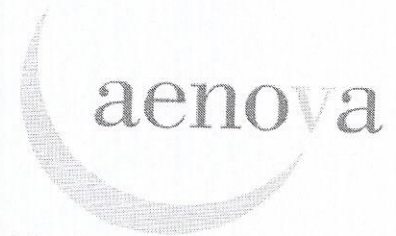


Certificate of Compliance/Analysis



Product: CONVENIA 80MG/ML INJ H/P

Lot number: 38113002

Page 1 of 2

Haupt Pharma Latina S.r.L.
S.S. 156 Km 47,800 - 04100 Borgo San Michele (Latina) Italy
Phone +39 0773 4251 Fax +39 0773 250920

Product: CONVENIA 80MG/ML INJ H/P
Lot number: 38113002 MFG: 06/2019 EXP: 05/2022
Package: 10 ml vial INJECTABLE
Strength/Potency: 80mg/ml
Destination country Hungary Portugal
Aut.nr EU/2/06/059/001
Diluent Lot No. V3A74

Test	Results	Methods
Specifications		
Reconst. Solut. Meets Test		
Appearance Meets test	PASS	A 28.01
Id. Cefovecin Meets test	PASS	A 28.0
Degrad. product Individual Unpsec: 1.0% max	PASS	C 35.2
Degrad. product UK-287,076: 1.8% max	PASS	C 35.2
Degrad. product H-49692-1: 0.7% max	0.0 %	C 35.2
Degrad. product Total: 3.0% max	0.4 %	C 35.2
Cefovecin sodiu 95-105% of LC	0.4 %	C 35.2
Identity (TLC) Meets test	100 %	C 35.2
Part.MatterVis. Meets Test	PASS	C 35.3
Id methylparab. Meets test	PASS	EP 2.9.20
Id propylparab. Meets test	PASS	M 40.86
Methylparaben Average is 90-110% of LC	PASS	M 40.86
Propylparaben Average is 90-110% of LC	101 %	M 40.86
Reconstit. Time less than 3.0 min	100 %	M 40.86
Sterility sterile	1.0 min	R 9.0
Water Content 0.8 % max	PASS	S 16.964
pH 6.2 - 7.5	0.3 %	W 1.87
	6.7	P 24.0

printed by Daniela Salvini on Fri Dec 18 14:03:17 CET 2019

Deutsche Bank S.p.A.
ALC1 NIK 820911
ABI 03104
IAB 03207

IBAN
IT88431040320700000820911
BIC
DEUTIT33HAN

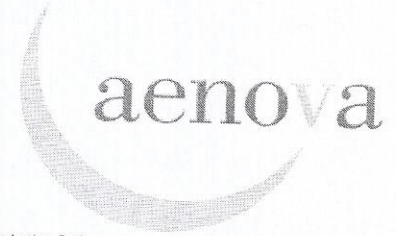
Commercial Register of Latina 174220
VAT: IT06785030980

An enterprise of the
Aenova Group

Diszpó: PN0808416951 Vevő: DR SZEKELY KFT Erd File név: PN00010346 Egyedi sorszám: PN0000093174 5 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0026/20
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2020.02.27
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v3.10

Certificate of Compliance/Analysis



Product: CONVENIA 80MG/ML INJ H/P

Lot number: 38113002

Page 2 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

Manufacturing/Quality site	Address	Auth. Nr
PFIZER - KALAMAZOO (US) HAUPT-PHARMA LATINA	7000 PORTAGE ROAD S.S. 156 KM 47.600	3010146372 26/2018/V
Manufacturing/Quality site	Certificate of GMP compliance	
PFIZER - KALAMAZOO (US) HAUPT-PHARMA LATINA	UK GMP 6268 Insp GMP 6579/6048 (EudraGMP) NBF/47/2018/V	(EudraGMP)

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. Deviations, when occurred, have been investigated and resolved successfully.

Batch Released

Date : Dec 11, 2019

User	Reason	Date (CET)
Rossi Vincenzo (Quality Control Manager & QP)	Approve final document	12/13/19 12:07 PM

This certificate was created by a validated system and is valid without manual signature

printed by Daniela Salvini on Fri Dec 13 14:03:17 CET 2019

Diszpó: PN0808416951 Vevő: DR SZEKELY KFT Erd File név: PN00010346 Egyedi sorszám: PN0000093174 5 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 2 Anyaglap: PN0026/20
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2020.02.27
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v3.10