

### Certificate of Analysis

**Product name:** Enrocin 10 % oral solution  
**Batch number:** 043010  
**Quantity:** 1000 x 1000 ml in HDPE flacon with PP cap  
**Date of manufacture:** 01/2020  
**Date of expiry:** 01/2022  
**No. of Analytical card:** QC-0043-01-015-01/2020

| 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                                                      | 12.4     |
| 2.3. Relative density         | 0.99 - 1.10                                                      | 1.04     |
| 3. Microbiological quality    |                                                                  |          |
| 3.1. TAMC                     | $< 10^3$ / ml                                                    | $< 10^3$ |
| 3.2. TYMC                     | $< 10^2$ / ml                                                    | $< 10^2$ |
| 3.3. E.coli                   | absent                                                           | 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                                              | 10.0     |
| 6.1. Assay of excipient       |                                                                  |          |
| Benzyl-alcohol                | 0.74-0.82 g/100 ml                                               | 0.78     |

**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, 28/01/2020

**LAVET Kft./Ltd.**  
 Meghatalmazott személy/  
 Qualified person (1.)

dr. Brigitta Szabó  
 Qualified person



LAVET GYÓGYSZERIPARI KFT. / LAVET PHARMACEUTICALS LTD.  
 Minőségbiztosítási Osztály / Quality Assurance/ Meghatalmazott személy / Qualified Person  
 Gyógyszergyártási engedély száma / Manufacturing authorisation No.: MA-HU/18V/2006/M14  
 GMP igazolás száma/GMP certificate No.: CG-HU/18V/2019, CG-HU/04V/2019, CG-HU/21V/2016  
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