

Certificate of Analysis

Certificate No.: 45793

Product:	Enrotron 100mg/ml inj 100ml EP RO		
Article number:	87254	Dosage form:	Solution for injection
Batch:	P-00504 Split: 0	Package size:	100ml
Quantity:	500 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.09.2021	Registration number:	190062
Expiry date:	31.08.2024	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	GY6
Particulate contamination	Practically free of visible particles	Corresponds to
pH	10,0 ... 12,0	10,9
Absolute density	1,0250 ... 1,0450 g/ml	1,0320 g/ml
Extractable volume	Min. 100,0 %	102,5 %
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	96,8 mg/ml
Assay: 1-butanol	27,0 ... 33,0 mg/ml	29,4 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.

 13. DEZ. 2021
Date, Signature Head of Quality Control

Batch certificate

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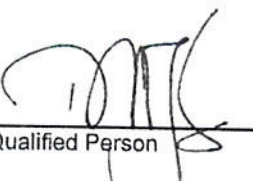
I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the marketing authorisation as laid down in the manufacturing 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:

Four horizontal lines for handwritten remarks, each with a diagonal slash through it.

14.02.2024 
Date, Signature Qualified Person

- ☒ Dr. Hans-Jörg Lange ☐ Gudrun Prusseit ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller
- ☐ Ulrich Kontny