sub> )                                                                                  |                                                  | 1.9 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.



*Hana*  
.....16/09/2020  
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HEAD of QC, QP