

CERTIFICATE OF ANALYSIS

Product: **SERGON PG 400+200 UI**
lioofilizat si solvent pentru solutie injectabila

Batch No.: **38 61 25 A**

Expiry: **13.11.2021**

Date of production: **14.11.2018**

Results of analysis:

Tests	Release limit	Shelf-life limit	Results
Appearance	White or almost white lyophilizate, free of any odour, easily soluble in solvent under occurrence of clear or not more than faintly opalescent colourless solution.		conforms
Sterility test	The product shall be sterile.		sterile
Identity	Enlargement of ovary weight.		conforms
Efficacy of chorionic gonadotropin	Activity of chorionic gonadotropin shall range between 75 % and 130 %.		98 %
Efficacy of serum gonadotropin	Efficacy of serum gonadotropin shall range between 75 % and 130 %.		110 %
Mannitol content	4.5 – 5.5 mg/dose		4.74 mg/dose
pH value	6.2 – 7.2		6.9
Test for vacuum	Max 2.66 Pa.		conforms
Residual humidity	Max. 0.35 mg/vial		0.30 mg/vial
Innocuousness test	The product conforms to the test if no mouse will perish within 24 hours.		conforms

Diluent

Tests	Release limit	Shelf-life limit	Results
Appearance	Clear colourless solution.		conforms
Sterility	The product shall be sterile.		sterile
Original package content	min. 2 ml, 10 ml, 20 ml, 40 ml		10.14 ml
pH value	6.5 – 7.2		7.1
Airtightness	The vial shall be airtight 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. 202,03.

.....18/12/2018
Mgr. Hana Nezvalová
HEAD of QC, QP

