

Certificate of Analysis

Product: **Vasotop P 0.625mg 3x28tab 296**
Batch: **A026B04**

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



Country: **Russian Fed.**
Sales Order Number: **1107912840 / 10**
Delivery Number: **1209959082 / 900001**

Material Number:
148582

Package Size:
28 TAB

Manufacturing Date: **18-Nov-2019**
Expiry Date: **Oct-2021**

Storage Conditions:
Below 25°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:
Function: **Dr. Kurt Krapfenbauer**
Qualified Person
Date: **17. Juni 2020**
Signature:

A handwritten signature in blue ink, appearing to be "KK", written over a blue ink stamp.

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Results of Analysis

<u>Test</u>	<u>Method</u>	<u>Specification</u>	<u>Result</u>
Appearance - Color	Visual Examination	brownish-orange	Complies
Form of tablet	Visual Examination	Oblong	Complies
Scoreline	Visual Examination	Scoreline Both Sides	Complies
Embossing Upper Side	Visual Examination	V - score line - V	Complies
Embossing Lower Side	Visual Examination	bottom side: score line	Complies
Length	Dimension Measurement	$7.9 \leq X \leq 8.1$ mm	8.1 mm
Width	Dimension Measurement	$3.9 \leq X \leq 4.1$ mm	4.1 mm
Height	Dimension Measurement	$2.9 \leq X \leq 3.3$ mm	3.1 mm
Identification Iron (coloring agent)	wet chemical test	Complies	Complies
Uniformity of Dosage Units	Ph. Eur. 2.9.40 & 2.2.29	complies with Ph. Eur.	Complies
Identification Ramipril (HPLC)	Ph. Eur. 2.2.29.	Complies	Complies
Assay Ramipril (HPLC)	Ph. Eur. 2.2.29.	$0.594 \leq X \leq 0.656$ mg/TBL	0.638 mg/TBL
Rel. Sub. Ramipril-Diketopiperazine	Ph. Eur. 2.2.29.	≤ 1.0 %	0.2 %
In-vitro Dissolution after 30min	Ph. Eur. 2.9.3 & 2.2.29	≥ 80 %	92 %
Microbial Purity Aerob. Bact	Ph. Eur.	$\leq 10^3$ Aerobic Bacteria cfu/g	Complies
Microbial Purity Yeasts/Molds	Ph. Eur.	$\leq 10^2$ Yeasts/Moulds cfu/g	Complies
Specified micro-organisms, E. coli	Ph. Eur.	Absence of E.coli	Complies
Specified micro-organisms, Salmonella	Ph. Eur.	Absence of Salmonella	Complies