

Certificate of Compliance



Latina S.r.l.

Product: ORBENIN DC 24X4,5ML H

Lot number: 46939302

Page 1 of 2

Inspiring Partner for Efficient Solutions

S.S. 156 Km 47,600 - 04100 Borgo San Michele (Latina) Italy
Phone +39 0773 4251 Fax +39 0773 250920
www.haupt-pharma.com

Product ORBENIN DC 24X4,5ML H

Lot number 46939302

Manufacturing date 06/2014
Expiration date 06/2018

Test	Specifications	Results	Methods
Appearance	White-off white susp. (note)	PASS	A 28.01
Extract. Mass	Meets Test Ph.Eur. for Intram.	PASS	PH. EUR.
Id. Cloxacillin	Positive	PASS	SAM A 509
Cloxacil.Conten	15.8%-17.5% w/w as free acid	15.9 %	SAM458/454
Water Content	1.5 % max	0.5 %	EP 2.5.12
Sterility	Sterile	PASS	EP 2.6.1

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with EU-GMP.
This certificate was created by a validated system and is valid without manual signature.

Batch Released

Date : Sep 4, 2014

Haupt Pharma Latina S.r.l. was formerly known as Pfizer Italia S.r.l.

Certificate of Compliance

Product: ORBENIN DC 24X4,5ML H

Lot number: 46939302

Page 2 of 2



Inspiring Partner for Efficient Solutions

S.S. 156 Km 47,600 - 04100 Borgo San Michele (Latina) Italy
Phone +39 0773 4251 Fax +39 0773 250920
www.haupt-pharma.com

User	Reason	Date (CET)
Rossi Vincenzo (Quality Control Manager & QP)	Approve final document	9/9/14 10:27 AM