

Certificate of Analysis

Product: **Bravecto TriUNO 600mg 3x1tab 582**
Batch: **24F6003AG1**

Country: Distribution via Lithuania

Sales Order Number: 1117693196 / 10

Delivery Number: 1221283579 / 900011



Material Number:
220155

Package Size:
1 TAB

Manufacturing Date:
23-Aug-2024

Expiry Date:
Jul-2026

Storage Conditions:
No Restrictions

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:

Dr. Kurt Knappe
Qualified Person

Function:

Date:

17. April 2025

Signature:

A handwritten signature in black ink, appearing to be 'K. Knappe'.



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Results of Analysis

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



MSD
Animal Health

Test	Method	Specification	Result
Appearance - Color	Intervet Vienna internal method	light pink to light brown mottled	Complies
Form of tablet	Intervet Vienna internal method	Round	Complies
Identity HPLC Fluralaner	Intervet Vienna internal method	Complies	Complies
Identity HPLC Pyrantel Pamoate	Intervet Vienna internal method	Complies	Complies
Identity HPLC Moxidectin	Intervet Vienna internal method	Complies	Complies
Identity HPLC BHT	Intervet Vienna internal method	Complies	Complies
Identity HPLC-PDA Fluralaner	Intervet Vienna internal method	Complies	Complies
Identity HPLC-PDA Pyrantel Pamoate	Intervet Vienna internal method	Complies	Complies
Identity HPLC-PDA BHT	Intervet Vienna internal method	Complies	Complies
Identity HPLC-PDA Moxidectin	Intervet Vienna internal method	Complies	Complies
Content Uniformity - Fluralaner	Intervet Vienna internal method	≤ 15.0	1.5
Content Uniformity - Pyrantel Pamoate	Intern (USP #, Ph Eur 2.9.40)	≤ 15.0	1.4
Content Uniformity - Moxidectin	Intern (USP #, Ph Eur 2.9.40)	≤ 15.0	1.8
Assay Fluralaner (HPLC)	Intervet Vienna internal method	$95.0 \leq X \leq 105.0 \%$	99.6 %
Assay Pyrantel Pamoate (HPLC)	Intervet Vienna internal method	$95.0 \leq X \leq 105.0 \%$	99.9 %
Assay Moxidectin (HPLC)	Intervet Vienna internal method	$95.0 \leq X \leq 105.0 \%$	97.4 %
Pyrantel Pamoate Impurity B	Intervet Vienna internal method	$\leq 1.0 \%$	0.0 %
Indiv. unsp. degradates/Pyrantel Pamoate	Intervet Vienna internal method	$\leq 1.0 \%$	0.3 %
Total degradates/Pyrantel Pamoate	Intervet Vienna internal method	$\leq 1.0 \%$	0.3 %
Individual unsp. degradates/Fluralaner	Intervet Vienna internal method	$\leq 1.0 \%$	0.3 %
Total degradates/Fluralaner	Intervet Vienna internal method	$\leq 1.0 \%$	0.3 %
Moxidectin Impurity D	Intervet Vienna internal method	$\leq 2.5 \%$	0.3 %
Moxidectin Impurity E	Intervet Vienna internal method	$\leq 1.0 \%$	0.3 %
Moxidectin Impurity L	Intervet Vienna internal method	$\leq 1.0 \%$	0.3 %
Moxidectin 23-keto Nemadectin	Intervet Vienna internal method	$\leq 1.0 \%$	0.3 %
Individual unsp. degradates/Moxidectin	Intervet Vienna internal method	$\leq 1.0 \%$	0.3 %
Total degradates/Moxidectin	Intervet Vienna internal method	$\leq 1.2 \%$	0.3 %
BHT content	Intervet Vienna internal method	$85.0 \leq X \leq 110.0 \%$	93.5 %
Ethanol content	Intervet Vienna internal method	$\leq 5000 \text{ ppm}$	300 ppm
Water content	Intervet Vienna internal method	$\leq 4.5 \%$	4.2 %
Fluralaner Dissolution after 30 min avg.	Intervet Vienna internal method	$\geq 80 \%$	85 %
Pyrantel Dissolution after 30 min avg.	Intervet Vienna internal method	$\geq 80 \%$	95 %
Moxidectin Dissolution after 30 min avg.	Intervet Vienna internal method	$\geq 80 \%$	95 %
Average tablet hardness	Ph. Eur. 2.9.8	$135 \leq X \leq 215 \text{ N}$	186 N
Average tablet weight	Intervet Vienna internal method	$4560 \leq X \leq 5040 \text{ Milligram}$	4822 Milligram



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<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
Microbial Purity Aerob. Bact	Ph. Eur. 2.6.12 & 2.6.13 / USP 61 & 62	NMT 10 ³ CFU/g	Complies
Microbial Purity Yeasts/Molds	Ph. Eur. 2.6.12 & 2.6.13 / USP 61 & 62	NMT 10 ³ CFU/g	Complies
Absence of E. coli	Ph. Eur. 2.6.12 & 2.6.13 / USP 61 & 62	Absence of E. coli in 1g	Complies

