

Certificate of Analysis

Product name: Enrocin 100 mg/ml oral solution
Batch number: 911E4AA
Quantity: 1000 x 1000 ml in HDPE flacon with PP cap
Date of manufacture: 05.2024
Date of expiry: 05.2026
No. of Analytical card: QC-0911-01-015-01/2024

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	12.2
2.3. Relative density	0.99– 1.10	1.04
3. Microbiological quality*		
3.1. TAMC	$< 10^3$ / ml	---
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 _t conforms to the standard	complies
5.2. Benzyl-alcohol	R _t 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

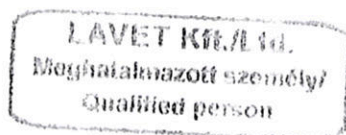
*periodic test, every 10th batch and at least once per year

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, 11/06/2024



dr. Brigitta Szabó

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 Qualified person

LAVET GYÓGYSZERIPARI KFT. / LAVET PHARMACEUTICALS LTD.
 Minőségbiztosítási Osztály / Quality Assurance/ Meghatalmazott személy / Qualified Person
 Gyógyszergyártási engedély száma / Manufacturing authorisation No.: MIA-HU-V-LAVET
 GMP igazolás száma/GMP certificate No.: CG-HU/14V/2023, CG-HU/02V/2024
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