



## CERTIFICATE OF ANALYSIS

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

Batch No.: **786231A**

Expiry: **11/2027**

Date of production: **9.12.2024**

### 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 must be sterile.                                                                                                      |                     | sterile    |
| Extractable volume                  | min. 10.0 ml                                                                                                                      |                     | 10.1 ml    |
| Identity of butorphanol tartrat     | Must be proved (HPLC).                                                                                                            |                     | complies   |
| Content of butorphanol base         | 9.5 – 10.5 mg/ml                                                                                                                  |                     | 10.4 mg/ml |
| Identity of benzethonium chloride   | Must be proved (HPLC).                                                                                                            |                     | complies   |
| Content of benzethonium chloride    | (0.09 – 0.11) mg/ml                                                                                                               |                     | 0.10 mg/ml |
| Purity tests                        |                                                                                                                                   |                     |            |
| - any individual undefined impurity | max. 0.4 %                                                                                                                        |                     | <0.4 %     |
| - sum of impurities                 | max. 1.5 %                                                                                                                        |                     | 1.2 %      |
| 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,V003.



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.....27/01/2025  
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