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zoetis

Certificate of EU release

Product	BANMINTH PASTE 10G
Manufacturing site	Lincoln, USA
FG lot number	2401751
Manufacturing date	08/2014
Expiry date	08/2017
Importing country	Hungary - Poland
Quantity released	4694


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: 10 April 2015

L. GIORA



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Deputy Qualified Person
Zoetis Belgium S.A.

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

BANMINTH PASTA DLA PSOW 10G

FP Batch Number: 2401751

OOS investigation: NA

Shipment number : 718544

Bulk lot number :2401149

Country: - NA

TEST / DATA	RESULT	UNIT	SPECIFICATION
Description	Conform	N/A	A light yellow opaque paste free from agglomerates or visible foreign particles.
Syringeability	Conform	N/A	Easily syringeable with no obstruction
Weight variation	Conform	N/A	No individual syringe less than 100%
Pyrantel identification	Conform	N/A	Retention time of sample and standard must concur
Methyl- and Propyl-Parabens identification	Conform	N/A	Retention time of sample and standard must concur
Pyrantel base assay	101	%	95%<=x<=105% of 7.5 mg/g
Methyl-Paraben potency	99	%	90%<=x<=110% of 1.8 mg/g
Propyl-paraben potency	98	%	90%<=x<=110% of 0.2 mg/g
Impurity cis-isomer	Not detected	%	Cis-isomer <=0.5%
Impurity amide	Not detected	%	Amide <=0.4%
Impurity total unspecified	Not detected	%	Total unspecified <=1.0%
Viable micro-organisms count	10	CFU/g	<=1000 CFU/g (interpreted as 2 x defined limit)
Moulds and yeast content	< 10	CFU/g	<=100 CFU/g (interpreted as 2 x defined limit)
E. coli content	0	germes/g	Not present in 1 g
Salmonella content	0	germes/g	Not present in 1 g
Pseudomonas aeruginosa content	0	germes/g	Not present in 1 g
Staph. aureus content	0	germes/g	Not present in 1 g
Other enterobacteriaceae content	0	CFU/g	<=100 CFU/g

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: 26-MAR-2015 08:37:06 Server Timestamp: 26-MAR-2015 08:37:05

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