

FAREVA AMBOISE was formerly known as Pfizer PGM

**Certificate of Analysis**

Material Name: ANTIROBE HARD CAPSULES 75MG B80 HUN  
 Material Code: 2217HUN

Lot Number: A549312  
 Specification Name: 12RS80375(04-04-2013)  
 Date of Manufacture: MAR. 18, 2015  
 Expiration Date: FEB. 29, 2020

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	99 %
Content uniformity (HPLC)	Acceptance value (AV) <= 15.0	4.3
Water content (KF)	Not more than 7.0%	5.2 %
Disintegration (water, 37°C with disc)	Maximum 30 minutes	4 min
7-Epiclindamycin	Not more than 2.0%	0.4 %
Clindamycin B	Not more than 2.0%	0.6 %
Any other impurity	Not more than 1.0%	0.2 %
Total	Not more than 4.5%	1.5 %

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: Beatrice CAZEAUX Lot Release Local Timestamp: 22-APR-2015 09:57:14