

CERTIFICATE OF ANALYSIS

Product: **OESTROPHAN, soluție injectabilă, 0,25 mg/ml**

Batch No.: **08 54 26 A**

Expiry: **02.04.2022**

Date of production: **03.04.2019**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Clear, almost colourless solution without visible particles.		conforms
Injection solution capacity available	min. 2 ml, min. 10 ml		10.3 ml
Sterility	The preparation must be sterile.		sterile
pH	5.5 – 6.5		6.0
Cloprostenol identity test	Identical position of peaks in the sample and standard HPLC chromatograms		conforms
Cloprostenol active 15 S epimer content	0.2375 – 0.2625 mg/ml	0.225 – 0.275 mg/ml	0.2461 mg/ml
Inactive 15-epimer content	max. 3 %		0.0 %
5,6-trans isomer content	max. 4 %		0.5 %
Chlorcresol	0.9 – 1.1. mg/ml		0.96 mg/ml
For 10ml packaging only: Pyrogenic substances	Must comply.		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. 301.



Hana
.....07/08/2019
Mgr. Hana Nezvalová
HEAD of QC, QP