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

Material Name: CERENIA TABS 60MG B4 ESP/HOL/HUN
Material Code: 5192M03

Lot Number: A427707

Specification: 00RS01360(20-04-2009)

Date of Manufacture: FEB. 13, 2014

Expiration Date: JAN-2017

TEST	Limit	Result
Identity-visual	Peach coloured oval tablet with a break line and dose descriptor on one side, and Pfizer script on the other.	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
Water content	6.0% maximum	3.5 %
Dissolution (15 minutes)	The requirements are met if the quantity of maropitant dissolved after 15 minutes conforms to the acceptance table below, where Q = 80%. Continue testing through two stages unless the results conform at stage 1. The quantity Q is the amount of maropitant dissolved expressed as a percentage of label claim. Stage : S1 - Number of tests : 6 - Acceptance Criteria : Each unit is not less than Q + 5%. Stage : S2 - Number of tests : 6 - Acceptance Criteria : Average of 12 units (S1+S2) is equal to or greater than Q and no result is less than Q-15%.	101 %
Assay (HPLC)	95-105% of label claim at time of release	100 %
Content uniformity	MEETS TEST	MEETS TEST
Individual degradation products	Maximum 0.5% each at time of release	0.0 %
Total degradation products	Maximum 1.0% at time of release	0.0 %

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

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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.

For Hungary only :
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: Beatrice CAZEAUX Lot Release Local Timestamp: 25-JUL-2014 09:29:13
