

Certificate of Compliance



Latina S.r.l.

Product: CONVENIA 80MG/ML INJ H/P

Lot number: 3S088800

Page 1 of 2

Inspiring Partner for Efficient Solutions

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DILUENT LOT N.: V3A36

Product CONVENIA 80MG/ML INJ H/P

Lot number 38088800

Manufacturing date 07-2013
Expiration date 06-2016

Test	Specifications	Results	Methods
Reconst. Solut.	Clear yellow-reddish brown sol	PASS	A 23.01
Appearance	off-white to yellow powder	PASS	A 23.0
Id. Cefovecin	Meets test	PASS	C 35.2
Unspecif. degr.	1.0% max, each	PASS	
UK-287,076	2.5% max	0.7 %	
H-49692-1	0.7% max	0.2 %	
Tot. degrad. pr	3.0% max	1.4 %	
Cefovecin HPLC	95-105% of LC (label instruct)	102 %	
Identity (ILC)	Meets test	PASS	C 35.3
Foreign Matter	practic. free from particles	PASS	EP 2.9.20
Id methylparab.	Meets test	PASS	C 186.6
Id propylparab.	Meets test	PASS	
methylparaben	90-110% of LC (label instruct)	95 %	
propylparaben	90-110% of LC (label instruct)	101 %	
Reconstit. Time	less than 3.0 min	1.0 min	R 9.0
Sterility	sterile	PASS	S 16.964
Water Content	0.8 % max	0.5 %	W 1.0
pH	6.2 - 7.5	6.7	P 24.0
Diluent certificate of analysis corresponds to the specifications 00-R5-35129 (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 : Dec 20, 2013

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

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Cassa di Roma SpA
Aut. No. 020911
ABI 03104
CAB 03207

IBAN: IT660310403207000000000011
BIC: DEUTIT33HAN

Commercial Register Latina 174220
VAT: IT06360530000

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Haupt Pharma Group

Diszpó: PN-ZA14000589 Vevő: Alpha- Vet Kft File név: PN00007769 Egyedi sorszám: PN0000071651 23 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0041/14
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2014.07.04
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v3.03

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Page 2 of 2



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User	Reason	Date (CET)
Rossi Vincenzo (Quality Control Manager)	Approve final document	12/20/13 5:19 PM

Printed by Daniela Salvini on Fri Dec 20 17:38:02 CET 2013

Diszpó: PN-ZA14000589 Vevő: Alpha- Vet Kft.
 Szállító: Zoetis Hungary Kft.
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 Kiszárolag a kek tincavai esignált másolat tekintendő hitelesnek!
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