

FAREVA AMBOISE was formerly known as Pfizer PGM

Certificate of Analysis

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

Lot Number: A488815  
 Specification Name: 00RS08057(17-05-2007)-100ML  
 Date of Manufacture: OCT, 06, 2014  
 Expiration Date: SEP, 30, 2016

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
Monothioglycerol content	4.5-5.5 mg/ml (90-110% of label claim)	5.0 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)	179 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)	2.50 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 ASSESMENT.

Electronic Signature: Christine LEVY Lot Release Local Timestamp: 24-NOV-2014 10:30:18