



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 216662

Product:	ENROFLOXACIN veterinary use
Lot:	216662
Expiry date:	01/07/2026
Reference:	Cumple PhEur10.5
Synonyms:	
Formula:	C ₁₉ H ₂₂ FN ₃ O ₃
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		
Heavy metals	<= 20 ppm	<= 20 ppm	#
Loss on drying	0,01 %	<= 1,0 %	
Sulphated ashes	0,01 %	<= 0,1%	
Assay	99,3 %	98,5 - 101,5 %	
Impurity B	<= 0,1 %	<= 0,5 %	
Impurity C	<= 0,1 %	<= 0,2 %	
Unspecified Impurities	<= 0,1 %	<= 0,2 %	
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: 16/12/2021

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00001 AARTI DRUGS LTD.

Manufacturer batch: ENR-12108303

Product	Name	Capacity	Batch
1112100	ENROFLOXACINO Uso Veterinario	1 kg	216662-P-1
1400064	ENROFLOXACINO Uso Veterinario	100 g	216662-J-1

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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