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zoetis

Certificate of EU release

Product	EXCENEL SP 4 G
Manufacturing site	Zoetis Kalamazoo, USA
FG lot number	4F1663
Bulk lot number	4S0963
Manufacturing date	11/2014
Expiry date	10/2017
Importing country	Hungary
Quantity released	246

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: 03/04/2015

Deputy Qualified Person
Zoetis Belgium S.A.



CERTIFICATE OF ANALYSIS



PRODUCT: EXCENEL 4G Hungary

SFP BATCH NUMBER: 4S0963

FP BATCH NUMBER: 4F1663

SHIPMENT NUMBER: 710407

	Results	Specification
Appearance	Meets test	Dry cake: A white to light brown freeze-dried solid
Appearance Reconstituted	Positive	A clear, brownish-yellow solution
Clarity of solution	Positive	Clear
Water content	0.5 %	Not more than 3.0%
Ceftiofur content	50.8 mg/ml	47.5 – 52.5 mg/ml
Identification (IR)	Positive	Spectrum conforms to reference standard or reference spectrum
Identification (HPLC)	Positive	The retention time of the major peak in the sample preparation corresponds to the Ceftiofur peak in the standard preparation
Impurities corrected	3.8 %	Not more than 8.6%
Impurities		
Delta-2-Anti- Oxime	0.3 %	Not more than 1.0%
Delta-3-syn- Oxime	0.1 %	Not more than 0.5%
Unspecified Impurity	0.1 %	Not more than 1.0%
Impurities Total	1.2 %	Not more than 3.3%
pH	7.1	5.5 – 7.5
Reconstitution Time	Meets test	Not more than 3 minutes
Uniformity of Mass	Meets test	Meets current Ph. Eur. requirements
Sterility	Sterile	Sterile
Endotoxins	< 0.25 EU/mg	Not more than 1.0 EU/mg of Ceftiofur

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: 26MAR15

