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**zoetis**

### Certificate of EU release

<b>Product</b>	Naxcel 100 MG/ML 100 ML
<b>Manufacturing site</b>	Kalamazoo, USA
<b>FG lot number</b>	4F0626
<b>Manufacturing date</b>	05/2014
<b>Expiry date</b>	04/2016
<b>Importing country</b>	Portugal - Poland - Hungary
<b>Quantity released</b>	2559

I hereby certify that the above information is authentic and accurate.  
This batch of product has been manufactured, including packaging and quality control in full compliance with the GMP requirements of the local regulatory authority and with those stipulated in the Marketing Authorization.

Date of EU release: 14/10/2014

**Deputy Qualified Person**  
Zoetis Belgium S.A.



Michel Forner

**CERTIFICATE OF ANALYSIS**



**PRODUCT:** Naxcel 100 MG/ML 100ML Portugal, Poland and Hungary

**SFP BATCH NUMBER:** 4S0404

**FP BATCH NUMBER:** 4F0626

**SHIPMENT NUMBER:** 9983469, 5699, 9983470 and 9983471

	Results	Specification
<b>Appearance</b>	Meets test	Opaque suspension
<b>Identification (HPLC)</b>	Positive	The retention time of the major peak in the sample preparation corresponds to the Ceftiofur peak in the standard preparation
<b>Ceftiofur content</b>	101.9 mg/ml	95.0 – 105.0 mg/ml
<b>Resuspendability</b>	Meets test	Not more than 60 seconds
<b>Impurities (HPLC)</b>		
<b>Delta-2-Anti Oxime</b>	2.0 %	Not more than 4.0%
<b>Individual Unspecified Impurity</b>	0.3 %	Not more than 1.0%
<b>Impurities Total</b>	3.7 %	Not more than 5.3%
<b>Impurities corrected (SEC-HPLC)</b>	2.2 %	Not more than 6.0%
<b>Drug release (t=120min)</b>	85%	120 min: Between 64 and 90%
<b>Endotoxins</b>	< 1.0 EU/mg	Not more than 1.0 EU/mg of Ceftiofur
<b>Volume</b>	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:**

**Date:** 10OCT2014

**J.Homs**



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