



## CERTIFICATE OF ANALYSIS

Product: **KETOPROFEN BIOVETA 100 mg/ml soluție injectabilă**

Batch No.: **345733A**

Expiry: **06/2028**

Date of production: **14.7.2026**

### Results of analysis:

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| Tests                                 | Release limits                                                                                                                                                                                                                                          | Shelf-life limits | Results      |
|---------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|--------------|
| Appearance                            | Clear, colourless or slightly yellowish solution free of visible particles. The solution is clear like water R. The solution is colourless like water R, may not be yellower than the reference solution Y5. The solution is free of visible particles. |                   | conforms     |
| Sterility                             | The product must be sterile.                                                                                                                                                                                                                            |                   | sterile      |
| Extractable volume                    | Min. 100.0 ml                                                                                                                                                                                                                                           |                   | 101.2 ml     |
| Ketoprofen identity test              | RT and UV spectrum match with standard                                                                                                                                                                                                                  |                   | conforms     |
| Ketoprofen assay                      | 95.0 – 105.0 mg/ml                                                                                                                                                                                                                                      |                   | 102.79 mg/ml |
| Benzyl alcohol identity test          | RT and UV spectrum match with standard                                                                                                                                                                                                                  |                   | conforms     |
| Benzyl alcohol assay                  | 9.0 – 11.0 mg/ml                                                                                                                                                                                                                                        |                   | 10.75 mg/ml  |
| Ketoprofen impurities content (HPLC): |                                                                                                                                                                                                                                                         |                   |              |
| - individual unknown impurity         | Max. 0.5 %                                                                                                                                                                                                                                              |                   | 0.0694 %     |
| - sum of impurities                   | Max. 0.5 %                                                                                                                                                                                                                                              |                   | 0.07 %       |
| pH                                    | 6.0 – 7.0                                                                                                                                                                                                                                               |                   | 6.8          |
| Airtightness                          | 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. 543,V001.



V. 2. 21 .....06/08/2026  
Mgr. Hana Nezvalová  
HEAD of QC, QP