

Batch certificate

Certificate No.: 58148

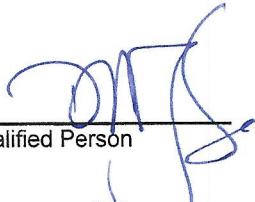
Product:	Enrotron 100mg/ml inj 100ml EP HU/RO		
Article number:	87083	Dosage form:	Solution for injection
Batch:	S-00102 Split: 0	Package size:	100ml
Quantity:	1.512 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.03.2023	Registration number:	HU:3104/1/12NÉBIH ÁTI RO: 190062
Expiry date:	28.02.2026	Distributor / Importer:	HU - Medicus Partner Kft

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:

26.6.2020 

Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange ☐ Stephan Bruns ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller ☐ Ulrich Kontny

Certificate of Analysis

Certificate No.: 58148

Product:	Enrotron 100mg/ml inj 100ml EP HU/RO		
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Parameter	Specification	Result
Appearance	Clear solution, slightly yellowish to yellowish orange	Corresponds to
Colour	Not more intensively coloured than reference solution GY3 or Y3	GY5
Particulate contamination	Practically free of visible particles	Corresponds to
pH	10,0 ... 12,0	11,0
Absolute density	1,0250 ... 1,0450 g/ml	1,0320 g/ml
Extractable volume	Min. 100,0 %	101,0 %
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	97,9 mg/ml
Assay: 1-butanol	27,0 ... 33,0 mg/ml	29,1 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: 2172

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

25. OKT. 2023

Date, Signature Head of Quality Control