

FAREVA

FAREVA AMBOISE
 ZONE INDUSTRIELLE
 29 ROUTE DES INDUSTRIES
 37530 POCE SUR GISSE - FRANCE
 TEL 33 2 47 23 77 78
 FAX 33 2 47 23 79 80

FAREVA AMBOISE was formerly known as Pfizer PGM

Certificate of Analysis

Material Name: ADVOCIN 180 INJ 100ML B1 HUN
 Material Code: 0522HUN

Lot Number: A562511
 Specification Name: 00R508057(17-05-2007)-100ML
 Date of Manufacture: APR. 14, 2015
 Expiration Date: MAR. 31, 2017

TEST	Limit	Result
Identity (HPTLC)	Retention factor comparable to a working standard of Danofloxacin Mesylate	MEETS TEST
Sterility	MEETS TEST	MEETS TEST
Appearance	Medium yellow to amber solution essentially free from foreign matter.	MEETS TEST
pH	7.2-7.8	7.5
Monohydroxyglycerol content	4.5-5.5 mg/ml (90-110% of label claim)	4.9 mg/ml
Bacterial endotoxins	150 IU/ml Maximum	<= 113 IU/ml
Extractable volume	MEETS TEST	MEETS TEST
Danofloxacin content (HPLC)	171-189 mg/ml (95-105% of label claim)	180 mg/ml
Identity (HPLC)	Retention time comparable to a working standard of Danofloxacin mesylate	MEETS TEST
Phenol content	2.38-2.63 mg/ml (95-105% of label claim)	2.47 mg/ml
Specified Degradation Products: CP-74,416	0.6 % maximum	0.0 %
Specified Degradation Products: CP-83,088	0.4 % maximum	0.0 %
Specified Degradation Products: CP-102,446	0.4 % maximum	0.0 %
Unspecified Degradation Product	0.4 % maximum each	0.0 %
Total Degradation Products	1.0 % maximum	0.0 %

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 Hungary or product specification file for investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

QUALIFIED PERSON ASSESSMENT.

Electronic Signature: Christine LEVY Lot Release Local Timestamp: 03-JUN-2015 10:04:27

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies. Distribution to third parties without prior permission is prohibited.

Kód: 0522HUN020

Instance Name: LICAFREP

Diagnóza: FN-2X15302131 Vevő: Alpha-Vet 6000 File név: PNO0008421 Egyedi sorozám: PNO000075016 7 másolat
 Szállító: Zoetis Hungary Kft. Oldal/Lap: 1/1 Anyaglap: PNO251/10
 Az engedélyezett csomag címkéi megelelnek! Nyomtatás dátuma: 2015.07.23

CertEx v3.03a