



## CERTIFICATE OF ANALYSIS

Product: **NARKAMON BIO, solutie injectabilă, 100 mg/ml**

Batch No.: **455728A**

Expiry: **13.7.2023**

Date of production: **14.7.2021**

### Results of analysis:

| Tests                           | Release limits                                           | Shelf-life limits | Results      |
|---------------------------------|----------------------------------------------------------|-------------------|--------------|
| Appearance                      | Clear, colourless solution free of mechanical particles. |                   | conforms     |
| Extractable volume              | min. 10.0 ml<br>min. 50.0 ml                             |                   | 50 ml        |
| pH of injection solution        | 4.5 – 5.5                                                |                   | 5.0          |
| Ketamine hydrochloride identity | Must comply.                                             |                   | conforms     |
| Ketamine hydrochloride content  | 109.57 – 121.11 mg/ml                                    |                   | 114.85 mg/ml |
| Impurities                      |                                                          |                   |              |
| impurity A                      | max. 0.5 %                                               |                   | 0.0 %        |
| individual unspecified impurity | max. 0.5 %                                               |                   | 0.0 %        |
| sum of impurities               | max. 1.0 %                                               |                   | 0.0 %        |
| Benzethonium chloride identity  | Must comply.                                             |                   | conforms     |
| Benzethonium chloride content   | 0.090 – 0.110 mg/ml                                      |                   | 0.101 mg/ml  |
| Disodium edetate identity       | Must comply.                                             |                   | conforms     |
| Disodium edetate content        | 0.090 – 0.110 mg/ml                                      |                   | 0.100 mg/ml  |
| Sterility                       | Must comply.                                             |                   | sterile      |
| Bacterial endotoxins            | Max. 25 IU/ml                                            |                   | <25 IU/ml    |
| Airtightness                    | The vial must be airtightly 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. 396.



  
.....9/8/2021  
Mgr. Hana Nezvalová  
HEAD of QC, QP