

# Certificate of Analysis

Product: **Bravecto 500mg 1x1tab 421**  
Batch: **23M3071H03**



Country: Distribution via Netherlands

Sales Order Number: 1114146332 / 10  
Delivery Number: 1217544881 / 900001

Material Number:  
**135531**

Package Size:  
**1 TAB**

Manufacturing Date:  
**12-Sep-2023**

Expiry Date:  
**Aug-2025**

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.


This batch has been released for: UA

Name:

Function:

Date:

Signature:

  
Dr. Helena Salapovic  
Qualified Person  
03. Nov. 2023

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Product: **Bravecto 500mg 1x1tab 421**  
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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	$0.0 \leq X \leq 5.0 \%$	2.9 %
Texture analysis	Intervet Vienna internal method	$17 \leq X \leq 37 \text{ N}$	27 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	$95.0 \leq X \leq 105.0 \%$	102.0 %
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 >	$0.0 \leq X \leq 15.0$	2.8
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