

Certificate of Analysis

Certificate No.: 63824

Product:	Cylanic 50mg/12,5mg 100tab PT/RO		
Article number:	00101261	Dosage form:	Tablet
Batch:	24E48 Split: 0	Package size:	100 tablets
Quantity:	2,734 Units	Marketing authorisation holder:	Livisto Int'l
Manufacturing date:	01.06.2024	Registration number:	PT: 1430/02/21DFVPT; RO: 210066
Expiry date:	31.10.2026	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, 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	106,8 mg/Tabl.
Thickness	2,3 ... 2,8 mm	2,5 mm
Disintegration time	Max. 15 min	< 2 min
Hardness	20 ... 60 N	42 N
Friability	Max. 1,0 %	0,1 %
Uniformity of dosage units (CU): amoxicillin base	AV <= 15,0	corresponds to
Uniformity of dosage units (CU): clavulanic acid	AV <= 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: 107 - 109 %; 107 %
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	49,7 mg/Tabl.
Assay: clavulanic acid	11,9 ... 13,1	12,9 mg/Tabl.
Related substances of amoxicillin base: any impurity, single	Max. 1,0 %	< 0,1 %
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 %
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



aniMedica Herstellungs GmbH
a LIVISTO company

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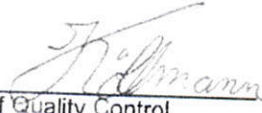
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Parameter	Specification	Result
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Template: 3674

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.

12.11.2024

Date, Signature Head of Quality Control