

CERTIFICATE OF ANALYSIS

Product: **Biocan P inj. sicc. ad-ne. vet.**

Batch No.: **20 61 25 A**

Expiry: **11.11.2020**

Date of production: **12.11.2018**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Lyophilised vaccine is spongy matter, cream and pinkish colour. After dissolving in diluent the vaccine is pink-red or yellowish colour with light opalescence.		conforms
Mycoplasma	Vaccine should not contain mycoplasma.		conforms
Extraneous viruses	Vaccine should not contain any extraneous viruses.		conforms
Residual humidity	Lyophilised product doesn't contain more than 3% residual humidity.		2.4 %
Airtightness	The vials should be hermetically sealed.		conforms
Sterility	Vaccine should be sterile.		sterile
pH	6.5 – 8.0		7.5
Virus titre	CPV – Parvovirus enteritidis canis min. $10^{5.0}$ TCID ₅₀ , max. $10^{6.2}$ TCID ₅₀		$10^{6.1}$ TCID ₅₀
Virus identity	CPV Neutralisation index ≥ 2 .		4.0
Efficacy	Vaccine should be efficient.		conforms
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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. 134..



.....29/01/2019
Mgr. Hana Nezvalová
HEAD of QC, QP