LAVET PHARMACEUTICALS
YOU LOVE WE CARE

FPR – 2020 / 1151 **Boehringer Ingelheim Vetmedica / Russia 200577821**

CERTIFICATE OF CONFORMITY

Product's name, strength	VETMEDIN S 10 mg chewable tablets
Active ingredient(s)	Pimobendan
Manufacturing specification:	GYÁR-047 v10
Batch number	580E0DD
Importing country:	Russia
Quantity	454 x 50 tablets in ALU/ALU blister foils and carton box
Manufacturing date:	04/2020
Expiry date:	04/2023
Testing specification:	LAV-SPV-036 v04

Statement:

I hereby certify , that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU , and the requirements of the Marketing Authorisation (s) of the destination 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: 15/07/2020

LAVET KFT.
Meghatalmazott személy/
Qualified person (1.)

HITELES PÉLDÁNY
LAVET
TRUE COPY

Boehringer Ingelheim
Москва

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/14V/2019, CG-HU/18V/2019, CG-HU/04V/2019
Cím/Address: H-2143 Kistarcsa, Batthyány utca 6., Hungary - Tel: (+36) 28/506-445
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FPR – 2020 / 1151 **Boehringer Ingelheim Vetmedica / Russia 200577821**

CERTIFICATE of ANALYSIS

Product name: **VETMEDIN S 10 mg chewable tablets**
Batch number: 580E0DD
Importing country: Russia
Quantity: 454 x 50 tablets in ALU/ALU blister foils and carton box
Date of manufacture: 04/2020
Expiry date: 04/2023
No.of Analytical card : QC-0580D-01-036-02/2020
Testing specification: LAV-SPV-036 v04

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)	0.2
3. Resistance to crushing *(Ph.Eur. 2.9.8)*	≤ 160 N	113
4. Loss on drying *(Ph.Eur 2.2.32)*	≤ 5.0%	3.5
5. Uniformity of dosage units *(Ph.Eur. in force 2.9.40 Mass uniformity)*	Acceptance value ≤ 15.0	1.3
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%	89-94 mean:92
• 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*)	≤ 10^3 CFU/g	---[1]
7.2. TYMC (*Total combined yeast/moulds count*)	≤ 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	9.5 – 10.5 mg/tablet (95 - 105 % of label claim)	9.8 98

*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, 15/07/2020

LAVET KFT. Meghatalmazott személy/ Qualified person

Dóra Benesóczki
QC Manager

dr. Brigitta Szabó
Qualified person

Boehringer Ingelheim Москва

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