

CERTIFICATE OF ANALYSIS

Product: **SERGON 1000 UI, liofilizat și solvent pentru soluție injectabilă**

Batch No.: **83 60 25 A**

Expiry: **03.10.2020**

Date of production: **04.10.2018**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Greyish white to greyish blue lyophilizate, after dissolving a clear or opalescent green-blue solution.		conforms
Sterility	The product shall be sterile.		sterile
Identity of active substance	Enlargement of ovary weight.		conforms
Efficacy of active substance	375 – 650 IU/ml Efficacy of serum gonadotropin shall range between 75 % and 130 %.		515 IU/ml 103 %
Identity of methylparahydroxybenzoate	Must comply.		conforms
Methylparahydroxybenzoate content	1.62 – 1.98 mg/ml		1.76 mg/ml
Identity of propylparahydroxybenzoate	Must comply.		conforms
Propylparahydroxybenzoate content	0.18 – 0.22 mg/ml		0.19 mg/ml
pH	7.0 – 8.0		7.7
Vacuum	Max 2.66 Pa.		conforms
Residual humidity	max. 5.0 %		0.6 %
Safety test	The product conforms to the test if no mouse will perish within 24 hours.		conforms

Diluent

Tests	Release limits	Shelf-life limits	Results
Appearance	Clear colourless solution.		conforms
pH	6.5 – 7.8		7.4
Extractable volume	min. 2 ml		2.2 ml
Airtightness	The vials must be airtight sealed.		conforms
Sterility test	The preparation must be sterile.		sterile

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. 200.



Mgr. Hana Nezvalová
HEAD of QC, QP

27/08/2019