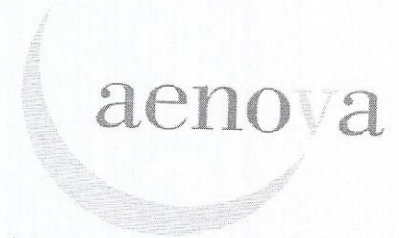


Certificate of Compliance/Analysis



Product: CONVENIA 80MG/ML INJ H/P
 Lot number: 38526702

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: 38526702 MFG: 08/2019
 Package: 10 ml vial INJECTABLE
 Strength/Potency: 80mg/ml
 EXP: 07/2022
 Destination country Hungary Portugal
 Aut.nr EU/2/06/059/001
 Diluent Lot No. V3A76

Test Specifications	Results	Methods
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	0.8 %	C 35.2
Identity (TLC) Meets test	103 %	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	100 %	M 40.86
Reconstit. Time less than 3.0 min	97 %	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	0.4 %	W 1.87
	6.8	P 24.0

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Deutsche Bank SpA
 Acct No 820911
 ABI 03104
 CAB 03207

IBAN:
 IT88N310403207000000820911
 BIC:
 DEUTITM1588

Commercial Register Latina 174220
 VAT: IT06385830080

An enterprise of the
 Aenova Group

Diszpő: PN0808995074 vevő: DR SZEKELY KFT Erd File név: PN00010412 Egyedi sorszám: PN0000094372 14 másolat
 Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0097/20
 Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2020.05.07
 Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v3.10

Certificate of Compliance/Analysis



Product: CONVENIA 80MG/ML INJ H/P
 Lot number: 38526702

Page 2 of 2

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

Diluent certificate of analysis corresponds to the specifications

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 : Feb 20, 2020

User	Reason	Date (CET)
Rossi Vincenzo (Quality Control Manager & QP)	Approve final document	2/25/20 9:13 AM

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

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