



aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 52603

Product:	Cylanic 250mg/62,5mg 100tab RO	Dosage form:	Tablet
Article number:	00100807	Package size:	100 tablets
Batch:	22J113 Split: 0	Marketing authorisation holder:	Livisto Int'l
Quantity:	688 Units	Registration number:	210067
Manufacturing date:	01.12.2022	Distributor / Importer:	RO - BistriVet Rumänien
Expiry date:	31.03.2025		

Parameter	Specification	Result
Appearance of tablet	White to slightly yellow, round and convex tablet with a cross-shaped break line on one side, 13 mm in diameter	White to slightly yellow, round and convex tablet with a cross-shaped break line on one side, 13 mm in diameter
Average tablet mass	508 ... 561	535 mg/Tabl.
Thickness	4,3 ... 4,8 mm	4,5 mm
Disintegration time	Max. 15 min	< 3 min
Hardness	50 ... 200 N	129 N
Friability	Max. 1,0 %	0,2 %
Uniformity of dosage units (CU): amoxicillin base	AV <= 15,0	corresponds to
Uniformity of dosage units (CU): clavulanic acid	AV <= 15,0	corresponds to
Dissolution: amoxicillin base	After 30 minutes = Q 85 %	S1: 101 - 104 %
Dissolution: clavulanic acid	After 30 minutes = Q 85 %	S1: 100 - 102 %
Identity: amoxicillin base	Retention time, peak shape and UV spectrum of standard and sample must correspond	Corresponds to
Identity: clavulanic acid	Retention time, peak shape and UV spectrum of standard and sample must correspond	Corresponds to
Assay: amoxicillin base	237,5 ... 262,5	252,8 mg/Tabl.
Assay: clavulanic acid	59,4 ... 65,6	62,4 mg/Tabl.
Related substances of amoxicillin base: any impurity, single	Max. 1,0 %	0,1 %
Related substances of amoxicillin base: total impurities	Max. 3,0 %	0,4 %
Related substances of clavulanic acid: any impurity, single	Max. 1,0 %	< 0,1 %
Related substances of clavulanic acid: total impurities	Max. 3,0 %	< 0,1 %

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
Thomas Hölter

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Deutschland

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www.livisto.com

Along with you



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Template: 3099

TAMC, TYMC and Escherichia coli are tested periodically every 5th batch.

The finished product has been tested in accordance with the testing instruction and is of the required quality.

10. JAN. 2023

Date, Signature Head of Quality Control

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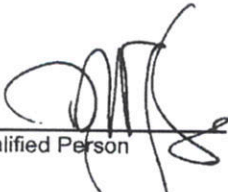
I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the marketing authorisation as laid down in the manufacturing and quality control instructions. The batch processing, packaging and analytical documentation has been reviewed and is in full compliance with GMP guidelines. All deviations were evaluated before batch release.

This batch has the required quality and

- ☐ is released for delivery
☒ is released for the market

Remarks:

Four horizontal lines for handwritten remarks, each with a diagonal slash mark.

13.01.2023 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange ☐ Stephan Bruns ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller ☐ Ulrich Kontny

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