

CERTIFICATE of ANALYSIS

Product name: VETMEDIN S 1.25 mg chewable tablets
Batch number: 547E0AA
Importing country: Russia
Quantity: 5178 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-0547A-01-033-01/2020
Testing specification: LAV-SPV-033 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) | ≤ 90 N | 40 |
| 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 | 1.8 |
| 6. Dissolution (Ph.Eur. 2.9.3 Paddle method 75 rpm/min, 45 min.) • S1 (6 units) • S2 (12 units) • S3 (24 units) | Q: 75% No single value < 80% Mean ≥ 75% No single value < 60% Mean ≥ 75% No single value < 50% 22 out of 24 values ≥ 60% Mean ≥ 75% | 88-95 mean: 92 N/A N/A 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) 7.2. TYMC (Total combined yeasts/moulds count) 7.3. Escherichia coli | ≤ 10 ³ CFU/g ≤ 10 ² CFU/g absent in 1 g | --- ¹ |
| 8. Related substances (UHPLC/UV) 8.1. Impurity A 8.2. Impurity B 8.3. Any other impurity 8.4. Total impurities | ≤ 0.5 % ≤ 0.5 % ≤ 0.5 % ≤ 1.0 % | < LOQ ² < LOQ ² < LOQ ² < 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 | 1.19 – 1.31 mg/tablet (95 - 105 % of label claim) | 1.24 100 |

*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.

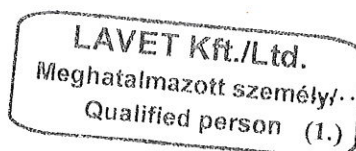
2: LOQ: 0.006% for all impurities

Qualification: *accepted*

Kistarcsa, 18/06/2020



[Signature]
Dóra Benesóczki
QC Manager




[Signature]
Vilmos Angyal
Qualified person

CERTIFICATE OF CONFORMITY

| | |
|------------------------------|---|
| Product's name, strength | VETMEDIN S 1.25 mg chewable tablets |
| Active ingredient(s) | Pimobendan |
| Manufacturing specification: | GYÁR-047 v10 |
| Batch number | 547E0AA |
| Importing country: | Russia |
| Quantity | 5178 x 50 tablets in ALU/ALU blister foils and carton box |
| Manufacturing date: | 04/2020 |
| Expiry date: | 04/2023 |
| Testing specification: | LAV-SPV-033 v 04 |

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 | Vilmos Angyal Qualified Person |
| Signature |  |

Date of signature: 18/06/2020

