

CERTIFICATE OF ANALYSIS

Product: **Biocan Novel Respi, picături nazale, liofilizat și solvent pentru suspensie**

Batch No.: **045128**
Expiry: **16.8.2022**
Date of production: **17.8.2020**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Freeze-dried fraction:			
Appearance	Lyophilised vaccine is spongy matter, white to yellowish colour.		conforms
Residual humidity	2.5 - 5 %		4.46 %
Vacuum	Residual pressure must be lower than 2.66 Pa.		conforms
Purity of freeze-dried fraction	Free from bacteria and fungi out of <i>Bordetella bronchiseptica</i> .		conforms
Mycoplasma	Free from mycoplasma.		conforms
Extraneous agents	Free from extraneous agents.		conforms
CPiV Virus titre	min. 10 ^{4.7} TCID ₅₀ max. 10 ^{5.8} TCID ₅₀	min. 10 ^{3.5} TCID ₅₀ max. 10 ^{5.8} TCID ₅₀	10 ^{4.8} TCID ₅₀
Identity of CPiV	Neutralisation index ≥ 2.		4.8
Number of <i>Bordetella bronchiseptica</i> particles	min. 10 ^{9.0} CFU max. 10 ^{9.8} CFU	min. 10 ^{8.0} CFU max. 10 ^{9.8} CFU	10 ^{9.3} CFU
Identity of <i>Bordetella bronchiseptica</i>	Function: The test is performed to confirm presence of <i>Bordetella bronchiseptica</i> antigen in the finished product.		conforms
Water for injection - liquid fraction:			
Appearance	Clear colourless liquid without taste and smell.		conforms
Extractable Volume	Minimum 0.5 ml		0.56 ml
Sterility	The preparation must be sterile.		sterile
Airtightness	The vial must be hermetically closed.		conforms
Acidity or alkalinity	Must comply with Ph. Eur.		conforms
Conductivity	Maximum 25 µS.cm ⁻¹		10.1 µS.cm ⁻¹
Oxidisable substances	Must comply with Ph. Eur.		conforms
Chlorides	Maximum 0.5 ppm.		<0.5 ppm
Nitrates	Maximum 0.2 ppm.		<0.2 ppm
Sulphates	Must comply with Ph.Eur.		conforms
Ammonium	Maximum 0.6 ppm.		<0.6 ppm
Calcium and magnesium	Must comply with Ph. Eur.		conforms
Residue on evaporation	Maximum 4 mg (0.004 %).		3 mg
Bacterial endotoxins	Less than 0.25 IU/ml.		<0.01 IU/ml
Reconstituted vaccine:			
Appearance	Whitish, yellowish to beige bleary liquid.		conforms
pH	7.0 – 8.0		7.7

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. 494.



Nezvalová
.....27/04/2021
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HEAD of QC, QP