

CERTIFICATE OF ANALYSIS

Product: **MORAXEBIN NEO, suspensie injectabilă**

Batch No.: **37 52 26 A**

Expiry: **19.08.2020**

Date of production: **20.02.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Light fluid containing greyish aluminium hydroxide sediment. When shaken, milky fluid free of coarse unshakeable particles is obtained.		conforms
Content of original package	Package per 5 doses - min. 10 ml Package per 10 doses - min. 20 ml Package per 25 doses - min. 50 ml Package per 50 doses - min. 100 ml Package per 125 doses - min. 250 ml Package per 250 doses - min. 500 ml		103 ml
Sterility	The vaccine shall be sterile.		sterile
Identity and efficacy	The vaccine shall be effective. The vaccine induces formation of the specified antibodies.		conforms
Bacterial endotoxins	The vaccine can contain max. 1×10^5 IU/dose		5.29×10^3 IU/dose
pH	6.8 – 7.8		7.5
Formaldehyde content	max 0.19 %		0.00 %
Thiomersal content	0.1 mg/ml (0.085 – 0.115)		0.101 mg/ml
Content of aluminum oxide	0.4 – 0.7 %		0.4 %
Airtightness	The vials 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. 230.



.....17/04/2019
Mgr. Hana Nezvalová
HEAD of QC, QP