

CERTIFICATE OF ANALYSIS



Generated Date:
Oct 18, 2019

ZOETIS LLC, a wholly-owned subsidiary of Zoetis Inc.
601 West Cornhusker Highway
Lincoln, NE 68521

Item: 10003170
 Title: Rimadyl Palatable Tablets, 100 mg
 Expiration Date: 07-2022
 Date Of Manufacture: 13-AUG-2019
 Market: 74-RS-040108 - EUROPE
 Lot Number: 394377 Associated Lots: 386837

<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
Appearance	A light-brown tablet, debossed "R" on one side and bisected on the opposite side.	N/A	Pass
Average Tablet Weight	2850 - 3150 mg	mg	3010
Uniformity of Mass	Meets requirements of Ph. Eur. 2.9.5	N/A	Pass
Water Content	2 - 7%	%	5
Friability	0.7% Maximum	wt%	0.1
Identification - Carprofen	Retention Time Compares to Standard	N/A	Pass
Impurities - HPLC: Ro 21-2760	≤ 0.2%	%	0.0
Impurities - HPLC: Ro 22-5152	≤ 0.2%	%	0.0
Impurities - HPLC: Ro 21-0537	≤ 0.2%	%	0.0
Impurities - HPLC: Ro 20-7302	≤ 0.2%	%	0.0
Impurities - HPLC: Ro 22-7280	≤ 0.2%	%	0.0
Unspecified Impurities	≤ 0.1% each	N/A	Pass
Total Impurities	≤ 1.0%	%	0.1

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<u>TEST NAME</u>	<u>SPECIFICATION</u>	<u>UNIT</u>	<u>RESULT</u>
Assay - Carprofen	95 - 105% of Label Claim	%	101
Dissolution	≥ 70% @ 90 Minutes	N/A	Pass
Microbial Limits: TAMC	10 ³ CFU/g Maximum	CFU/g	< 5
Microbial Limits: TYMC	10 ² CFU/g Maximum	CFU/g	< 5
Microbial Limits: E. coli	Not present in 1 gram	N/A	Negative
Microbial Limits: Salmonella	Not present in 1 gram	N/A	Negative
Microbial Limits: Pseudomonas aeruginosa	Not present in 1 gram	N/A	Negative
Microbial Limits: Staphylococcus aureus	Not present in 1 gram	N/A	Negative
Microbial Limits: Other Enterobacteriaceae	10 ² CFU/g Maximum	CFU/g	< 10

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: Oct 18, 2019 5:58:48 PM UTC

Full Name: Nathan Tullis
Signature: *Nathan Tullis*
Date: 18 OCT 19