

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: B446006
For information registered specification 00RS01376(09-05-2005 DR)
Date of Manufacture 09-2019
Expiration Date: 08-2022
Testing Date (DD/MM/YYYY) : 05/11/2019

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	99 %
Metacresol content	C 188.95	95-105% of nominal content	101 %
SBECD content	C 166.23	95-105% of nominal content	102 %
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

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Test	Method	Limit	Result
Visible particles	PE	Should be clear and essentially free from readily detectable visible particles	MEETS TEST
Sterility	Ph. Eur	Meets test	MEETS TEST

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

QUALIFIED PERSON ASSESSMENT.

Electronic Signature: BEDFERT Fabien

Lot Release Local Timestamp: 05/11/2019 15:28:11
(DD/MM/YYYY)