

Certificate of Compliance/Analysis



Product: CONVENIA 80MG/ML INJ H/P

Lot number: 30635813

Page 1 of 2

Haupt Pharma Latina S.r.l.
S.S. 156 Km 47,600 - 04100 Borgo San Michele (Latina) Italy
Phone +39 0773 4251 Fax +39 0773 250920

Product CONVENIA 80MG/ML INJ H/P

Lot number 30635813

Diluent Lot No. V3A71

Manufacturing date 06/2018

Expiration date 05/2021

Test	Specifications	Results	Methods
Reconst. Solut.	Meets Test	PASS	A 28.01
Appearance	Meets test	PASS	A 28.0
Id. Cefovecin	Meets test	PASS	C 35.2
Degrad. product	Individual Unpsec: 1.0% max	PASS	
Degrad. product	UK-287,076: 1.8% max	0.0 %	
Degrad. product	H-49692-1: 0.7% max	0.0 %	
Degrad. product	Total: 3.0% max	0.5 %	
Cefovecin sodiu	95-105% of LC	100 %	
Identity (TLC)	Meets test	PASS	C 35.3
Part.MatterVis.	Meets Test	PASS	EP 2.9.20
Id methylparab.	Meets test	PASS	M 40.86
Id propylparab.	Meets test	PASS	
Methylparaben	Average is 90-110% of LC	97 %	
Propylparaben	Average is 90-110% of LC	96 %	
Reconstit. Time	less than 3.0 min	0.3 min	R 9.0
Sterility	sterile	PASS	S 16.964
Water Content	0.8 % max	0.2 %	W 1.87
pH	6.2 - 7.5	6.9	P 24.0
Diluent certificate of analysis corresponds to the specifications 00-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 : Mar 27, 2019

printed by Destro Maria Fedele on Tue Apr 02 09:45:43 CEST 2019

Deutsche Bank SpA
Acct No. 820911
ABI 03104
CAB 03207

IBAN
IT86NC310403207000000820911
BIC
DEUTITM1588

Commercial Register Latina 174220
VAT: IT06385930990

An enterprise of the
Aenova Group

Diszpó: PN0806279899 Vevő: DR SZEKELY KFT Erd File név: PN00010004 Egyedi sorszám: PN0000090651 19 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0120/19
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2019.05.28
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v3.10

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User	Reason	Date (CET)
Rossi Vincenzo (Quality Control Manager & QP)	Approve final document	4/1/19 12:00 PM

printed by Destro Maria Fedele on Tue Apr 02 09:45:43 CEST 2019

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