

CERTIFICATE OF ANALYSIS

Product: **Kolibin RC Neo, emulsie injectabilă**

Batch No.: **31 52 26 A**

Expiry: **31.01.2021**

Date of production: **01.02.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	White up to pinkish oily fluid containing the sediment that can be easily shaken.		complies
Content of original packaging	min. 2 ml, 4 ml, 10 ml, 20 ml, 50 ml, 100 ml, 250 ml		10.2 ml
Sterility	The vaccine must be sterile.		sterile
Potency:			
- E.Coli	RP $\geq$ 1*		15.08
- Corona	RP $\geq$ 1*		1.23
- Rota	RP $\geq$ 1*		1.91
-	*Relative potency established in guinea pigs by serological method (ELISA) in comparison with the reference serum prepared from the reference vaccine with minimal content of antigen		
Inactivation*	Must contain inactivated antigens. * The in-operation test is performed during manufacturing of the concentrated antigens.		complies
Identity	The vaccine must induce formation of specific antibodies against declared antigens.		complies
Specified extraneous agents	The vaccine complies with the test if it does not stimulate the formation of antibodies against bovine herpesvirus 1 (BHV1), bovine leukaemia virus (BLV) and bovine viral diarrhoea virus (BVDV).		complies
Bacterial endotoxins**	max. 2.5×10^5 IU/dose ** The in-operation test is performed after the concentration of E. coli bacterins.		1.03×10^4 IU/d.
Formaldehyde	max. 0.19 %.		0.009 %
Thiomersal	0.1 mg/ml (0.085-0.115 mg/ml)		0.103 mg/ml
Airtightness	The vials must be closed hermetically.		complies
Viscosity	20.0 – 40.0 mPa.s		32.3 mPa.s

I certify that this product has been tested in the laboratories of a.s. Bioveta and has been found to meet specification requirements. Preparation is suitable with control regulations of the valid PN No. 109,spec.04.



24/06/2019
Mgr. Hana Nezvalová
HEAD of QC, QP