

Certificate of Analysis

Certificate No.: 67509

Product:	Enrotron 100mg/ml inj 100ml EP RO		
Article number:	87254	Dosage form:	Solution for injection
Batch:	T-00502 Split: 0	Package size:	100ml
Quantity:	1,008 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.09.2024	Registration number:	190062
Expiry date:	31.08.2027	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear solution, slightly yellowish to yellowish orange	Clear solution, slightly yellowish to yellowish orange
Colour	Not more intensively coloured than reference solution GY3 or Y3	GY4
Particulate contamination	Practically free of visible particles	Corresponds to
pH	10.0 ... 12.0	11,6
Absolute density	1.0250 ... 1.0450 g/ml	1,0330 g/ml
Extractable volume	Min. 100,0 %	103,0 %
Identity: enrofloxacin	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Identity: 1-butanol	Retention time of standard and sample must correspond	Corresponds to
Assay: enrofloxacin	95,0 ... 105,0 mg/ml	100,9 mg/ml
Assay: 1-butanol,	27,0 ... 33,0 mg/ml	30,5 mg/ml
Purity: ciprofloxacin	Max. 1,0 %	< 0,1 %
Single other impurity	Max. 1,0 %	< 0,1 %
Sum of impurities	Max. 3. %	< 1 %
Sterility	Sterile	Corresponds to

Template: 1629

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

15. JAN. 2025

Date, Signature Head of Quality Control