

CERTIFICATE OF ANALYSIS

Product: **CLOTEID 4, suspensie injectabilă**

Batch No.: **57 61 26 A**

Expiry: **05.11.2022**

Date of production: **06.11.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Gray-white up to grey-brown suspension, without rough inshakeable particles. Standing is created shakeable sediment.		conforms
Content of the original package	min. 1, 5, 10, 20 ml		1 ml
Sterility	Vaccine must be sterile.		sterile
Residual toxicity	Complies with Eu. Pharm. in law, 5 guinea pigs (350 – 450 g) are subcutaneously administered by 5 ml of the vaccine. No animal has symptoms of disease or die of causes attributed to the vaccine. Vaccine must be safe.		conforms
Identity and efficacy	Complies with Eu. Pharm. in law, min.30 IU/ml. Vaccine must be efficient.		32 IU/ml
Content of aluminum oxide	1.5 – 3.0 mg/ml		1.5 mg/ml
Thiomersal content	0.15 mg/ml (0.1275 – 0.1725 mg/ml)		0.1700 mg/ml
pH	6.8 – 8.0		7.4
Air tightness	The vials must 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. 341.



.....08/01/2020
Mgr. Hana Nezvalová
HEAD of QC, QP