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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	

BANMINTH 10g

FP Batch Number: 2331387

Manufacturing date: 04-FEB-2013

Expiration Date: FEB-2016

Country: - HUNGARY - POLAND


SFP Batch Number: 2330982

FP received at ELC on: 18/06/2013

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	97	%	95% ≤ x ≤ 105% of 7.5 mg/g
Methyl-Paraben potency	100	%	90% ≤ x ≤ 110% of 1.8 mg/g
Propyl-paraben potency	100	%	90% ≤ x ≤ 110% of 0.2 mg/g
Impurity cis-isomer	0.0	%	Cis-isomer ≤ 0.5%
Impurity amide	0.0	%	Amide ≤ 0.4%
Impurity total unspecified	0.0	%	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

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: 24 JUL 2013

Signature: 

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Node: emaedcs080

Instance Name: LIGRBE7P

Diszpó: PN-ZA14000037 Vevő: Alpha-Vet 8000

Szállító: Zoetis Hungary Kft.

Az eredetiről készült hiteles másolat.

Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

File név: PN00007708

Egyedi sorszám: PN0000070365

5 másolat

Oldal/Lap 1 / 1 Anyaglap: PN0467/13

Nyomtatás dátuma: 2014.01.14

CertEx v3.02