

### Certificate of EU release

<b>Product</b>	Simparica 80mg x 3 tabs
<b>Manufacturing site</b>	Lincoln, USA
<b>FG lot number</b>	266398A
<b>Bulk number</b>	266398
<b>Manufacturing date</b>	10/2017
<b>Expiry date</b>	03/2020
<b>Destination country</b>	Czech Republic - Hungary - Poland - Slovakia
<b>Quantity released</b>	9172

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: 30 MAI 2018

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

**Toan-Danh DANG**  
Product Release Associate  
Zoetis Belgium SA



## CERTIFICATE OF ANALYSIS



Generated Date:  
May 9, 2018

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: 266398A

TEST NAME	SPECIFICATION	UNITS	RESULT
Description	A mottled brown colored, square shaped 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%	%	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	%	99.4
Any unspecified degradation products by HPLC	Any unspecified Degradation Product <= 1.0	%	0.1
Total degradation products by HPLC	Total Degradation Products <= 2.0	%	0.1
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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Diszpó: PN0803761164 Vev: PRIMAVET File név: PN00009654 Egyedi sorszám: PN000008731 7 másolat  
Szállító: Zoetis Hungary Kft. Oldal/Lap 3 / 2 Anyaglap: PN0242/18  
Az eredetivel megegyez elektronikus másolat a(z):  
Háznagyné Fekete min.bizt.gyógyszerész által küldve. Nyomatás dátuma: 2018.06.22 CertEx v 3.03a

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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 Electronic Signature: Laurence Ribonnet

Lot Release System Timestamp: May 9, 2018 2:05:15 PM

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Diszpó: PN0803761164	Vev: PRIMAVET	File név: PN00009654	Egyedi sorszám: PN00008731	7	másolat
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