

Certificate of EU release

Product	Simparica 10mg X 3 tabs
Manufacturing site	Lincoln, USA
FG lot number	219761E
Bulk number	219761
Manufacturing date	03/2017
Expiry date	08/2019
Destination country	Czech Republic – Hungary – Poland – Slovakia
Quantity released	6754

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 AOUT 2017**

Deputy Qualified Person
Zoetis Belgium S.A.

JOAN-DAN H. DAN G


CERTIFICATE OF ANALYSIS



Generated Date:
Aug 1, 2017

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

Item: 10012598
Title: Simparica 10mg
Market: N/A
Lot Number: 219761C ✓

TEST NAME	SPECIFICATION	UNITS	RESULT
Description	A mottled brown colored, squareshaped tablets with rounded edges. Tablet is debossed " 10 " on one face of the tablet.	N/A	Conform
Identification of Sarolaner by HPLC	The retention time of sarolaner (PF-06450567) peak in sample chromatogram corresponds to that in the reference standard chromatogram when run under the same conditions.	N/A	Conform
Identification of Sarolaner by PDA	Diode array shows a UV spectrum for the major chromatographic peak that is essentially same as that of the reference standard of sarolaner (PF-06450567).	N/A	Conform
Water content	<=8%	%	3
Uniformity of content	Conforms with EP 2.9.40	N/A	Conform
Sarolaner assay by HPLC	95.0%<=x<=105.0% of label claim	%	97.7
Any unspecified degradation products by HPLC	Any unspecified Degradation Product <= 1.0	%	0.3
Total degradation products by HPLC	Total Degradation Products <= 2.0	%	0.3
Dissolution	Dissolution at 60 minutes (Q=75%)	N/A	Conform
Viable micro-organisms count	<=2000	CFU/g	< 10
Moulds and yeast content	<=200	CFU/g	< 10
Salmonella content	Absent in 1 g	germs / g	0
E. coli content	Absent in 1 g	germs / g	0

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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 Signature: Héliène Vergnet

Lot Release System Timestamp: Aug 1, 2017 10:58:39 AM

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Diszpó: PN0803157563	Vev: Szabolcs-Sz-B m-i	File név: PN00009304	Egyedi sorszám: PN000008649	22 másolat
Szállító: Zoetis Hungary Kft.		Oldal/Lap 3 / 3	Anyaglap: PN0271/17	
Az eredetivel megegyez elektronikus másolat a(z): Háznagyné Fekete min.bizt.gyógyszerész által küldve.				Nyomtatás dátuma: 2018.04.04
				CertEx v 3.03a