Certificate of Analysis

zoetis

ZOETIS BELGIUM SA
PREVIOUSLY NAMED
PFIZER ANIMAL HEALTH SA
RUE LAID BURNIAT, 1
B-1348 LOUVAIN-LA-NEUVE
BELGIUM
AUTHORIZATION NUMBER 419 V

RIMADYL 50MG

FP Batch Number: 2400552
Manufacturing date: 21-MAR-2014
Expiration Date: 01-MAR-2017
Country: - SLOVENIA - HUNGARY

SFP Batch Number:2400342
FP received at LC on:02/06/2014
Shipment Number:9665293

TEST / DATA	RESULT	UNIT	SPECIFICATION
Description	Conform	N/A	Light-brown tablet, debossed "R" on one side and bisected on the opposite side
Average tablet weight	1512	mg	1425-1575 mg
Uniformity of mass	Conform	N/A	Meets requirements of Ph. Eur. 2.9.5
Water content	4	%	2%<=x<=7%
Friability	0.2	%	0.7% maximum
Carprofen identification (HPLC)	Conform	N/A	Retention time of sample and standard must concur
Impurities HPLC (Ro 21-2760)	Not detected	%	<= 0.2%
Impurities HPLC (Ro 22-5152)	Not detected	%	<= 0.2%
Impurities HPLC (Ro 21-0537)	Not detected	%	<= 0.2%
Impurities HPLC (Ro 20-7302)	Not detected	%	<= 0.2%
Impurities HPLC (Ro 22-7280)	Not detected	%	<= 0.2%
Unspecified impurities (HPCL)	Not detected	%	<= 0.1% of each
Total impurities	Not detected	%	<= 1.0%
Carprofen assay	100	%	95%<=x<=105% of label claim
Dissolution	92	%	>= 70% at 90 minutes
Viable micro-organisms count	< 10	CFU/g	<=1000 CFU/g (interpreted as 2 x defined limit)
Moulds and yeast content	< 10	CFU/g	<=100 CFU/g (interpreted as 2 x defined limit)
E. coli content	0	germes/g	Not present in 1 g
Salmonella content	0	germes/g	Not present in 1 g
Pseudomonas aeruginosa content	0	germes/g	Not present in 1 g
Staph. aureus content	0	germes/g	Not present in 1 g
Other enterobacteriaceae content	0	CFU/g	<=100 CFU/g

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control in full compliance with the GMP requirements of the local regulatory authority and with those stipulated in the Marketing Authorization.

Date: 07/07/2014

Signature: Françoise DELHALLE
Product Release Manager
Zoetis Belgium SA