

CERTIFICATE OF ANALYSIS

Product: **BIOMEK, 10 mg/ml, soluție injectabilă pentru bovine, suine, ovine**

Batch No.: **25 60 26 B**

Expiry: **23.10.2021**

Date of production: **24.10.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Clear, colourless or yellowish solution.		conforms
Content of the original package	min. 20 ml, 50 ml, 100 ml, 250 ml, 500ml		101 ml
Ivermectin identity test	It must be proved.		conforms
Ivermectin B _{1a} + B _{1b} content	0.95 – 1.05 g/100 ml		1.03 g/100 ml
Ivermectin impurities			
- impurities with a relative retention of 1.2 -1.5	max. 2.5%		0.81 %/2.39 %
- any individual undefined impurity	max. 1.0 %		<1.0 %
- sum of impurities	max. 5.0 %		4.82 %
Density at 20 °C	1.08 – 1.20 g/cm ³		1.11 g/cm ³
Airtightness	The vials must be closed hermetically.		conforms
Sterility	The preparation must be sterile.		sterile

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. 380.




25/11/2019
Mgr. Hana Nezvalová
HEAD of QC, QP