

ZOETIS BELGIUM SA
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Certificate of EU release

Product	DECTOMAX SOL 10MG/MLX50ML BTX1
Manufacturing site	INOVAT Industria Farmaceutica Ltda, Brasil
FG lot number	1933427
Bulk	1930707
Lot (analysis and retain sample)	1933425
Manufacturing date	07/2019
Expiry date	07/2022
Destination country	HU
Quantity released	1504

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: 03/02/2020

Deputy Qualified Person
Zoetis Belgium S.A.

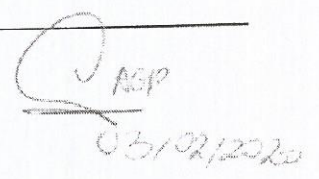
Generated Date:
Jan 30, 2020

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: 4000083
Title: Dectomax inj 50 ml ✓
Market: N/A
Lot Number: 1933425 ✓

TEST NAME	SPECIFICATION	UNITS	RESULT
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	10.3 ✓
Total degradation by HPLC	Maximum 2	%	0 ✓
Water content	Maximum 0.05	%	0.01 ✓
Butylated Hydroxyanisol content	$50 \leq x \leq 125$	ppm	80 ✓
Density	$0.902 \leq x \leq 0.912$	g/mL	0.909 ✓
Sterility	No growth	N/A	No Growth ✓
Endotoxin content	Maximum 165	EU/mL	1 ✓
OOS investigations: N/A			✓

All documentation has been reviewed and found to be in compliance with specification.



 ASP

 05/02/2020

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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: Colas Swalus ✓

Lot Release System Timestamp: Jan 30, 2020 10:12:54 AM

03/02/2020

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