



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 226478**

Product:	ENROFLOXACIN veterinary use
Lot:	226478
Expiry date:	31/08/2026
Reference:	Cumple PhEur11.0
Synonyms:	
Formula:	C <sub>19</sub> H <sub>22</sub> FN <sub>3</sub> O <sub>3</sub>
Molecular weight:	359,4 g/mol

Assay	Result	Specification	
Identification	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	
Impurity A	< 0,2 %	< 0,2%	
Related substances	Conform		
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,01 %	<= 1,0 %	
Sulphated ashes	0,00 %	<= 0,1%	
Assay	99,8 %	98,5 - 101,5 %	
Nitrosamine impurities	Conform	NA	#
Impurity B	< 0,1 %	<= 0,5 %	
Impurity C	< 0,1 %	<= 0,2 %	
Unspecified Impurities	< 0,1 %	<= 0,20 %	
Total impurities	< 0,1 %	<= 1,0 %	
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Chlorobenzene	< 360 ppm	<= 360 ppm	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 17/02/2023

Judgement:  
APPROVED

Responsible: M. Mesa

Technical director: Montserrat Enrique

Manufacturer: F00001 AARTI DRUGS LTD.

Manufacturer batch: ENR-12109336

Product	Name	Capacity	Batch
1112100	ENROFLOXACINO Uso Veterinario	1 kg	226478-P-1
1112100	ENROFLOXACINO Uso Veterinario	1 kg	226478-P-2

1112100	ENROFLOXACINO Uso Veterinario	1 kg	226478-P-3
1112102	ENROFLOXACINO Uso Veterinario	25 kg	226478-T-1
1400064	ENROFLOXACINO Uso Veterinario	100 g	226478-J-1
1400064	ENROFLOXACINO Uso Veterinario	100 g	226478-J-2
1400064	ENROFLOXACINO Uso Veterinario	100 g	226478-J-3

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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