

Certificate of EU release

Product	STRONGHOLD 15 MG X 3 tubes
Manufacturing site	Zoetis Kalamazoo, USA
FG lot number	3S1147
Bulk lot number	3F15352
Manufacturing date	10/2013
Expiry date	09/2016
Importing country	Hungary / Estonia / Lithuania
Quantity released	2829


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: 30/06/2014

Deputy Qualified Person
Zoetis Belgium S.A.



Michel Foneri.

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

STRONGHOLD 45MG

FP Batch Number: 3F15383

Bulk number : 3S1147

Country:.. - NA

OOS investigations: N/A

Shipment number : 9332693

TEST / DATA	RESULT	UNIT	SPECIFICATION
Description	Conform	N/A	Clear, yellow to colorless solution
Description of container closure system (Blister/Package)	Conform	N/A	conforme à la SOP PQC1010
Description of container closure system (Tube)	Conform	N/A	conforme à la SOP PQC1010
Identification of Selamectin by TLC	Conform	N/A	Shows a major band with the same relative mobility and detection characteristics as the working standard of UK-124, 114 when both are chromatographed simultaneously
Identification of Selamectin by HPLC	Conform	N/A	Shows a peak whose retention time and detection characteristics are the same as the working standard of UK-124, 114 when both are chromatographed under identical conditions
Selamectin-HPLC Content	101	%	93<=x<= 107 of label claim
Total impurities-HPLC	0.6	%	maximum 4.0
Identification of BHT by HPLC	Conform	N/A	Shows a peak whose retention time is the same as the working standard of BHT when both are chromatographed under identical conditions
BHT-HPLC Content	100	%	90<=x<=110 of intent
Mean dose volume	96	%	Minimum 80 of intent
Dose volume % RSD	1	%	Maximum 5
Water content	0.2	%	Maximum 2.0

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: 03-APR-2014 11:39:02 Server Timestamp: 03-APR-2014 11:38:56

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