PFIZER PGM
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

Certificate of Analysis

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

Lot Number: A415713
Specification: 12RS80375 (02-06-2006)
Date of Manufacture: JAN. 08, 2014
Expiration Date: DEC-2018

TEST	Limit	Result
Description	Hard gelatin capsule (green / white) identified "Clin 75" and "Pfizer" containing a white powder	MEETS TEST
Identification HPLC (Clindamycin)	Retention time similar to the standard	MEETS TEST
Water content (KF)	7.0% maximum	4.7 %
Average weight	239 - 292mg	266 mg
Identified impurities each	2.0% maximum	0.5 %
Unidentified impurities each	2.0% maximum	0.2 %
Total related impurities	4.5% maximum	1.4 %
Dissolution rate	The requirements are met if the quantities of active ingredient dissolved after 30 minutes conform to the acceptance table below where Q=75%. Continue testing through the three stages unless the results conform either Stage 1 or Stage 2. The quantity Q is the amount dissolved expressed as a percentage of label claim. Stage S1 Number Tested 6 Acceptance Criteria : Each unit is not less than Q+5%. Stage S2 Number Tested 6 Acceptance Criteria : Average of 12 units (S1+S2) is equal to or greater than Q, and no unit is less than Q-15%. Stage S3 Number Tested 12 Acceptance Criteria : Average of 24 units (S1+S2+S3) is equal or greater than Q, and not more than 2 units are less than Q-15% and no unit is less than Q-25%.	98 %
Assay of Clindamycin	95% - 105% of label claim	98 %
Content uniformity	MEETS TEST	MEETS TEST

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

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Diszpó: PN-ZA14000453 Vevõ: TolnAgro Kft 7100 File név: PN00007837 Egyedi sorszám: PN000007131 5 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0166/14
Az eredetivel megegyezõ elektronikus másolat a(z):
Dr. Nagy Edith min.bizt.gyógyszerész által küldve. Nyomtatás dátuma: 2014.05.22 CertEx v 3.03

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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 ASSESSMENT.

Electronic Signature: Christine LEVY Lot Release Local Timestamp: 11-MAR-2014 09:30:52

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