



aniMedica GmbH  
a LIVISTO company

## Certificate of Analysis

Certificate No.: 69498

|                     |                                   |                                 |                         |
|---------------------|-----------------------------------|---------------------------------|-------------------------|
| Product:            | Enrotron 100mg/ml inj 100ml EP RO |                                 |                         |
| Article number:     | 87254                             | Dosage form:                    | Solution for injection  |
| Batch:              | V-003A03 Split: 0                 | Package size:                   | 100ml                   |
| Quantity:           | 1,008 Units                       | Marketing authorisation holder: | aniMedica GmbH          |
| Manufacturing date: | 01.05.2025                        | Registration number:            | 190062                  |
| Expiry date:        | 30.04.2028                        | 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       | GY7            |
| Particulate contamination | Practically free of visible particles                                 | Corresponds to |
| pH                        | 10.0 ... 12.0                                                         | 11,1           |
| Absolute density          | 1.0250 ... 1.0450 g/ml                                                | 1.0320 g/ml    |
| Extractable volume        | 100.0 ... 103.0 %                                                     | 102,5 %        |
| Identity: enrofloxacin    | Retention time and UV spectrum 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                                                  | 99,1 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.

15. JULI 2025

Date, Signature Head of Quality Control

Amtsgericht Coesfeld  
HRB-Nr. 7210  
Geschäftsführer:  
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