

CERTIFICATE OF ANALYSIS



Generated Date:
Oct 14, 2019

ZOETIS LLC, a wholly-owned subsidiary of Zoetis Inc.
2605 E. KILGORE RD
KALAMAZOO, MI 49001 USA

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: 06-2021
 Date Of Manufacture: 16-JUL-2019
 Market: 9211-02 74-RS - REST OF WORLD (ROW)
 Lot Number: 379827 Associated Lots: 385207

<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
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%	%	3.2
Content Uniformity	Conforms with USP <905>	N/A	Pass
Assay	90.0 - 110.0% of Label Claim	%	102.2
Degradation Products: Indiv Unspecified	≤ 1.0% each	%	0.0
Degradation Products: Total	≤ 3.0%	%	0.2
Dissolution @ 90 minutes (Q = 75%)	Conforms with USP <711>	N/A	Pass
Microbial Quality: TAMC	≤ 2000 CFU/g	CFU/g	30
Microbial Quality: TYMC	≤ 200 CFU/g	CFU/g	< 5
Microbial Quality: Escherichia coli	Absent	N/A	Negative

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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: Heather Noble
Lot Release System Timestamp: Oct 4, 2019 6:47:12 PM UTC

Full Name: _____
Signature: _____
Date: _____