

FAREVA AMBOISE was formerly known as Pfizer PGM

Certificate of Analysis

Material Name: DRAXXIN 50ML B1 HUN/EST
 Material Code: 0671HUN

Lot Number: A624418
 Specification Name: 00RS65327(04-2003)-50ML
 Date of Manufacture: NOV. 02, 2015
 Expiration Date: OCT. 31, 2018

<u>TEST</u>	<u>Limit</u>	<u>Result</u>
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	97 %
pH	5.1 to 5.7	5.4
Sterility	MEETS TEST	MEETS TEST
Assay (HPLC) (CP-472,295+CP-547,272)	95% to 105% of label claim	99 %
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	0.0 %
Unspecified Degradation Products	<1.0% each	0.0 %
Total Degradation Products	2.0% maximum	0.0 %
Identity (TLC)	Mobilities (Rf) of CP-472,295 and CP-547,272 are the same as those of the identity standard.	MEETS TEST
Extractable volume	MEETS TEST	MEETS TEST
Bacterial endotoxins	200 IU/ml maximum	< 50 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 :

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QUALIFIED PERSON ASSESMENT.

Electronic Signature: Romain CHAUVET Lot Release Local Timestamp: 30-NOV-2015 08:47:51
