

Certificate of Analysis

Certificate No.: 28172

Product:	Enrotron 100mg/ml inj 100ml EP RO	Dosage form:	
		Package size:	100ml
Product:	87254	Marketing authorisation holder:	aniMedica GmbH
Batch:	N-00101 Split: 0	Registration number:	120046
Quantity:	1.000 Units		
Manufacturing date:	01.01.2020		
Expiry date:	31.12.2022		

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	clear, weak yellow solution
Colour	not more coloured than GY3 oder Y3	complies
Particulate contamination	free of particles	particle free
pH	10,0 ... 12,0	11,0
Absolute density (20°C)	1,0250 ... 1,0450 g/ml	1,0330 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	100,5 mg/ml
Assay 1-Butanol	27,0 ... 33,0 mg/ml	28,5 mg/ml
Related Substances Ciprofloxacin	Max. 1,0 %	0,0 %
Other impurities, single	Max. 0,5 %	0,0 %
Sum of impurities	Max. 2 %	0 %
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.

24. MRZ. 2020



Date, Signature Head of Quality Control

Batch certificate

Certificate No.: 28172

Product: Enrotron 100mg/ml inj 100ml EP RO

Dosage form:

Product 87254

Package size: 100ml

Batch: N-00101 Split: 0

Marketing authorisation holder: aniMedica GmbH

Quantity: 1.000 Units

Registration-No.: 120046

Manufacturing 01.01.2020

Expiry date: 31.12.2022

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.

260326
Date, Signature Qualified Person☒ Dr. Hans-Jörg Lange☐ Gudrun Prußeit☐ Dr. Jürgen Schlüter☐