

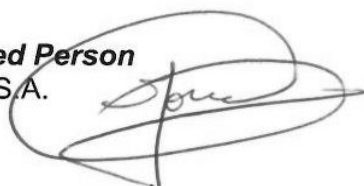
Certificate of EU release

Product	Dectomax Injectable 500ml
Manufacturing site	Pfizer Guarulhos, Brazil
FG lot number	50454531GA
Bulk number	50454531G
Manufacturing date	06/2015
Expiry date	06/2018
Importing country	Hungary
Quantity released	1164

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: 04/02/2016

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

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DECTOMAX INJ 500 ML

Batch Number: 50454531GB

OOS investigations: N/A

Shipment number :215130

Country: - NA

TEST / DATA	RESULT	UNIT	SPECIFICATION
Description	Conform	N/A	Clear, colorless to pale yellow solution conforming to parenteral standards, in amber glass vials
Color	0.1	N/A	The absorbance of undiluted test sample, using a 1cm pathlength cell at 400 nm, should be not greater than 0.2 absorbance units
Volume in container	Conform	N/A	Not less than the labeled volume
Identification of Doramectin by HPLC	Conform	N/A	Shows a peak whose retention time and retention characteristics are the same as the working standard of doramectin when both are chromatographed under identical conditions
Doramectin content by HPLC	10.3	mg/ml	$9.5 \leq x \leq 10.5$ (95 - 105% of label claim)
Total degradation by HPLC	0	%	Maximum 2
Water content	0.01	%	Maximum 0.05
Butylated Hydroxyanisol content	94	ppm	$50 \leq x \leq 125$
Density	0.907	g/ml	$0.902 \leq x \leq 0.912$
Sterility	No growth	N/A	No growth
Endotoxin content	< 1	EU/ml	Maximum 165

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: 14-JAN-2016 15:30:36 Server Timestamp: 14-JAN-2016 15:30:22

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

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Node: emaedics060

Instance Name: LICRBE7P

Diszpó: PN0081600639 Vev: TolnAgro Kft File név: PN00008725 Egyedi sorszám: PN000008061 5 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 2 Anyaglap: PN0066/16
Az eredetivel megegyez elektronikus másolat a(z):
Dr. Jakab Mihály min.bízt.gyógyszerész által küldve. Nyomtatás dátuma: 2016.03.04 CertEx v 3.03a