

## CERTIFICATE OF ANALYSIS

Product: **BIOCAN M, suspensie injectabilă**

Batch No.: **21 52 26 A**

Expiry: **11.02.2021**

Date of production: **12.02.2019**

### Results of analysis:

| Tests                      | Release limits                                                                                                     | Shelf-life limits | Results                      |
|----------------------------|--------------------------------------------------------------------------------------------------------------------|-------------------|------------------------------|
| Appearance                 | Yellowish-brown up to brown liquid. Greyish-brown sediment can be observed, if shaken, it will disperse uniformly. |                   | conforms                     |
| Original package content   | min. 1 ml                                                                                                          |                   | 1.1 ml                       |
| Sterility                  | The vaccine shall be sterile.                                                                                      |                   | sterile                      |
| Inactivation               | The vaccination strain <i>Microsporium canis</i> in the vaccine must be inactivated.                               |                   | conforms                     |
| Efficacy- challenge test   | Vaccine shall be efficacious in challenge biological experiment ( <i>only in case of MSL change</i> ).             |                   | conforms                     |
| Efficacy                   | The vaccine shall contain from $5 \times 10^5$ to $6 \times 10^6$ vegetative forms in 1 ml.                        |                   | $3.94 \times 10^6$ v.f./1 ml |
| Hydrogen ion concentration | pH 6.3 – 7.7                                                                                                       |                   | 7.4                          |
| Alumina hydroxide content  | 0.2 – 0.4 %                                                                                                        |                   | 0.30 %                       |
| Airtightness               | The vials shall be hermetically 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. 131, spec.03.



26/03/2019  
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HEAD of QC, QP