

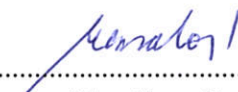
CERTIFICATE OF ANALYSIS

Product: **TULATHROMYCIN Bioveta 100 mg/ml, soluție injectabilă**Batch No.: **025632A**Expiry: **05/2027**Date of production: **17.6.2025**

Results of analysis:

Tests	Release limits	Shelf-life limits	Results
Appearance	Clear (like water R), colourless to slightly yellow solution (NMT Y6) free of visible particles.		complies
Extractable volume	min. 50.0 ml; 100.0 ml		50.80 ml
pH	5.1 – 5.7		5.31
Tulathromycin A identity test	Retention time and UV spectrum must comply.		complies
Tulathromycin B identity test	Retention time and UV spectrum must comply.		complies
Monothioglycerol identity test	Retention time and UV spectrum must comply.		complies
Tulathromycin content (Σ tulathromycin A and B)	95.0 – 105.0 mg/ml		100.85 mg/ml
Tulathromycin B content (% - referred to Σ tulathromycin A and B)	8.0 – 13.0 %	6.0 – 14.0 %	9.38 %
Monothioglycerol content	4.5 – 5.5 mg/ml	max. 5.5 mg/ml	5.35 mg/ml
Purity test - impurity C - impurity D - impurity E - any individual undefined impurity - sum of impurities	max. 1.0 % max. 1.0 % max. 1.0 % max. 1.0 % max. 3.0 %		ND ND 0.48 % 0.12 % 0.60 %
Sterility	The product must be sterile.		sterile
Airtightness	Must comply.		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. 563,V001.


.....25/08/2025
Mgr. Hana Nezvalová
HEAD of QC, QP

