

Certificate of Analysis

Certificate No.: 56930

Product:	Enrotron 100mg/ml inj 100ml EP RO		
Article number:	87254	Dosage form:	Solution for injection
Batch:	R-00804 Split: 0	Package size:	100ml
Quantity:	504 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.12.2022	Registration number:	190062
Expiry date:	30.11.2025	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear solution, slightly yellowish to yellowish orange	corresponds to
Colour	Not more intensively coloured than reference solution GY3 or Y3	corresponds to
Particulate contamination	Practically free of visible particles	Corresponds to
pH	10,0 ... 12,0	10,9
Absolute density	1,0250 ... 1,0450 g/ml	1,0330 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	100,7 mg/ml
Assay: 1-butanol	27,0 ... 33,0 mg/ml	30,4 mg/ml
Purity: ciprofloxacin	Max. 1,0 %	< 0,1 %
Single other impurity	Max. 1,0 %	0,0 %
Sum of impurities	Max. 3 %	< 1 %
Sterility	Sterile	Corresponds to

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

31. JULI 2023

Date, Signature Head of Quality Control

