

CERTIFICATE OF ANALYSIS

Product: **BIOCAN M, suspensie injectabilă**

Batch No.: **17 62 25 A**

Expiry: **03.12.2020**

Date of production: **04.12.2018**

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 5×10^5 to 6×10^6 vegetative forms in 1 ml.		4.86×10^6 v.f./1 ml
Hydrogen ion concentration	pH 6.3 – 7.7		7.4
Alumina hydroxide content	0.2 – 0.4 %		0.28 %
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.




.....08/02/2019
Mgr. Hana Nezvalová
HEAD of QC, QP