

Certificate of Analysis

Certificate No.: 53715

Product:	Tullavis 100mg/ml solution for injection 250ml EP RO		
Article number:	00100738	Dosage form:	Solution for injection
Batch:	22046701 Split: 0	Package size:	250ml
Quantity:	200 Units	Marketing authorisation holder:	Livisto Int'l
Manufacturing date:	13.12.2022	Registration number:	9481
Expiry date:	30.11.2025	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear, colourless to yellowish solution	corresponds to
Colour	Brighter than BY4 / Y4	BY6
Particulate contamination	Free of particles	Corresponds to
pH	5,0 ... 5,8	5,4
Absolute density	1,060 ... 1,070 g/ml	1,066 g/ml
Filling volume	Min. 100 %	101 %
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	99,1 mg/ml
Assay: monothioglycerol	3,5 ... 5,5 mg/ml	4,9 mg/ml
Ratio tulathromycin B relative to total tulathromycin	8 ... 13 %	11 %
Any unspecified degradation product	Max. 1,0 %	< 0,3 %
Total degradation products	Max. 3,0 %	< 0,3 %
Sterility	Sterile	Corresponds to

Template: 2877

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

27.02.2023 
Date, Signature Head of Quality Control