Hoge Wei 10 - B-1930 Zaventem (Belgium)
RPR Brussel - RPM Bruxelles
B.T.W.-T.V.A.-BE-0478 242 365
☎ +32-2-722 02 11
🖷 +32-2-721 19 25

Pfizer Service Company B.V.B.A.-S.P.R.L.

Certificate of EU release

Product	NAXCEL 200MG/ML 100ML
Manufacturing site	PGM – Kalamazoo, USA
Lot number	4F0213
Manufacturing date	02/2014
Expiry date	01/2016
Importing country	Poland - Hungary - Portugal
Quantity released	3498

This is to confirm that the above batch is released for sale in accordance with the Marketing Authorization and Council Directive 2001/83/EC as amended.
The product has been manufactured, packaged and tested in full compliance with current GMP requirements of the local Regulatory Authorities.
The Certificate of Compliance and the Certificate of Analysis coming from the manufacturer of the above mentioned batch have been reviewed.
The certificate of the EU test laboratory (~~Pfizer-Puurs, Belgium~~) has been reviewed.
The product has been received and stored according to the labeled conditions.
Temperature deviations, if any, have been reviewed and approved by the manufacturer.
Labeling is conform to the registration file.
This batch is judged acceptable and released to the market.

Date of EU release : 05/08/2014

~~A. Bricteux~~ Michel Forer
Deputy *Qualified Person*
~~Pfizer Service Company (PSC)~~
Zoetis BE

ZOETIS MANUFACTURING & RESEARCH SPAIN, S.L. (Formerly PFIZER OLOT, S.L.)
Ctra. Camprodon, s/n Finca La Riba
17813 VALL DE BIANYA (Girona)
T +34 972 29 00 01
F +34 972 29 01 02

CERTIFICATE OF ANALYSIS

zoetis

PRODUCT: Naxcel 200 MG/ML100ML Hungary

SFP BATCH NUMBER: 4S0145

FP BATCH NUMBER: 4F0213

SHIPMENT NUMBER: 9674461

	Results	Specification
Appearance	Meets test	Opaque suspension
Identification (HPLC)	Positive	The retention time of the major peak in the sample preparation corresponds to the Ceftiofur peak in the standard preparation
Identification (IR)	Positive	Spectrum of the sample preparation comparable to spectrum of the reference standard
Ceftiofur content	197 mg/ml	190 - 210 mg/ml
Resuspendability	Meets test	Not more than 60 seconds
Impurities (HPLC)		
Delta-2-Anti Oxime	1.9 %	Not more than 3.0%
Delta-3-Syn-oxime	0.3 %	Not more than 1.0%
Ceftiofur fuoric amide	0.2 %	Not more than 1.0%
Individual Unspecified Impurity	0.1%	Not more than 1.0%
Impurities Total	3.0 %	Not more than 4.0%
Impurities corrected (SEC-HPLC)	1.1 %	Not more than 4.0%
Drug release (t=60min)	82 %	1 hour: Between 68 and 90%
Content Uniformity	Meets test	Meets test
Endotoxins	< 0.76 EU/mg	Not more than 0.76 EU/mg of Ceftiofur
Volume	Meets test	Meets test

CONCLUSIONS:

All documentation has been reviewed and found in compliance with specification.

Explanations for Out of Specifications (OOS) investigations, if any, are attached.

No OOS investigations

This Certificate of Analysis does not constitute product release.

Quality Control Manager: J.Homs

Date: 30JUL14

zoetis

Ctra. Camprodon, s/n
Vall de Bianya - Girona