

Certificate of Analysis

Product: **Bravecto 250mg 1x1tab 579**
Batch: **U305Z03**

Country: Hungary

Sales Order Number: 1107810204 / 10

Delivery Number: 1209742256 / 900001

Material Number: 141166

Package Size: 1 TAB

Expiry Date: Sep-2021

Manufacturing Date: 30-Oct-2019

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:

Dr. Christian Prohaska
Qualified Person

Function:

Date:

24 April 2020

Signature:

Certificate of Analysis

Product: **Bravecto 250mg 1x1tab 579**
 Batch: **U305203**

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	≤ 5.0 %	2.7 %
Texture analysis	Interwet Vienna internal method	15 - 35 N	23 N
Identity A (UPLC - retention time)	Interwet Vienna internal method	Complies	Complies
Identity B (UPLC-UV Spectrum)	Interwet Vienna internal method	Complies	Complies
Assay Furalaner (UPLC)	Interwet Vienna internal method	95.0 - 105.0 %	102.1 %
Degradation Product A0431246	Interwet Vienna internal method	≤ 0.4 %	0.4 %
Degradation Product IOBA	Interwet Vienna internal method	≤ 0.4 %	0.4 %
Unspecified degradation products (each)	Interwet Vienna internal method	≤ 1.0 %	Complies
Total degradation products (UPLC)	Interwet Vienna internal method	≤ 1.0 %	1.0 %
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/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