



LIVISTO

aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 48619

Product:	Cylanic 50mg/12,5mg 100tab RO	Dosage form:	Tablet
Article number:	00100826	Package size:	100 tablets
Batch:	21K147 Split: 0	Marketing authorisation holder:	Livisto Int'l
Quantity:	1.098 Units	Registration number:	
Manufacturing date:	01.11.2021	Distributor / Importer:	
Expiry date:	30.04.2024		

Parameter	Specification	Result
Appearance of tablet	White to slightly yellow, round and convex tablet with a cross-shaped break line on one side, 8 mm in diameter	White to slightly yellow, round and convex tablet with a cross-shaped break line on one side, 8 mm in diameter
Average tablet mass	101,5 ... 112,2	107,3 mg/Tabl.
Thickness	2,3 ... 2,8 mm	2,3 mm
Disintegration time	Max. 15 min	< 2 min
Hardness	20 ... 60 N	36 N
Friability	Max. 1,0 %	0,7 %
Uniformity of dosage units (CU): amoxicillin base	AV $\leq$ 15,0	complies
Uniformity of dosage units (CU): clavulanic acid	AV $\leq$ 15,0	complies
Dissolution: amoxicillin base	After 30 minutes = Q 85 %	102 - 104 %
Dissolution: clavulanic acid	After 30 minutes = Q 85 %	97 - 100 %
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	47,5 ... 52,5	51,0 mg/Tabl.
Assay: clavulanic acid	11,9 ... 13,1	12,2 mg/Tabl.
Related substances of amoxicillin base: any impurity, single	Max. 1,0 %	0,2 %
Related substances of amoxicillin base: total impurities	Max. 3,0 %	0,3 %
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 %



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Parameter	Specification	Result
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Template: 3080

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.

27. APR. 2022

Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
Thomas Höltker

Im Südfeld 9
48308 Senden-Bösensell
Deutschland

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www.livisto.com

Along with you



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Batch certificate

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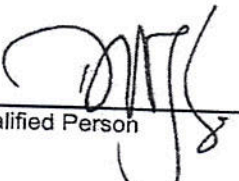
I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the marketing authorisation as laid down in the manufacturing 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:

27.4.2022 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange

☐ Gudrun Prußeit

☐ Dr. Jürgen Schlüter

☐ Dr. Bernd Manfred Müller

☐ Ulrich Kontny

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