



PFIZER PGM  
ZONE INDUSTRIELLE  
29 ROUTE DES INDUSTRIES  
37530 POCE SUR CISSE - FRANCE  
TEL 33 2 47 23 77 78  
FAX 33 2 47 23 79 80

### Certificate of Analysis

PN0377/13

SKN

Material Name: CERENIA IV 20ML B1 ESP/POL/HUN  
Material Code: 5181M02

Lot Number: Z268402  
Specification: 00RS01376(15-05-2006 DR)  
Date of Manufacture: SEP. 01, 2011  
Expiration Date: AUG-2014

TEST	Limit	Result
Appearance	A clear, colourless to light yellow solution, in an amber vial with suitable stopper and overseal	MEETS TEST
Identity-Maropitant (HPLC/UV-DAD)	Shows a major chromatographic peak with a retention time that is essentially the same as that of the maropitant citrate reference standard when chromatographed sequentially. Diode array shows a UV spectrum for the major chromatographic peak that is essentially the same as that of the maropitant citrate reference standard.	MEETS TEST
Visible particles	Should be clear and essentially free from readily detectable visible particles	MEETS TEST
Maropitant content	95-105% of label claim	100 %
Metacresol content	95-105% of nominal content	99 %
Identity-Metacresol	Shows a major chromatographic peak with a retention time that is essentially the same as that of the metacresol reference standard when chromatographed sequentially.	MEETS TEST
SBECD content	95-105% of nominal content	101 %
pH	4.1-4.7	4.4
Individual degradation products	Maximum 0.5% each	< 0.3 %
Total Degradation Products	Maximum 1.0%	0.0 %
Bacterial endotoxins	Maximum 5.0 IU/mg Maropitant	< 5.0 IU/mg
Sterility	MEETS TEST	MEETS TEST

Cerenia was manufactured according to GMP and complies with the approved specifications.

Only for Hungary :

Page 1 of 2

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Node: emaedics059

Instance Name: LICFR6P

Diszpó: PN-ZA13001006 Vevő: PRIMAVET File név: PN00007591 Egyedi sorszám: PN0000069749 1 másolat  
Szállító: Zoetis Hungary Kft. Oldal/Lap 2 / 1 Anyaglap: PN0377/13  
Az eredetiről készült hiteles másolat. Nyomtatás dátuma: 2013.10.24  
Kizárólag a kék tintával szignált másolat tekinthető hitelesnek!

CertEx v3.02



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DS Now

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I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of Hungary or product specification file for Investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

#### QUALIFIED PERSON ASSESSMENT.

Electronic Signature: Christine LEVY Lot Release Local Timestamp: 10-SEP-2013 09:54:51

Diszpó: PN-ZA13001006 Vevő: PRIMAVET

Szállító: Zoetis Hungary Kft.

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Nyomtatás dátuma: 2013.10.24

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