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CERTIFICATE OF ANALYSIS

Generated Date: Jul 7, 2022 ZOETIS LLC, a wholly-owned subsidiary of Zoetis Inc. 2605 E. KILGORE RD KALAMAZOO, MI 49001 USA



Item:

10022529

Title:

Simparica Chewable Tablets, 80 mg - Europe

Expiration Date:

02-2024

Date Of Manufacture:

23-SEP-2021

Market:

9211-01 74-RS - EUROPE

Lot Number:

586499

Associated Lots:

547002

TEST NAME	SPECIFICATION	UNIT	RESULT
Appearance	A mottled brown colored, square shaped tablet with rounded edges, tablet is debossed "80" on one face of the tablet		Pass
Identification by 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 by 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%	%	4.2
Content Uniformity	Conforms with EP 2.9.40	N/A	Pass
Assay	95.0 - 105.0% of Label Claim	%	101.3
Degradation Products: Indiv. Unspecified	≤ 1.0% each	%	0.0
Degradation Products: Total	≤ 2.0%	%	0.1
Dissolution (Q = 75%) @ 90 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



ZOETIS BELGIUM SA Rue Laid Burniat 1 1348 Louvain-La-Neuve Belgium Page 2 of 2

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TEST NAME

SPECIFICATION

UNIT

RESULT

Microbial Limits: Salmonella

Absent

N/A

Negative

Not suitable for EU

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:

Jul 6, 2022

6:21:08 PM UTC

ROFITS BELGIEM SA Rue Laid Burnlet I Sis Copyolit La-Neisy Statement