FAREVA AMBOISE
ZONE INDUSTRIELLE
29 ROUTE DES INDUSTRIES
37530 POCE SUR CISSE - 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: DRAXXIN 100ML B1 HUN/EST/LTU
Material Code: 0672HUN

Lot Number: A578004
Specification Name: 00RS65327(04-2003)-100ML
Date of Manufacture: JUN. 08, 2015
Expiration Date: MAY. 31, 2018

TEST	Limit	Result
Appearance	Clear, colorless to slightly yellow solution essentially free from foreign matter.	MEETS TEST
Particulate Contamination: Visible Particles	Vial is essentially free of visible foreign matter.	MEETS TEST
Monothioglycerol	90% to 110% of label claim	96 %
pH	5.1 to 5.7	5.5
Sterility	MEETS TEST	MEETS TEST
Identity (TLC)	Mobilities (Rf) of CP-472,295 and CP-547,272 are the same as those of the identity standard.	MEETS TEST
Assay (HPLC) (CP-472,295+CP-547,272)	95% to 105% of label claim	100 %
Identity CP-472,295 (HPLC)	Peak retention time of CP-472,295 is the same as that of the identity standard.	MEETS TEST
Identity CP-547,272 (HPLC)	Peak retention time of CP-547,272 is the same as that of the identity standard.	MEETS TEST
%CP-547,272 Ratio Relative to Total Tulathromycin	8% to 13%	11 %
Specified Degradation Products CP-60,300	0.8% maximum	0.0 %
Specified Degradation Products CP-651,595	0.8% maximum	0.1 %
Unspecified Degradation Products	<1.0% each	0.0 %
Total Degradation Products	2.0% maximum	0.1 %
Extractable volume	MEETS TEST	MEETS TEST
Bacterial endotoxins	200 IU/ml maximum	<= 100 IU/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 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.

For Hungary only :

Node: emaodcs059

Instance Name: LICRFR8P

FAREVA

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QUALIFIED PERSON ASSESMENT.

Electronic Signature: Helene RIVARD Lot Release Local Timestamp: 04-AUG-2015 09:55:34

Instance Name: LICRPT6P