



aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 69943

Product: Cylanic 50mg/12,5mg 100tab PT/RO
Article number: 00101261
Batch: 25D162 Split: 0
Quantity: 3,234 Units
Manufacturing date: 01.04.2025
Expiry date: 30.09.2027
Dosage form: Tablet
Package size: 100 tablets
Marketing authorisation holder: Livisto Int'l
Registration number: PT: 1430/02/21DFVPT; RO: 210066
Distributor / Importer: 1430/01/21 DFVPT

* correction
11.08.2025
S. Klein

Parameter

Appearance of tablet

Specification

White to slightly yellow, round and convex tablet with a cross-shaped break line on one side, 8 mm in diameter

Result

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	108,1 mg/Tabl.
Thickness	2,3 ... 2,8 mm	2,5 mm
Disintegration time	Max. 15 min	< 2 min
Hardness	20 ... 60 N	27 N
Friability	Max. 1,0 %	0,1 %
Uniformity of dosage units (CU): amoxicillin base	AV $\leq$ 15,0	Corresponds to
Uniformity of dosage units (CU): clavulanic acid	AV $\leq$ 15,0	Corresponds to
Dissolution: amoxicillin base	After 30 minutes = Q 85 %	S1: 100%; 99-104%
Dissolution: clavulanic acid	After 30 minutes = Q 85 %	S1: 100%; 98-102%
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	47,5 ... 52,5	50,8 mg/Tabl.
Assay: clavulanic acid	11,9 ... 13,1	12,6 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 %	0,6 %
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 %
Microbiological purity: TAMC	Max. 1000 CFU/g	< 100 CFU/g
Microbiological purity: TYMC	Max. 100 CFU/g	< 100 CFU/g
Microbiological purity: Escherichia coli	Absence/g	Absence/g

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
Thomas Hölter

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Along with you



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*correction
11.08.2025
Sylvia B.

Parameter	Specification	Result
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Template: 3674

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.

11. AUG. 2025 *Frederickmann*
Date, Signature Head of Quality Control

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