

Certificate of Analysis

Certificate No.: 41408

Product:	Tullavis 100mg/ml solution for injection 250ml EP RO		
Article number:	00100738	Dosage form:	Solution for injection
Batch:	21034402 Split: 0	Package size:	250ml
Quantity:	300 Units	Marketing authorisation holder:	Livisto Int'l
Manufacturing date:	25.06.2021	Registration number:	9481
Expiry date:	31.05.2023	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear, colourless to yellowish solution	complies
Colour	Brighter than BY4 / Y4	BY4
Particulate contamination	Free of particles	Corresponds to
pH	5,0 ... 5,8	5,2
Absolute density	1,060 ... 1,070 g/ml	1,066 g/ml
Filling volume	Min. 100 %	102 %
Identity: tulathromycin A	Retention times and UV spectrum of standard and sample must correspond	Corresponds to
Identity: tulathromycin B	Retention times and UV spectrum of standard and sample must correspond	Corresponds to
Identity: monothioglycerol	Retention times and UV spectrum of standard and sample must correspond	Corresponds to
Assay: tulathromycin A+B	95,0 ... 105,0 mg/ml	98,3 mg/ml
Assay: monothioglycerol	3,5 ... 5,5 mg/ml	4,7 mg/ml
Ratio tulathromycin B relative to total tulathromycin	8 ... 13 %	11 %
Any unspecified degradation product	Max. 1,0 %	0,0 %
Total degradation products	Max. 3,0 %	0,0 %
Sterility	Sterile	Corresponds to

Template: 2877

The finished product has been tested in accordance with the testing instruction and is of the required quality.

15. JULI 2021



Date, Signature Head of Quality Control

Batch certificate

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I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the marketing authorisation as laid down in the manufacturing and quality control instructions. The batch processing, packaging and analytical documentation has been reviewed and is in full compliance with GMP guidelines. All deviations were evaluated before batch release.

This batch has the required quality and

- ☐ is released for delivery
- ☒ is released for the market

Remarks:

Four horizontal lines for handwritten remarks, each with a diagonal slash mark.

Date, Signature Qualified Person

☐ Dr. Hans-Jörg Lange ☐ Gudrun Prußeit ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller ☐