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	DRAXXIN SOL 25MG/MLX100ML VLX1
Manufacturing site	INOVAT Industria Farmaceutica Ltda, Brasil
FG lot number	2022788
Bulk	2018908
Analysis Lot	2022811
Manufacturing date	05/2020
Expiry date	04/2023
Destination country	FI – HU
Quantity released	500

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: 24/9/2020

Deputy Qualified Person
Zoetis Belgium S.A.

Sophie LE GRELLE
Product Supply Chain Manager
Zoetis Belgium SA

CERTIFICATE OF ANALYSIS

Generated Date:
Aug 13, 2020

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

Item: 40012391
Title: Draxxin Injectable Solution 100mL

Market: N/A

Lot Number: 2022811

TEST NAME	SPECIFICATION	UNITS	RESULT
Description	Clear colorless to slightly yellow solution essentially free from foreign matter	N/A	Conform
Particulate contamination	Vial is essentially free of visible foreign matter	N/A	Conform
Identification of Tulathromycin by TLC	Mobilities (Rf) of CP-472,295 and CP-547,272 are the same as those of the identity standard	N/A	Conform
Identification of Tulathromycin by HPLC	Peak retention times of CP-472,295 and CP-547,272 are the same as those of the identity standards	N/A	Conform
Tulathromycin-HPLC Content	95<=x<=105 of label claim	%	102
CP-547,272 ratio to total Tulathromycin	8<=x<=13	%	11
Degradation product CP-60,300	Maximum 0.8	%	0,0
Degradation product CP-651,595	Maximum 0.8	%	0,0
Unspecified degradation products	<1.0 each	%	0,0
Total degradation products	Maximum 2.0	%	0,0
Volume in container	Not less than the labeled volume	N/A	Conform
Monothioglycerol content	90<=x<=110 of label claim	%	98
pH	5.1<=x<=5.7	N/A	5,5

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Item: 40012391

Title: Draxxin Injectable Solution 100mL

Market: N/A

Lot Number: 2022811

TEST NAME	SPECIFICATION	UNITS	RESULT
Sterility	No growth	N/A	No Growth
Endotoxin content	Maximum 50	EU/mL	< 5

OOS investigations: N/A

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: Genevieve Deschuyteneer

Lot Release System Timestamp: Aug 13, 2020 1:00:23 PM UTC