



CERTIFICATE OF ANALYSIS

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

Batch No.: **276131A**

Expiry: **10/2026**

Date of production: **4.11.2024**

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		101.6 ml
Ketoprofen identity test	RT and UV spectrum match with standard		conforms
Ketoprofen assay	95.0 – 105.0 mg/ml		102.48 mg/ml
Benzyl alcohol identity test	RT and UV spectrum match with standard		conforms
Benzyl alcohol assay	9.0 – 11.0 mg/ml		10.74 mg/ml
Ketoprofen impurities content (HPLC):			
- individual unknown impurity	Max. 0.5 %		<0.5 %
- sum of impurities	Max. 0.5 %		0.09 %
pH	6.0 – 7.0		6.8
Airtightness	Must comply.		conforms

I certify that this product complies with the requirements of the European Pharmacopoeia (Ph. Eur.) and the United States Pharmacopoeia (USP).

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.



V2 12/12/2024
Mgr. Hana Nezvalová
HEAD of QC, QP