



BATCH CERTIFICATE / CERTIFICATE OF ANALYSIS  
RF-781.5

Dopharma Holding B.V.  
Zalmweg 24  
4941 VX Raamsdonksveer  
The Netherlands  
Tel: +31 (0) 162 58 20 00

Productname: DORAFLOX 100MG/ML INJ 100ML  
Lotno: 17/08-09C4  
Production date: 09-2017  
Expiry date: 09-2019  
Storage conditions:

Reg.number(incl. country): HU:2917/2/11 RO:160153  
Ordernumber:

TEST	RESULT	UNIT	SPEC
CHARACTERS Appearance	CONFORM		
PH pH	11.0		>=10.8 <=11.5
DENSITY Density	1.0578	g/ml	>=1.03 <=1.1
CHARACTERS Appearance	CONFORM		
APPEARANCE OF SOLUTION Clarity and opalescence	CONFORM		
Colour	CONFORM		
DENSITY Density	1.0585	g/ml	>=1.03 <=1.1
PH pH	10.9		>=10.8 <=11.5
IDENTIFICATION BENZYL ALCOHOL Identification of benzyl alcohol by HPLC	CONFORM		
ASSAY-LC Benzyl alcohol	7.49	mg/ml	>=7.4 <=8.2
IDENTIFICATION ENROFLOXACIN Identification of enrofloxacin by HPLC	CONFORM		
ASSAY-LC Enrofloxacin	97.09	mg/ml	>=95 <=105
ASSAY Disodium edelate	9.9	mg/ml	>=9.5 <=10.5
VISIBLE PARTICLES Overall performance	CONFORM		
BIOBURDEN TAMC	.0	CFU/100ml	<10
STERILITY Sterility	CONFORM		
EXTRACTABLE VOLUME Extractable volume	102	ml	Microbial growth <=103 >=100
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Release Date: 14-NOV-2017  
Disposition Code: FULL RELEASE  
Released By: J. Rijnen  
Job Title: Q.P.

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control in full compliance with the GMP requirements of the local Regulatory Authority and within the specifications in the Marketing Authorisation in the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. The Batch certificate/certificate of analysis has been produced by a validated Laboratory Information Management System and therefore bears no handwritten signature. GMP Cert.no.: NL/V 14/0005; GMP+:GMP010348.