

CERTIFICATE OF ANALYSIS

Product: **VITSEL E, soluție injectabilă**

Batch No.: **21 52 26 B**

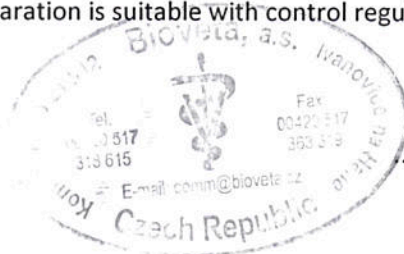
Expiry: **04.02.2021**

Date of production: **05.02.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Slightly opalescent solution without mechanical impurities.		complies
Extractable volume	min. 50.0 ml, 100.0 ml		51.0 ml
Sterility	The product must be sterile.		sterile
pH	5.00 – 6.75		6.12
Density	1.0060 – 1.0100 g/cm ³		1.0081 g/cm ³
Identity of vitamin E acetate	Must comply.		complies
Content of alpha-tocopherol acetate	23.75 – 26.25 mg/ml		25.87 mg/ml
Identity of selenite	Must comply.		complies
Selenium content	950 – 1050 µg/ml		1 042.2 µg/ml
Identity of benzyl alcohol	Must comply.		complies
Content of benzyl alcohol	18.0 – 22.0 mg/ml		21.36 mg/ml
Identity of edetate disodium	Must comply.		complies
Content of edetate disodium	180 – 220 µg/ml		198.4 µg/ml
Purity tests			
Individual unknown impurity > 0.3% (relative to the peak of alpha-tocopherol acetate)	max. 1.0 %		<1.0 %
Tocopherol content - free	max. 1.0 %		0.0 %
Sum of impurities	max. 2.0 %		1.2 %
Air tightness	The vial must be hermetically sealed.		complies

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. 381.



.....09/04/2019
Mgr. Hana Nezvalová
HEAD of QC, QP