ZOETIS BELGIUM SA
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zoetis

Certificate of EU release

Product	Draxxin 25mg/ml 100ml
Manufacturing site	Pfizer Guarhulhos, Brazil
FG lot number	504DR502BD
Manufacturing date	05/2015
Expiry date	05/2018
Importing country	Finland - Hungary
Quantity released	1123

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: 01 OKT. 2015

Deputy Qualified Person
Zoetis Belgium S.A.

Certificate of Analysis

ZOETIS BELGIUM SA
PREVIOUSLY NAMED
PFIZER ANIMAL HEALTH SA
RUE LAID BURNIAT, 1
B-1348 LOUVAIN-LA-NEUVE
BELGIUM
AUTHORIZATION NUMBER 419 V

DRAXXIN INJ 100 ML
Batch Number: 504DR502BG

OOS investigations: N/A
Shipment number :215099

Country: - NA

TEST / DATA	RESULT	UNIT	SPECIFICATION
Description	Conform	N/A	Clear colorless to slightly yellow solution essentially free from foreign matter
Particulate contamination	Conform	N/A	Vial is essentially free of visible foreign matter
Identification of Tulathromycin by TLC	Conform	N/A	Mobilities (Rf) of CP-472,295 and CP-547,272 are the same as those of the identity standard
Identification of Tulathromycin by HPLC	Conform	N/A	Peak retention times of CP-472,295 and CP-547,272 are the same as those of the identity standards
Tulathromycin-HPLC Content	100	%	95<=x<=105 of label claim
Percentage of CP-547,272 ratio relative to total Tulathromycin	11	%	8<=x<=13
Degradation product CP-60,300	0.0	%	Maximum 0.8
Degradation product CP-651,595	0.0	%	Maximum 0.8
Unspecified degradation products	0.0	%	<1.0 each
Total degradation products	0.0	%	Maximum 2.0
Volume in container	Conform	N/A	Not less than the labeled volume
Monothioglycerol content	97	%	90<=x<=110 of label claim
pH	5.3	N/A	5.1<=x<=5.7
Sterility	No growth	N/A	No growth
Endotoxin content	< 5	EU/ml	Maximum 50

All documentation has been reviewed and found to be in compliance with specification. Explanations for Out Of Specification (OOS) investigations or regulatory deviations, if any, are attached. This Certificate of Analysis does not constitute product release

Electronic Signature: Hélène Vergnet Lot Release Local Timestamp: 30-SEP-2015 12:44:27 Server Timestamp: 30-SEP-2015 12:44:22

Document approved electronically through a validated system hence no handwritten signature needed.