

Certificate of Analysis

Product: Bravecto 1400mg 1x1tab 579
Batch: U471Z03

Country: Hungary

Sales Order Number: 1108091456 / 10

Delivery Number: 1210039611 / 900001

Material Number: 145342

Package Size: 1 TAB

Manufacturing Date: 14-May-2020

Expiry Date: Apr-2022

Storage Conditions: Below 30°C

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.

CERTIFICATION BY THE MANUFACTURER

Name:

Dr. Christian Prohaska
Qualified Person

Function:

Date:

08. Juli 2020

Signature:



Animal Health



Intervet GeesmbH
Zürhrt Richard-Neutra-Gasse 1
Siemensstraße 107
1210 WIEN
AUSTRIA

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Product: **Bravecto 1400mg 1x1tab 579**
 Batch: **U471Z03**

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)	Interwet Vienna internal method	$0.0 \leq X \leq 5.0 \%$	1.9 %
Texture analysis	Interwet Vienna internal method	$25 \leq X \leq 50 \text{ N}$	37 N
Identity A (UPLC - retention time)	Interwet Vienna internal method	Complies	Complies
Identity B (UPLC-VY Spectrum)	Interwet Vienna internal method	Complies	Complies
Assay Fluralaner (UPLC)	Interwet Vienna internal method	$95.0 \leq X \leq 105.0 \%$	100.1 %
Degradation Product A0431246	Interwet Vienna internal method	$0.0 \leq X \leq 0.4 \%$	0.4 %
Degradation Product I0BA	Interwet Vienna internal method	$0.0 \leq X \leq 0.4 \%$	0.4 %
Unspecified degradation products (each)	Interwet Vienna internal method	$\leq 1.0 \%$	Complies
Total degradation products (UPLC)	Interwet Vienna internal method	$0.0 \leq X \leq 1.0 \%$	1.0 %
Uniformity of dosage units	USP < 905 >	$0.0 \leq X \leq 15.0$	1.2
Dissolution after 24 hours	USP 711 / Ph.Eur. 2.9.3	$\geq 70 \%$	100 %
Microbial Purity Aerob. Bact	USP/NF 61/62 / Ph. Eur. 2.6.12 / 2.6.13	$\leq 10^3$ Aerobic Bacteria cfu/g	Complies
Microbial Purity Yeasts/Molds	USP/NF 61/62 / Ph. Eur. 2.6.12 / 2.6.13	$\leq 10^2$ Yeasts/Molds 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