

CERTIFICATE OF ANALYSIS

Generated Date:
Jul 26, 2018ZOETIS LLC, a wholly-owned subsidiary of Zoetis Inc.
601 West Cornhusker Highway
Lincoln, NE 68521**zoetis**

zoetis

Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

Item: 10020103
 Title: Simparica Chewable Tablets, 40 mg - ROW
 Document No.: 9211-02 74-RS Version: 1.0 Effective Date: 08 Sep 2016
 Expiration Date: 03-2020
 Date Of Manufacture: 25-APR-2018
 Market: 9211-02 74-RS - REST OF WORLD (ROW)

Lot Number: 301406 Associated Lots: 301406
 302572

TEST NAME	SPECIFICATION	UNIT	RESULT
Appearance	A mottled brown colored, square shaped tablet with rounded edges, tablet is debossed "40" on one face of the tablet.	N/A	Pass
Identification: 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	Pass
Identification: PDA	Diode array shows a UV spectrum for the major chromatographic peak that is essentially the same as that of the Simparica (PF-06450567) reference standard of Sarolaner	N/A	Pass
Water Content - KF	≤ 10.0%	%	3.0
Content Uniformity	Conforms with USP <905>	N/A	Pass
Assay	90.0 - 110.0% of Label Claim	%	100.4
Degradation Products: Indiv Unspecified	≤ 1.0% each	%	0.0
Degradation Products: Total	≤ 3.0%	%	0.0
Dissolution @ 90 minutes (Q = 75%)	Conforms with USP <711>	N/A	Pass
Microbial Quality: TAMC	≤ 2000 CFU/g	CFU/g	15
Microbial Quality: TYMC	≤ 200 CFU/g	CFU/g	< 5
Microbial Quality: Escherichia coli	Absent	N/A	Negative

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TEST NAME	SPECIFICATION	UNIT	RESULT
Microbial Quality: Salmonella	Absent	N/A	Negative

Product meets requirements for Residual Solvent USP <467>, calculated based on Option 1.

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 Electronic Signature: Nathan Tullis

Lot Release System Timestamp: Jul 26, 2018 7:02:42 PM

Full Name: Nathan Tullis
Signature: [Handwritten Signature]
Date: 26 Jul 18