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zoetis

Certificate of EU release

Product	Rimadyl Injectable 20ml
Manufacturing site	Pfizer Guarhulhos, Brazil
FG lot number	404RI018AF
Manufacturing date	04/2014
Expiry date	03/2017
Importing country	Hungary
Quantity released	475

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 of EU release: 03/03/2015

Deputy Qualified Person
Zoetis Belgium S.A.

Certificate of Analysis

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

RIMADYL 20ML

FP Batch Number: 404RI018AF

OOS investigations: N/A

Country: - HUNGARY

TEST / DATA	RESULT	UNIT	SPECIFICATION
Description (Undiluted)	Conform	N/A	Not more opalescent than reference suspension Ph. Eur. II and pratically free from particles. Yellow to maximum slightly brownish yellow solution.
Description (Diluted)	Conform	N/A	Not more coloured than reference solution Ph. Eur. Y1 or GY1 (CO1)
pH	6.1	N/A	5.0 - 7.0
Density	1.050	g/cm3	1.040 - 1.060 g/cm3
Individual volume	21.0	ml	20.0 - 21.5 ml
Benzyl Alcohol content	10	mg/ml	9 - 11 mg/ml
Identification of Benzyl Alcohol by TLC	Positive	N/A	Positive for Benzyl Alcohol (Rf≈0.75)
Identification of Carprofen by TLC	Positive	N/A	Positive for Carprofen (Rf≈0.5)
Identification of Lecithin by TLC	Positive	N/A	Positive for Lecithin (Rf≈0.2-0.3)
Identification of Glycocholic Acid by TLC	Positive	N/A	Positive for Glycocholic Acid (Rf≈0.1-0.2)
Identification of Carprofen by HPLC (Method I)	Conform	N/A	The retention time of the sample and standard solutions must concur.
Content of Carprofen (Method I)	50.8	mg/ml	47.5 - 52.5 mg/ml
Degradation product Ro 21-2760	Not detected	%	<=0.5%
Degradation product Ro 22-5152	Not detected	%	<=0.5%
Other related substances	0.0	%	<=0.5%
Total Impurities	0.0	%	<=1.5%
Endotoxin content	< 18	IU/ml	<=18IU/ml
Sterility	No growth	N/A	No growth

All documentation has been reviewed and found to be in compliance with specification. Explanations for Out Of Specification (OOS) investigations or regulatory deviations, if any, are attached. This Certificate of Analysis does not constitute product release.

Electronic Signature: Hélène Vergnet Lot Release Local Timestamp: 12-FEB-2015 15:53:52 Server Timestamp: 12-FEB-2015 15:53:47

Document approved electronically through a validated system hence no handwritten signature needed.