

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 20ML B1 RUS

Material Code: 5180RUS
Lot Number: B520604
For information registered specification 00RS01376(09-05-2005 DR)
Date of Manufacture 05-2020
Expiration Date: 04-2023

Testing Date (DD/MM/YYYY) : 09/07/2020

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	100 %
Metacresol content	C 188.95	95-105% of nominal content	102 %
SBECD content	C 166.23	95-105% of nominal content	101 %
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 %
Bacterial endotoxins	PE/USP	Maximum 5.0 IU/mg Maropitant	<0,3 IU/mg
Visible particles	PE	Should be clear and essentially free from readily detectable visible particles	MEETS TEST
Sterility	Ph. Eur	Meets test	MEETS TEST

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Page 1 of 2

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AMBOISE

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

QUALIFIED PERSON ASSESSMENT.

Electronic Signature: RIVARD Hélène

Lot Release Local Timestamp:
(DD/MM/YYYY)

10/07/2020 10:26:14

H. RIVARD
13 JUL. 2020
Pharmacien Assurance Qualité
FAREVA AMBOISE

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Page 2 of 2