

# Certificate of Compliance

aeno a

Product: CONVENIA 80MG/ML INJ H/P

Lot number: 5S019904

Page 1 of 2

Haupt Pharma Latina S.r.L.  
S.S. 156 Km 47,500 - 04100 Borgo San Michele (Latina) Italy  
Phone +39 0773 4251 Fax +39 0773 250920

**Product** CONVENIA 80MG/ML INJ H/P

**Lot number** 5S019904  
Diluent Lot No. V3A50

**Manufacturing date** 02-2015  
**Expiration date** 01-2018

Test	Specifications	Results	Methods
Reconst. Solut.	Clear yellow-Reddish brown sol	PASS	A 28.01
Appearance	off-white to yellow powder	PASS	A 28.0
Id. Cefovecin	Meets test	PASS	C 35.2
Unspecif. degr.	1.0% max, each	PASS	
UK-287,076	2.5% max	0.3 %	
H-49692-1	0.7% max	0.2 %	
Tot. degrad. pr	3.0% max	1.5 %	
Cefovecin HPLC	95-105% of LC (label instruct)	102 %	
Identity (TLC)	Meets test	PASS	C 35.3
Foreign Matter	practic. free from particles	PASS	EP 2.9.20
id methylparab.	Meets test	PASS	M 40.86
Id propylparab.	Meets test	PASS	
methylparaben	90-110% of LC (label instruct)	98 %	
propylparaben	90-110% of LC (label instruct)	95 %	
Reconstit. Time	less than 3.0 min	1.0 min	R 9.0
Sterility	sterile	PASS	S 16.964
Water Content	0.8 % max	0.3 %	W 1.87
pH	6.2 - 7.5	6.8	P 24.0
Diluent certificate of analysis corresponds to the specifications			
50-RS-35199 (see attached)			

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 : Oct 6, 2015**

printed by Daniela Salvini on Thu Oct 08 14:48:55 CEST 2015

Deutsche Bank AG  
Acci No. 820911  
ABI 03104  
CAB 03207

IBAN: IT68831090320700000820911  
BIC: DEUTITM1599

Commercial Register Latina 174220  
VAT: IT0638593090

An enterprise of the  
Aeno Group

Diszpó: PN0081705421 Vevő: DR SZEKELY KFT Erd File név: PN00008560 Egyedi sorszám: PN0000080797 3 másolat  
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0401/15  
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2016.03.21  
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

**CertEx v3.03a**

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User	Reason	Date (CET)
Rossi Vincenzo (Quality Control Manager & QP)	Approve final document	10/7/15 2:51 PM

Printed by Daniela Salvini on Thu Oct 08 14:48:55 CEST 2015

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