

CERTIFICATE OF ANALYSIS

Product: **OXYTOCIN BIOVETA, soluție injectabilă, 5 UI/ml**

Batch No.: **28 53 26 A**

Expiry: **12.03.2021**

Date of production: **13.03.2019**

Results of analysis:

Tests	Specification		Results
	Release limits	Shelf-life limits	
Appearance	Clear, colourless solution, without visible particles.		conforms
Injection solution actual acidity	3.6 – 4.0	3.2 – 4.3	4.0
Injection solution volume	min. 10 ml, min. 20 ml, min. 50 ml		51.0 ml
Air-tightness	Hermetically closed vial.		conforms
Content of active substances and excipients:			
Oxytocin and chlorobutanol identity test	Conformity of RT peak of standard and sample.		conforms
Oxytocin content determination (HPLC) method	4.75 – 5.25 IU/ml	4.5 – 5.5 IU/ml	4.905 IU/ml
Chlorobutanol hemihydrate content determination (HPLC) method	3.8 – 4.2 mg/ml	3.6 – 4.4 mg/ml	3.92 mg/ml
Microbiological tests			
Sterility test	The product 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. 333, spec.01.



.....02/04/2019
Mgr. Hana Nezvalová
HEAD of QC, QP