

FAREVA AMBOISE was formerly known as Pfizer PGM

Certificate of Analysis

Material Name: ANTIROBE HARD CAPSULES 75MG B60 HUN/EST/LTU
 Material Code: 2217HUN

Lot Number: A460211
 Specification Name: 12RS60375(04-04-2013)
 Date of Manufacture: MAY, 30, 2014
 Expiration Date: APR, 30, 2019

TEST Description	Limit	Result
	Hard opaque gelatin capsules, size N°3, with green cap and white body, overprinted in black with Pfizer logo and the code "CLIN 75" and containing a white powder.	MEETS TEST
Identification HPLC (Clindamycin)	Retention time similar to the standard	MEETS TEST
Assay of Clindamycin	95 - 105% of Label Claim	101 %
Content uniformity (HPLC)	Acceptance value (AV) <= 15.0	3.9
Water content (KF)	Not more than 7.0%	4.9 %
Disintegration (water, 37°C with disc)	Maximum 30 minutes	< 30 min
7-Epiclindamycin	Not more than 2.0%	0.4 %
Clindamycin B	Not more than 2.0%	0.5 %
Other impurities each	Not more than 1.0%	0.2 %
Total related impurities	Not more than 4.5%	1.3 %

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:

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: 21-OCT-2014 09:28:10

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Model: ameboc026

Invoice Name: LIORP60P

Diszpó: FN-ZX15001848 Szállító: Ecotis Hungary Rft. Az eredetiről készült hiteles másolat. Niszárolag a kék tintával szignált másolat tekintendő hitelesnek!	Vevő: Alpha-Vet 8000 File név: PNO0008114 Oldal/Lap: 1 / 1 Nyomtatás dátuma: 2015.05.18	Egyedi sorozám: PNO000074564 Anyaglap: PNO454/14 2. másolat
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