

Certificate of EU release

Product	STRONGHOLD 240 MG X 3 tubes
Manufacturing site	Zoetis Kalamazoo, USA
FG lot number	4F01431
Bulk lot number	4S0099
Manufacturing date	02/2014
Expiry date	01/2017
Importing country	Hungary / Estonia / Lithuania
Quantity released	400


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: 02/07/2014

Deputy Qualified Person
Zoetis Belgium S.A.



Michel Fover

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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 240MG

FP Batch Number: 4F01436

OOS investigations: N/A

Bulk Number :4S0099

Country: - NA

TEST / DATA	RESULT	UNIT	SPECIFICATION
Description	Conform	N/A	Clear, yellow to colorless solution
Description of container closure system (Blister/Package)	Conform	N/A	Meets test
Description of container closure system (Tube)	Conform	N/A	Meets test
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	0.4	%	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	101	%	Minimum 80 of intent
Dose volume % RSD	0	%	Maximum 5
Water content	0.2	%	Maximum 2.0

Electronic Signature: Hélène Vergnet Lot Release Local Timestamp: 01-JUL-2014 08:14:30 Server Timestamp: 01-JUL-2014 08:14:25