

ZOETIS BELGIUM SA
Rue Laid Burniat 1
Louvain-la-Neuve
B - 1348 BELGIUM

T +32 10 80 80 80
VAT BE 0401 953 350

zoetis

Certificate of EU release

Product	Dectomax injectable 10mg/ml 500ml
Manufacturing site	Inovat Brazil
FG lot number	1807978
Bulk number	1801967
Lot (analysis and retained samples)	1807962
Manufacturing date	01/2018
Expiry date	12/2020
Destination country	Hungary
Quantity released	495

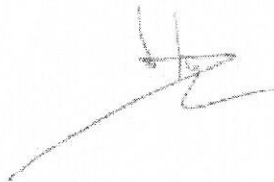
I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination country/countries

Date of EU release:

04 JUL 2018

Deputy Qualified Person
Zoetis Belgium S.A.

Teon-Dana DANG
Deputy Qualified Person
Zoetis Belgium SA



Diszpó: PN0804595148 Vevő: DR SZEKELY KFT Erd File név: PN00009697 Egyedi sorszám: PN0000088267 25 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 3 / 1 Anyaglap: PN0297/18
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2018.10.10
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v3.10

Generated Date
Jul 3, 2018

CERTIFICATE OF ANALYSIS

ZOETIS BELGIUM SA, a wholly-owned subsidiary of Zoetis Inc.
RUE LAID BURNIAT, 1
B-1348 LOUVAIN-LA-NEUVE
BELGIUM
AUTHORIZATION NUMBER 419V

zoetis

Item: 40000055
Title: Dectomax inj 500 ml
Market: N/A
Lot Number: 1807962

TEST NAME	SPECIFICATION	UNITS	RESULT
Shipment number	N/A	N/A	LE 18/318
Description	Clear, colorless to pale yellow solution conforming to parenteral standards, in amber glass vials	N/A	Conform
Color	The absorbance of undiluted test sample, using a 1cm pathlength cell at 400 nm, should be not greater than 0.2 absorbance units	N/A	0.1
Volume in container	Not less than the labeled volume	N/A	Conform
Identification of Doramectin by HPLC	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	N/A	Conform
Doramectin content by HPLC	$9.5 \leq x \leq 10.5$ (95 – 105% of label claim)	mg/ml	9.8
Total degradation by HPLC	Maximum 2	%	1
Water content	Maximum 0.05	%	0.01
Butylated Hydroxyanisol content	$50 \leq x \leq 125$	ppm	91
Density	$0.902 \leq x \leq 0.912$	g/mL	0.906
Sterility	No growth	N/A	No Growth
Endotoxin content	Maximum 165	EU/mL	1
OOS investigations: N/A			

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RUE LAID BURNIAT, 1
B-1348 LOUVAIN-LA-NEUVE
BELGIUM
AUTHORIZATION NUMBER 419V



Item: 40000085
Title: Dectomax inj 500 ml
Market: N/A
Lot Number: 1807962

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.

Lot Release Electronic Signature: Laurence Ribonnet

Lot Release System Timestamp: Jul 3, 2018 7:35:13 AM

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