



CERTIFICATE OF ANALYSIS

Product: **MARBOFLOXACIN BIOVETA 100 mg/ml, soluție injectabilă**

Batch No.: **045533A**

Expiry: **04/2029**

Date of production: **13.5.2026**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Yellow-greenish to yellow-brownish clear solution, free of visible particles. The solution is clear like water R. Solution is not more intensely coloured than reference solution GY1.		conforms
Extractable volume	min. 100.0 ml		101.00 ml
pH	3.0 – 4.5		3.58
Marbofloxacin identity test	Retention time and UV spectrum must comply.		conforms
Marbofloxacin content	95.0 – 105.0 mg/ml		100.39 mg/ml
Monothioglycerol identity test	Retention time and UV spectrum must comply.		conforms
Monothioglycerol content	0.85 – 1.10 mg/ml	max. 1.10 mg/ml	1.100 mg/ml
Metacresol identity test	Retention time and UV spectrum must comply.		conforms
Metacresol content	1.80 – 2.20 mg/ml		2.010 mg/ml
Disodium edetate identity test	Retention time and UV spectrum must comply.		conforms
Disodium edetate content	90 – 110 µg/ml		101.0 µg/ml
Purity test any individual marbofloxacin impurity	max. 1.0 %		0.59 %
sum of marbofloxacin impurities	max. 1.5 %		0.73 %
Sterility	The product must be sterile.		sterile
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. 571,V001.



12/08/2026
Mgr. Hana Nezvalová
HEAD of QC, QP