Intervet GesmbH
Zufahrt Richard-Neutra-Gasse 1
Siemensstraße 107
1210 WIEN
AUSTRIA

MSD Animal Health

Certificate of Analysis

Product: ***Bravecto 112,5mg 1x1tab EU6***
Batch: ***A014A03***

Country: Hungary

Sales Order Number: **1103626842 / 10**
Delivery Number: **1204552730 / 900003**

Material Number:
149450

Package Size:
1 TAB

Manufacturing Date:
10-Mar-2015

Expiry Date:
Feb-2017

Storage Conditions:
Below 30°C

CERTIFICATION BY THE MANUFACTURER

I herewith certify that the presented information is authentic and accurate. All measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended. This batch has been manufactured /fabricated (incl. APIs and intermediates if applicable) including packaging and quality control, in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Name:
Function:
Date:
Signature:

Printed: 02-Apr-2015 14:27:43
Profile: Z052 P-302800 1
Form: Z1QM_QCERT_10

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Results of Analysis

Test	Method	Specification	Result
Appearance - Color	Visual Examination	Light brown to dark brown	Complies
Appearance - Physical state	Visual Examination	chewable tablet	Complies
Appearance - Physical state	Visual Examination	smooth or slightly rough surface	Complies
Form of tablet	Visual Examination	practically round shape	Complies
Appearance - Physical state	Visual Examination	some marbling or specks or both	Complies
Water content (KF)	Intervet Vienna internal method	≤ 5.0 %	2.7 %
Identity A (UPLC - retention time)	Intervet Vienna internal method	Complies	Complies
Identity B (UPLC-UV Spectrum)	Intervet Vienna internal method	Complies	Complies
Assay CBPI (UPLC)	Intervet Vienna internal method	95.0 - 105.0 %	102.2 %
Degradation Product A0431246	Intervet Vienna internal method	≤ 0.4 %	0.3 %
Degradation Product IOBA	Intervet Vienna internal method	≤ 0.4 %	0.3 %
Unspecified degradation products (each)	Intervet Vienna internal method	≤ 1.0 %	Complies
Total degradation products	Intervet Vienna internal method	≤ 1.0 %	0.0 %
Uniformity of dosage units (UPLC)	USP < 905 >	≤ 15.0	3.7
Dissolution after 24 hours	USP 711 / Ph.Eur. 2.9.3	≥ 70 %	101 %
Microbial Purity Aerob. Bact	USP/NF 61/62 / Ph. Eur. 2.6.12 / 2.6.13	≤ 10^3 Aerobic Bacteria cfu/g	Complies
Microbial Purity Yeasts/Molds	USP/NF 61/62 / Ph. Eur. 2.6.12 / 2.6.13	≤ 10^2 Yeasts/Moulds cfu/g	Complies
Specified micro-organisms, E. coli	USP/NF 61/62 / Ph. Eur. 2.6.12 / 2.6.13	Absence of E.coli	Complies

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