

CERTIFICATE OF ANALYSIS

Product: **NALGOSED 10 mg/ml, soluție injectabilă**

Batch No.: **276027A**

Expiry: **30.9.2022**

Date of production: **1.10.2020**

Results of analysis:

Tests	Release limits	Shelf – life limits	Results
Appearance	Colorless, clear liquid, free of visible particles. The solution is as colorless as water R. The solution is as clear as water R.		complies
Sterility	The product shall be sterile.		sterile
Extractable volume	min. 10.0 ml		10.3 ml
Identity of butorphanol tartrat	Must be proved (HPLC).		complies
Content of butorphanol base	9.5 – 10.5 mg/ml		10.2 mg/ml
Identity of benzethonium chloride	Must be proved (HPLC).		complies
Content of benzethonium chloride	(0.09 – 0.11) mg/ml		0.11 mg/ml
Purity tests			
- any individual undefined impurity	max. 0.4 %		<0.4 %
- sum of impurities	max. 1.5 %		0.3 %
pH	3.5 – 4.5		4.1
Air tightness	The vials 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. 480.



Hana
.....25/01/2021
Mgr. Hana Nezvalová
HEAD of QC, QP