LAVET PHARMACEUTICALS
YOU LOVE WE CARE

FPR – 2019 / 1567 **Boehringer Ingelheim Vetmedica / Russia 200543165**

CERTIFICATE OF CONFORMITY

Product's name, strength	VETMEDIN S 5 mg chewable tablets
Active ingredient(s)	Pimobendan
Manufacturing specification:	GYÁR-047 v01
Batch number	866I9CC
Importing country:	Russia
Quantity	2014 x 50 tablets in ALU/ALU blister foils and carton box
Manufacturing date:	09/2019
Expiry date:	03/2022
Testing specification:	LAV-SPV-035 v 03

Statement:

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. Any deviations have been assessed prior to batch release. The batch has been released by a Qualified Person.

Name and position of person authorizing batch release for shipment	dr. Brigitta Szabó Qualified Person
Signature	

Date of signature: 07/10/2019

LAVET Kft./Ltd.
Meghatalmazott személy/
Qualified person (1.)

HITELES PÉLDÁNY
LAVET
TRUE COPY

LAVET GYÓGYSZERIPARI KFT. / LAVET PHARMACEUTICALS LTD.
Minőségbiztosítási Osztály / Quality Assurance/ Meghatalmazott személy / Qualified Person
Gyógyszergyártási engedély száma / Manufacturing authorisation No.: MA-HU/18V/2006/M14
GMP igazolás száma/GMP certificate No.: CG-HU/23V/2016
Cím/Address: H-2143 Kistarcsa, Batthyány utca 6., Hungary - Tel: (+36) 28/506-445
E-mail: lavet@lavet.hu
www.lavet.hu

LAVET PHARMACEUTICALS
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FPR – 2019 / 1635 **Boehringer Ingelheim Vetmedica / Russia 200543165**

CERTIFICATE of ANALYSIS

Product name: **VETMEDIN S 5 mg chewable tablets**
Batch number: 867I9CA
Importing country: Russia
Quantity: 5886 x 50 tablets in ALU/ALU blister foils and carton box
Date of manufacture: 09/2019
Expiry date: 03/2022
No. of Analytical card: QC-0867C-01-035-01/2019
Testing specification: LAV-SPV-035 v 03

Parameters, *method*	**Specification**	**Result**
1. Appearance *(visual)*	brownish, oval, divisible, centre scored tablets	complies
2. Friability *(Ph.Eur 2.9.7)*	≤ 1.0% (taken from IPC)	0.1
3. Resistance to crushing *(Ph.Eur. 2.9.8)*	≤ 160 N	94
4. Loss on drying *(Ph.Eur 2.2.32)*	≤ 5.0%	3.6
5. Uniformity of dosage units *(Ph.Eur. in force 2.9.40 Mass uniformity)*	Acceptance value ≤ 15.0	1.8
6. Dissolution *(Ph.Eur. 2.9.3 Paddle method 75 rpm/min, 45 min.)*	Q: 75%	
• S1 (6 units)	No single value < 80% Mean ≥ 75%	94-104 (mean:97)
• S2 (12 units)	No single value < 60% Mean ≥ 75%	N/A N/A
• S3 (24 units)	No single value < 50% 22 out of 24 values ≥ 60% Mean ≥ 75%	N/A N/A N/A
7. Microbiological quality* *(Ph.Eur. 5.1.4, 2.6.12 and 2.6.13 Plate count method)*		
7.1. TAMC *(Total aerobic microbial count)*	$\leq 10^3$ CFU/g	---[1]
7.2. TYMC *(Total combined yeasts/moulds count)*	$\leq 10^2$ CFU/g	
7.3. Escherichia coli	absent in 1 g	
8. Related substances *(UHPLC/UV)*		
8.1. Impurity A	≤ 0.5 %	< LOQ[2]
8.2. Impurity B	≤ 0.5 %	< LOQ[2]
8.3. Any other impurity	≤ 0.5 %	< LOQ[2]
8.4. Total impurities	≤ 1.0 %	< LOQ[2]
9. Identification of active ingredient *(UHPLC/UV)*	Rt and the UV-VIS spectrum of the main peak is similar to RS	complies
10. Assay *(UHPLC/UV)* Pimobendan	4.75 – 5.25 mg/tablet (95 - 105 % of label claim)	5.00 100

*Not routinely, every 10th batch and at least once per year
1: Test is carried out on a spot-check basis. We confirm however compliance with the inspection and requirements also for this batch.
2: LOQ: 0.006% for all impurities

Qualification: ***accepted***

Kistarcsa, 11/10/2019

Dóra Benesóczki
QC Manager

LAVET Kft./Ltd.
Meghatalmazott személy/
Qualified person (1.)

dr. Brigitta Szabó
Qualified person

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