

Certificate of Analysis

Certificate No.: 41615

Product:	Enrotron 100mg/ml inj 100ml EP RO		
Article number:	87254	Dosage form:	Solution for injection
Batch:	P-00304 Split: 0	Package size:	100ml
Quantity:	500 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.04.2021	Registration number:	190062
Expiry date:	31.03.2024	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Extractable volume	Min. 100,0 %	102,0 %
Batch packaging record	batch packaging record complies	Corresponds to
Appearance	clear, weak yellow to yellow-orange solution	complies
Colour	not more coloured than GY3 oder Y3	GY6-5
Particulate contamination	free of particles	complies
pH	10,0 ... 12,0	10,9
Absolute density (20°C)	1,0250 ... 1,0450 g/ml	1,0320 g/ml
Identity Enrofloxacin	Retention time and UV-Spectroscopy of standard and sample must be identical	Corresponds to
Identity 1-Butanol	Retention time of standard and sample must be identical	Corresponds to
Assay Enrofloxacin	95,0 ... 105,0 mg/ml	99,9 mg/ml
Assay 1-Butanol	27,0 ... 33,0 mg/ml	30,0 mg/ml
Related Substances Ciprofloxacin	Max. 1,0 %	< 0,1 %
Other impurities, single	Max. 0,5 %	0,0 %
Sum of impurities	Max. 2 %	< 1 %
Sterility	sterile	Corresponds to
Sterilisation documents Labiana	must be available	Corresponds to

Template: 1629

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

22. JULI 2021



Date, Signature Head of Quality Control

Batch certificate

Certificate No.: 41615

Product:	Enrotron 100mg/ml inj 100ml EP RO		
Article number:	87254	Dosage form:	Solution for injection
Batch:	P-00304 Split: 0	Package size:	100ml
Quantity:	500 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.04.2021	Registration number:	190062
Expiry date:	31.03.2024	Distributor / Importer:	RO - BistriVet Rumänien

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:

Date, Signature Qualified Person

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