

FAREVA AMBOISE was formerly known as Pfizer PGM

Certificate of Analysis

Material Name: ANTIROBE HARD CAPSULES 25MG B80 HUN
 Material Code: 2203HUN

Lot Number: A509010
 Specification Name: 12RS80325(02-06-2006)
 Date of Manufacture: NOV. 21, 2014
 Expiration Date: OCT. 31, 2019

TEST	Limit	Result
Description	Hard gelatin capsule (yellow / white) identified "Clin 25" 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	5.5 %
Average weight	225 - 275 mg	250 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%.	96 %
Assay of Clindamycin	95% -105% of label claim	102 %
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 requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of Hungary

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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: 13-FEB-2015 10:18:53
