



LIVISTO

aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 48646

Product: Cylanic 500mg/125mg 100tab RO
Article number: 00100845
Batch: 21K150 Split: 0
Quantity: 648 Units
Manufacturing date: 01.11.2021
Expiry date: 30.04.2024
Dosage form: Tablet
Package size: 10 tablets
Marketing authorisation holder: Livisto Int'l
Registration number:
Distributor / Importer:

Parameter	Specification	Result
Appearance of tablet	White to slightly yellow, round and convex tablet with a cross-shaped break line on one side, 15 mm in diameter	White to slightly yellow, round and convex tablet with a cross-shaped break line on one side, 15 mm in diameter
Average tablet mass	1016 ... 1122	1066 mg/Tabl.
Thickness	6,5 ... 7,0 mm	6,9 mm
Disintegration time	Max. 15 min	< 4 min
Hardness	50 ... 250 N	131 N
Friability	Max. 1,0 %	0,9 %
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 %	99 - 101 %
Dissolution: clavulanic acid	After 30 minutes = Q 85 %	98 - 101 %
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	475 ... 525	498 mg/Tabl.
Assay: clavulanic acid	118,7 ... 131,3	123,1 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: 3118

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.

26. APR. 2022

Date, Signature Head of Quality Control



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Batch certificate

Certificate No.: 48646

Product:	Cylanic 500mg/125mg 100tab RO		
Article number:	00100845	Dosage form:	Tablet
Batch:	21K150 Split: 0	Package size:	10 tablets
Quantity:	648 Units	Marketing authorisation holder:	Livisto Int'l
Manufacturing date:	01.11.2021	Registration number:	
Expiry date:	30.04.2024	Distributor / Importer:	

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 crossed out with a diagonal line.

02604.222
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange

☐ Gudrun Prußeit

☐ Dr. Jürgen Schlüter

☐ Dr. Bernd Manfred Müller

☐ Ulrich Kontry

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
Thomas Hölter

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Along with you