

CERTIFICATE OF ANALYSIS FOR FINISHED PRODUCT

No. 362 / 27.04.2020

NAME AND ADDRESS OF EXPORTING MANUFACTURER  ROMVAC COMPANY S.A. No. 7 Centurii Road, Voluntari, IF-077190, ROMANIA Phone/Fax: (+4) 021 350 3109 / (+4) 021 350 3110 Email: romvac@romvac.ro	MANUFACTURING AUTH. RO 01 / - 27.11.2019	GMP CERTIFICATE Nr.: 63/2019/RO
	BATCH NO. 5	PRODUCT CODE 82590
NAME OF PRODUCT / DOSAGE FORM ENROFLOXAROM 10% Injectable solution	DATE OF MANUFACTURE .04.2020	EXPIRY DATE .04.2022
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REF./ S.O.P. #	TEST	TEST DATES		LIMITS/CRITERIA ADMISSIBILITY	RESULTS	USE CODE S – SATISFACTORY U – UNSATISFACTORY I – INCONCLUSIVE NT – NO TEST
		START	END			
SOP#F3.2.-22.	Appearance	01.04.20	01.04.20	Clear solution	Clear solution	S
SOP#F3.2.-22	Colour	01.04.20	01.04.20	Yellowish	Yellowish	S
SOP#F3.2.-22	Odour	01.04.20	01.04.20	Odourless	Odourless	S
IS 4.1.	pH	01.04.20	01.04.20	11 – 13	12.60	S
IS 4.2.	Identification: Enrofloxacin	01.04.20	01.04.20	Positive	Positive	S
IS 4.3.1	Content in: Enrofloxacin	01.04.20	06.04.20	9.50 – 10.50 g/100 ml.	10.49 g/100 ml.	S
IS 4.1.	Control of microbiological sterility	01.04.20	16.04.20	Sterile	Sterile	S
IS 4.1.	Control of quantity per package	01.04.20	01.04.20	min. 100 ml./vial	Correspond	S

BATCH SIZE			REMARKS
NO. OF COMMERCIAL UNITS(1)	AMOUNT PER COMMERCIAL UNIT (2)	TOTAL (1 x 2)	
409 vials	100 ml	40900 ml	

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

DISPOSITION BY FIRM

☒ ELIGIBLE FOR RELEASE

☐ TO BE REPROCESSED OR RETESTED

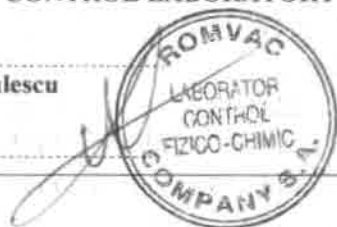
☐ DESTROYED

☐ OTHERS (Explain)

SIGNATURES

HEAD OF QUALITY CONTROL LABORATORY

Biochim. Silvia Stănculescu
 Head of Laboratory
 Date: 27.04.2020



QUALIFIED PERSON

Chim. Carmen DIACONU
Biochim. Andrei George NICA
 Date: 27.04.2020

