



anMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 58925

Product:	Cylanic 500mg/125mg 100tab PT/RO	Dosage form:	Tablet
Article number:	00101268	Package size:	100 tablets
Batch:	23E29 Split: 0	Marketing authorisation holder:	Livisto Int'l
Quantity:	1,481 Units	Registration number:	
Manufacturing date:	01.06.2023	Distributor / Importer:	
Expiry date:	30.04.2026		

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	1068 mg/Tabl.
Thickness	6,5 ... 7,0 mm	6.8 mm
Disintegration time	Max. 15 min	< 7 min
Hardness	50 ... 250 N	166 N
Friability	Max. 1,0 %	0.3 %
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: 97 - 102 %
Dissolution: clavulanic acid	After 30 minutes = Q 85 %	S1: 99 - 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	475 ... 525	493 mg/Tabl.
Assay: clavulanic acid	118,7 ... 131,3	123.0 mg/Tabl.
Related substances of amoxicillin base: any impurity, single	Max. 1,0 %	0.4 %
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 Höltker

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Along with you



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Parameter	Specification	Result
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Template: 3682

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.

 13. DEZ. 2023
Date, Signature Head of Quality Control

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