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

T +3210808080
VAT BE 0401 953 350

zoetis

Certificate of EU release

Product	DECTOMAX Solution for injection 10MG/MLX500ML
Manufacturing site	Inovat Brazil
FG lot number	1839536
Bulk	1834299
Lot (analysis and retain sample)	1839549
Manufacturing date	08/2018
Expiry date	07/2021
Destination country	Hungary
Quantity released	999

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: 21 JAN 2019

Deputy Qualified Person
Zoetis Belgium S.A.

Diszpó: PN0806279898 Vevő: DR SZEKELY KFT Erd File név: PN00009920 Egyedi sorszám: PN0000090650 7 másolat
Szállító: Zoetis Hungary Kft.
Az eredetiről készült hiteles másolat.
Oldal/Lap 2 / 1 Anyaglap: PN0042/19
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek! Nyomtatás dátuma: 2019.05.28
CertEx v 3.10

CERTIFICATE OF ANALYSIS

Generated Date:
04 Oct 2018
Generated by:
MAALVES

INOVAT Indústria Farmacêutica Ltda.
CNPJ: 27.864.378/0001-90
IE: 796.591.145.110
Av. Presidente Tancredo de Almeida Neves 1555
07112-070 - Guarulhos - SP - Brazil

Product:	6100767
Description:	DECTOMAX SOL 10MG/MLX500ML BTX1
Expiry Date:	31.Jul.2021
Manufacture Date:	23.Aug.2018
Specification:	00-RS-06646-2 - Effect. date 01-Sep-1993
Batch:	1839536
Associated Lots:	1834299

TEST NAME	TEST METHOD	SPECIFICATION	UNIT	RESULT
Appearance	USP/A 28.01	Clear, colorless to pale yellow solution conforming to parenteral standards, in amber glass vials.	n/a	Meets test
Color	C 7.024	The absorbance of the undiluted test sample, using a 1cm path length cell at 400nm, should not be greater than 0.2 absorbance units.	APHA	0.1
Fill volume - decto 500mL	V 17.22	Should be not less than the labeled volume	ml	510
Assay - HPLC	D 144.2	The concentration of Doramectin should be not less than 95% and not more than 105% of label claim	%	102
Identity - HPLC	D 144.2	Shows a peak whose retention time and response characteristics are the same as the working standard of Doramectin when both are chromatographed, under identical conditions	n/a	Meets test
Water content	W 1.0	Not greater than 0.05% w/w	%	0.01
Sterility	03-GTP-164	Meets test requirements	n/a	Meets test
Bacterial endotoxin - final result	LS 10.73	Not greater than 165 EU/mL	EU/mL	< 15

After reviewing all manufacturing and testing data, I hereby certify that the above information is authentic and accurate. The batch has been tested and manufactured including packaging and quality control in full compliance with Good Manufacturing Practices and in compliance with methods and standards, as described in the applicable quality agreements, the local regulatory requirements and those requirements stipulated in the marketing authorization.

Lot Release Signature: MARIA APARECIDA DE FARIA ALVES
Lot Release Local Timestamp: 04 Oct 2018 08:42:29 AM

21 JAN 2019

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies. Distribution to third parties without prior permission is prohibited.

Zoetis | This copy of the document was retrieved from the system by Anna Gopfauf on 21 Jan 2019.

Diszpó: PN0806279898 Vevő: DR SZEKELY KFT Erd File név: PN00009920 Egyedi sorszám: PN0000090650 7 másolat
Szállító: Zoetis Hungary Kft.
Az eredetiről készült hiteles másolat.
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek! Oldal/Lap 2 / 2 Anyaglap: PN0042/19 Nyomtatás dátuma: 2019.05.28
CertEx v3.10