

### Certificate of Analysis



**Product name:** Enrocin 100 mg/ml oral solution  
**Batch number:** 310I4AA  
**Quantity:** 1000 x 1000 ml in HDPE flacon with PP cap  
**Date of manufacture:** 09.2024  
**Date of expiry:** 09.2026  
**No. of Analytical card:** QC-1310-01-015-01/2024

| Tests parameters              | Requirements                                                     | Results  |
|-------------------------------|------------------------------------------------------------------|----------|
| 1. Leírás / Appearance        | clear, yellowish solution, free from visible suspended particles | complies |
| 2. Tests                      |                                                                  |          |
| 2.1. Volume in container      | 100 - 105 % of nominal value                                     | 100      |
| 2.2. pH                       | 11.0 - 13.0                                                      | 12.3     |
| 2.3. Relative density         | 0.99 - 1.10                                                      | 1.04     |
| 3. Microbiological quality*   |                                                                  |          |
| 3.1. TAMC                     | $< 10^3$ / ml                                                    | ---1     |
| 3.2. TYMC                     | $< 10^2$ / ml                                                    |          |
| 3.3. E.coli                   | absent                                                           |          |
| 4. Chemical purity            |                                                                  |          |
| 4.1. Impurity B               | Max. 1.0%                                                        | < 0.3    |
| 4.2. Total impurities         | Max. 1.5%                                                        | < 0.3    |
| 5. Identification             |                                                                  |          |
| 5.1. Enrofloxacin             | R <sub>t</sub> conforms to the standard                          | complies |
| 5.2. Benzyl-alcohol           | R <sub>t</sub> conforms to the standard                          | complies |
| 6. Assay of active ingredient |                                                                  |          |
| Enrofloxacin                  | 9.5 - 10.5 g/100 ml                                              | 10.1     |
| 6.1. Assay of excipient       |                                                                  |          |
| Benzyl-alcohol                | 0.74 - 0.82 g/100 ml                                             | 0.78     |

\*periodic test, every 10<sup>th</sup> batch and at least once per year

1: Test is carried out on a spot-check basis. We confirm however compliance with the inspection and requirements also for this batch.

**Qualification:** **accepted**

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the cGMP requirements of the EU, and with the requirements of the Marketing Authorisation of the destination country.

Kistarcsa, 17/10/2024

LAVET Kft./Ltd.  
 Meghatalmazott személy/  
 Qualified person

.....  
 dr. Brigitta Szabó  
 Qualified person