


LIVISTOaniMedica Herstellungs GmbH
a LIVISTO company**Certificate of Analysis**

Certificate No.: 35713

Product:	Tullavis 100mg/ml solution for injection 250ml EP RO	Dosage form:	Solution for injection
		Package size:	250ml
Product:	00100738	Marketing authorisation holder:	Livisto Int'l
Batch:	20042703 Split: 0	Registration number:	9481
Quantity:	300 Units	Distributor / Importer:	RO - BistriVet Rumänien
Manufacturing date:	01.12.2020		
Expiry date:	30.06.2022		

Parameter	Specification	Result
Appearance	Clear, colourless to yellowish solution	Complies
Colour	Brighter than BY4 / Y4	brighter than GY4
Particulate contamination	Free of particles	Corresponds to
pH	5,0 ... 5,8	5,3
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
Assay: tulathromycin A+B	95,0 ... 105,0 mg/ml	98,7 mg/ml
Assay: monothioglycerol	3,5 ... 5,5 mg/ml	4,7 mg/ml
Any unspecified degradation product	Max. 1,0 %	0,4 %
Total degradation products	Max. 3,0 %	0,4 %
Sterility	Sterile	Corresponds to

Template: 2877

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

16. DEZ. 2020

Date, Signature Head of Quality Control


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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:

16.12.20

Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange☐ Gudrun Pruß☐ Dr. Jürgen Schlüter☐