

FAREVA Amboise
 ZI de Pocé-sur-Cisse
 29 Route des Industries
 37530 Pocé-sur-Cisse
 TEL (+33) : 247237778
 FAX (+33) : 247237980

Certificate of Analysis

Material Name: CERENIA INJ 20mlB1 ESP/POL/HUN
 Material Code: 5180M02
 Lot Number: A613709
 For information registered specification 00RS01376(15-05-2006 DR)
 Date of Manufacture 10-2015
 Expiration Date: 09-2018
 Testing Date (DD/MM/YYYY) : 12/02/2016

Test	Method	Limit	Result
Appearance	A 28.01	A clear, colourless to light yellow solution, in an amber vial with suitable stopper and overseal	MEETS TEST
Identity-Maropitant (HPLC/UV-DAD)	M 161.0	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
Maropitant content	C 188.95	95-105% of label claim	98 %
Metacresol content	C 188.95	95-105% of nominal content	100 %
Identity-Metacresol	C 188.95	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	C 166.23	95-105% of nominal content	100 %
pH	P 24.0	4.1-4.7	4,4
Individual degradation products	C 188.96	Maximum 0.5% each	0,0 %
Total Degradation Products	C 188.96	Maximum 1.0%	0,0 %

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies. Distribution to third parties without prior permission is prohibited.

Page 1 of 3

Siège sociale FAREVA Amboise ZI de Pocé-sur-Cisse 37530 Pocé-sur-Cisse France - Tél(+33) : 247237778 - Fax : 247237980 <http://www.fareva.com>
 S.A.S. associée unique au capital de 100000 euros - 799995386 - RCS Bobigny - N°TVA : FR4579995386

FAREVA®

Diszpó: PN0081776015 Vev: TolnAgro Kft File név: PN00008720 Egyedi sorszám: PN000008096 7 másolat
 Szállító: Zoetis Hungary Kft. Oldal/Lap 3 / 1 Anyaglap: PN0067/16
 Az eredetivel megegyez elektronikus másolat a(z):
 Dr. Jakab Mihály min.bízt.gyógyszerész által küldve. Nyomtatás dátuma: 2016.04.01 CertEx v 3.03a

FAREVA Amboise
 ZI de Pocé-sur-Cisse
 29 Route des Industries
 37530 Pocé-sur-Cisse
 TEL (+33) : 247237778
 FAX (+33) : 247237980

Certificate of Analysis

Material Name: CERENIA INJ 20mlB1 ESP/POL/HUN
 Material Code: 5180M02
 Lot Number: A613709
 For information registered specification 00RS01376(15-05-2006 DR)
 Date of Manufacture 10-2015
 Expiration Date: 09-2018
 Testing Date (DD/MM/YYYY) : 12/02/2016

Test	Method	Limit	Result
Bacterial endotoxins	PE/USP	Maximum 5.0 IU/mg Maropitant	<0,29999 IU/mg
Visible particles	PE	Should be clear and essentially free from readily detectable visible particles	MEETS TEST
Sterility	PE	MEETS TEST	MEETS TEST

Destination: Hungary, Poland and Spain

FAREVA Amboise
 Zone Industrielle
 29 route des industries
 37530 Pocé Sur Cisse
 France

Manufacturing license n° V 0018/78
 GMP Certificate n° 14/0575

Marketing authorisation number: EU/2/06/062/005

Active Substance: Maropitant Citrate .
 Amount in dosage unit : 10 mg/ml.

Dosage Form : Injectable solution .

Type of packaging: 20 ml vial .
 Packaging size: 1 vial per box .

For only Hungary :

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

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies. Distribution to third parties without prior permission is prohibited.

Page 2 of 3

Siège sociale FAREVA Amboise ZI de Pocé-sur-Cisse 37530 Pocé-sur-Cisse France - Tél(+33) : 247237778 - Fax : 247237980 <http://www.fareva.com>
 S.A.S. associé unique au capital de 100000 euros - 799995386 - RCS Bobigny - N°TVA : FR45799995386

FAREVA®

Diszpó: PN0081776015 Vev: TolnAgro Kft File név: PN00008720 Egyedi sorszám: PN000008096 7 másolat
 Szállító: Zoetis Hungary Kft. Oldal/Lap 3 / 2 Anyaglap: PN0067/16
 Az eredetivel megegyez elektronikus másolat a(z):
 Dr. Jakab Mihály min.bízt.gyógyszerész által küldve. Nyomtatás dátuma: 2016.04.01 CertEx v 3.03a

FAREVA Amboise

ZI de Pocé-sur-Cisse

29 Route des Industries

37530 Pocé-sur-Cisse

TEL (+33) : 247237778

FAX (+33) : 247237980

Certificate of Analysis

Material Name: CERENIA INJ 20mlB1 ESP/POL/HUN

Material Code: 5180M02

Lot Number: A613709

For information registered specification 00RS01376(15-05-2006 DR)

Date of Manufacture 10-2015

Expiration Date: 09-2018

Testing Date (DD/MM/YYYY) : 12/02/2016

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.

For only Poland and Spain :

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 the importing country 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: Hélène RIVARD

Lot Release Local Timestamp: 19/02/2016 18:42:02
(DD/MM/YYYY)

Documentation is considered PROPRIETARY and is made available for business operations and review by employees and regulatory agencies. Distribution to third parties without prior permission is prohibited.

Page 3 of 3

Siège social FAREVA Amboise ZI de Pocé-sur-Cisse 37530 Pocé-sur-Cisse France - Tél(+33) : 247237778 - Fax : 247237980 <http://www.fareva.com>

S.A.S. associé unique au capital de 100000 euros - 799995386 - RCS Bobigny - N°TVA : FR45799995386

FAREVA®

Diszpó: PN0081776015 Vev: TolnAgro Kft File név: PN00008720 Egyedi sorszám: PN000008096 7 másolat
Szállító: Zoetis Hungary Kft. Oldal/Lap 3 / 3 Anyaglap: PN0067/16
Az eredetivel megegyez elektronikus másolat a(z):
Dr. Jakab Mihály min.bízt.gyógyszerész által küldve. Nyomtatás dátuma: 2016.04.01 CertEx v 3.03a