

Certificate of Analysis

Certificate No.: 62343

Product:	Enrotron 100mg/ml inj 100ml EP RO		
Article number:	87254	Dosage form:	Solution for injection
Batch:	S-00403 Split: 0	Package size:	100ml
Quantity:	504 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.11.2023	Registration number:	190062
Expiry date:	31.10.2026	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear solution, slightly yellowish to yellowish orange	Corresponds to
Colour	Not more intensively coloured than reference solution GY3 or Y3	GY6
Particulate contamination	Practically free of visible particles	Corresponds to
pH	10,0 ... 12,0	11,0
Absolute density	1,0250 ... 1,0450 g/ml	1,0330 g/ml
Extractable volume	Min. 100,0 %	102,0 %
Identity: enrofloxacin	Retention time and 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	99,5 mg/ml
Assay: 1-butanol	27,0 ... 33,0 mg/ml	29,5 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.

31. MAI 2024

Date, Signature Head of Quality Control



aniMedica GmbH
a LIVISTO company

Batch certificate

Certificate No.: 24904

Product:	Enrotron 100mg/ml inj 100ml EP RO		
Article number:	87254	Dosage form:	
Batch:	S-00403 Split: 0	Package size:	100ml
Quantity:	504 Units	Marketing authorisation holder:	
Manufacturing date:	01.11.2023	Registration number:	120046 130062 6/0406.24
Expiry date:	31.10.2026	Distributor / Importer:	RO - BistriVet Rumänien

Certification statement:

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Remarks:

04.06.24
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange ☐ Stephan Bruns ☐ Dr. Jürgen Schlüter ☐ Ulrich Kontry