

Certificate of Analysis

Certificate No.: 60871

aniMedica GmbH
a LIVISTO company

Product:	Enrotron 100mg/ml inj 100ml EP HU/RO		
Article number:	87083	Dosage form:	Solution for injection
Batch:	S-00304 Split: 0	Package size:	100ml
Quantity:	448 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.09.2023	Registration number:	HU:3104/1/12NÉBIH ÁTI RO: 190062
Expiry date:	31.08.2026	Distributor / Importer:	

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	10,9
Absolute density	1,0250 ... 1,0450 g/ml	1,0320 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	99,2 mg/ml
Assay: 1-butanol	27,0 ... 33,0 mg/ml	29,9 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.

Date, Signature Head of Quality Control

27. MRZ. 2024