

Certificate of Analysis

Certificate No.: 63831

Product:	Cylanic 500mg/125mg 100tab PT/RO		
Article number:	00101268	Dosage form:	Tablet
Batch:	24E50 Split: 0	Package size:	100 tablets
Quantity:	1,649 Units	Marketing authorisation holder:	Livisto Int'l
Manufacturing date:	01.06.2024	Registration number:	1430/03/21DFVPT; 210066
Expiry date:	30.04.2027	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	1072 mg/Tabl.
Thickness	6,5 ... 7,0 mm	6,9 mm
Disintegration time	Max. 15 min	< 7 min
Hardness	50 ... 250 N	189 N
Friability	Max. 1,0 %	0,5 %
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: 101 - 103 %; 102 %
Dissolution: clavulanic acid	After 30 minutes = Q 85 %	S1: 103 - 105 %; 104 %
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	500 mg/Tabl.
Assay: clavulanic acid	118,7 ... 131,3	126,6 mg/Tabl.
Related substances of amoxicillin base: any impurity, single	Max. 1,0 %	0,3 %
Related substances of amoxicillin base: total impurities	Max. 3,0 %	0,9 %
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 %



aniMedica Herstellungs GmbH
a LIVISTO company

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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.

22 JUL 2024

Date, Signature Head of Quality Control