

CERTIFICATE OF ANALYSIS



Generated Date:
Feb 21, 2023

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

Item: 10022530
Title: Simparica Chewable Tablets, 10 mg - Europe
Expiration Date: 10-2024
Date Of Manufacture: 10-MAY-2022
Market: 9211-01 74-RS - EUROPE
Lot Number: 643903 Associated Lots: 599133

TEST NAME	SPECIFICATION	UNIT	RESULT
Description	A mottled brown colored, square shaped tablet with rounded edges, tablet is debossed "10" on one face of the tablet	N/A	Pass
Identification: HPLC	The retention time of the Simparica (PF-06450567) peak in the 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	N/A	Pass
Water Content	≤ 8%	%	5.0
Content Uniformity	Conforms with EP 2.9.40	N/A	Pass
Assay	95.0 - 105.0% of Label Claim	%	99.5
Degradation Products: Indiv. Unspecified	≤ 1.0% each	%	0.0
Degradation Products: Total	≤ 2.0%	%	0.0
Dissolution (Q = 75%) @ 60 minutes	Conforms with EP 2.9.3	N/A	Pass
Microbial Limits: TAMC	≤ 2000 CFU/g	CFU/g	5
Microbial Limits: TYMC	≤ 200 CFU/g	CFU/g	< 5
Microbial Limits: E. coli	Absent	N/A	Negative

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<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
Microbial Limits: Salmonella	Absent	N/A	Negative

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: Shannon Manchester
Lot Release System Timestamp: Feb 15, 2023 2:10:14 PM UTC