

### Certificate of EU release

<b>Product</b>	Simparica 80mg x 3 tabs
<b>Manufacturing site</b>	Lincoln, USA
<b>FG lot number</b>	197051A
<b>Bulk number</b>	197051
<b>Manufacturing date</b>	11/2016
<b>Expiry date</b>	04/2019
<b>Destination country</b>	Czech Republic - Hungary - Poland - Slovakia
<b>Quantity released</b>	15940

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: 16 FEB. 2017

**Deputy Qualified Person**  
Zoetis Belgium S.A.

JOHN-DAN H DANG



## CERTIFICATE OF ANALYSIS



Generated Date:  
Feb 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: 10012531  
Title: Simparica 80mg  
Market: N/A  
Lot Number: 197051A

<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNITS</u>	<u>RESULT</u>
Description	A mottled brown colored, squareshaped tablets with rounded edges. Tablet is debossed " 80 " 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%	%	2
Uniformity of content	Conforms with EP 2.9.40	N/A	Conform
Sarolaner assay by HPLC	95.0%<=x<=105.0% of label claim	%	101.4
Any unspecified degradation products by HPLC	Any unspecified Degradation Product <= 1.0	%	0.1
Total degradation products by HPLC	Total Degradation Products <= 2.0	%	0.2
Dissolution	Dissolution at 75 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

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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.

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Lot Release Signature: Hélène Vergnet

Lot Release Local Timestamp: Feb 1, 2017 12:15:33 PM

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Diszpó: PN0803013974	Vev: Szabolcs-Sz-B m-i	File név: PN00009135	Egyedi sorszám: PN000008628	18 másolat
Szállító: Zoetis Hungary Kft.		Oldal/Lap 3 / 3	Anyaglap: PN0090/17	
Az eredetivel megegyez elektronikus másolat a(z):				
Dr. Jakab Mihály	min.bízt.gyógyszerész által küldve.	Nyomtatás dátuma: 2018.03.14	CertEx v	3.03a