

Certificate of Analysis

Product: **Bravecto 1400mg 1x1tab 421**
Batch: **22M5018A03**

Country: **Ukraine**
Sales Order Number: **1111838849 / 10**
Delivery Number: **1214379243 / 900001**

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



MSD
Animal Health

Material Number:
125163

Package Size:
1 TAB

Manufacturing Date:
02-Feb-2022

Expiry Date:
Jan-2024

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 Regulation (EU) 2019/6. 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:

Stefanie Erbler
Qualified Person

19. Juli 2022

Certificate of Analysis

Product: **Bravecto 1400mg 1x1tab 421**
Batch: **22M5018A03**

Results of Analysis

Intervet GesmbH
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MSD

Animal Health

<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
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	$0.0 \leq X \leq 5.0 \%$	1.8 %
Texture analysis	Intervet Vienna internal method	$25 \leq X \leq 50 \text{ N}$	32 N
Identity A (UPLC - retention time)	Intervet Vienna internal method	Complies	Complies
Identity B (UPLC-UV Spectrum)	Intervet Vienna internal method	Complies	Complies
Assay Fluralaner (UPLC)	Intervet Vienna internal method	$95.0 \leq X \leq 105.0 \%$	100.1 %
Degradation Product A0431246	Intervet Vienna internal method	$\leq 0.4\%$	<0.3 %
Degradation Product IOBA	Intervet Vienna internal method	$\leq 0.4\%$	<0.3 %
Unspecified degradation products (each)	Intervet Vienna internal method	$\leq 1.0\%$	<0.3 %
Total degradation products	Intervet Vienna internal method	$\leq 1.0\%$	no reportable impurities
Uniformity of dosage units (UPLC)	USP < 905 >	$0.0 \leq X \leq 15.0$	1.1
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/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



Certificate of Analysis

Product: **Bravecto 250mg 1x1tab 421**
Batch: **21M2049A01**

Country: **Ukraine**
Sales Order Number: **1111839039 / 10**
Delivery Number: **1214379243 / 900002**

Material Number:
135921

Package Size:
1 TAB

Manufacturing Date: **06-Dec-2021**
Expiry Date: **Nov-2023**

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 Regulation (EU) 2019/6. 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:

Stefanie Erbler
Qualified Person

19. Juli 2022

A handwritten signature in blue ink, appearing to read 'Stefanie', followed by a long horizontal flourish.

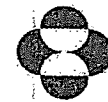
Certificate of Analysis

Product: **Bravecto 250mg 1x1tab 421**
Batch: **21M2049A01**

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	$0.0 \leq X \leq 5.0 \%$	2.8 %
Texture analysis	Intervet Vienna internal method	$15 \leq X \leq 35 \text{ N}$	21 N
Identity A (UPLC - retention time)	Intervet Vienna internal method	Complies	Complies
Identity B (UPLC-UV Spectrum)	Intervet Vienna internal method	Complies	Complies
Assay Fluralaner (UPLC)	Intervet Vienna internal method	$95.0 \leq X \leq 105.0 \%$	97.9 %
Degradation Product A0431246	Intervet Vienna internal method	$\leq 0.4\%$	<0.3 %
Degradation Product IOBA	Intervet Vienna internal method	$\leq 0.4\%$	<0.3 %
Unspecified degradation products (each)	Intervet Vienna internal method	$\leq 1.0\%$	<0.3 %
Total degradation products	Intervet Vienna internal method	$\leq 1.0\%$	no reportable impurities
Uniformity of dosage units (UPLC)	USP < 905 >	$0.0 \leq X \leq 15.0$	2.2
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/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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