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zoetis


Certificate of EU release

Product	EXCENEL FLOW 50MG/ML 100 ML
Manufacturing site	Kalamazoo, USA
FG lot number	4F0266
Manufacturing date	11/2013
Expiry date	10/2015
Importing country	HUNGARY
Quantity released	899

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: 24 JUNI 2014

Deputy Qualified Person
Zoetis Belgium S.A.



MICHEL FORIER

CERTIFICATE OF ANALYSIS



PRODUCT: EXCENEL FLOW 50MG/ML 100ML Hungry
SFP BATCH NUMBER: 3S1234
FP BATCH NUMBER: 4F0266
SHIPMENT NUMBER: 9717993

	Results	Specification
Appearance	Meets test	Opaque suspension, white to off-white (including shades of yellow and pink)
Identification (UHPLC)	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 conforms to reference standard or reference spectrum
Ceftiofur content	48.2 mg/ml	47.5 – 52.5 mg/ml
Water content	0.8 %	0.5% - 0.9%
Resuspendability	Meets test	Not more than 40 seconds
Impurities (UHPLC)		
Delta-2-Anti Oxime	1.6 %	Not more than 4.2%
Unidentified A	0.2 %	Not more than 1.4%
Individual Unspecified Impurity	0.2 %	Not more than 1.0%
Impurities Total	2.8 %	Not more than 7.2%
Impurities corrected (HPLC)	3.2 %	Not more than 8.3%
Endotoxins	Meets test	Not more than 1.0 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:

Date: 11JUN14


J.Homs



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