



aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 58924

Product:	Cylanic 250mg/62,5mg 100tab PT/RO		
Article number:	00101265	Dosage form:	Tablet
Batch:	23E28 Split: 0	Package size:	100 tablets
Quantity:	1,282 Units	Marketing authorisation holder:	Livisto Int'l
Manufacturing date:	01.06.2023	Registration number:	
Expiry date:	31.10.2025	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, 13 mm in diameter	White to slightly yellow, round and convex tablet with a cross-shaped break line on one side, 13 mm in diameter
Average tablet mass	508 ... 561	534 mg/Tabl.
Thickness	4,3 ... 4,8 mm	4.7 mm
Disintegration time	Max. 15 min	< 5 min
Hardness	50 ... 200 N	80 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: 99 - 101 %
Dissolution: clavulanic acid	After 30 minutes = Q 85 %	S1: 100 - 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	237,5 ... 262,5	250.7 mg/Tabl.
Assay: clavulanic acid	59,4 ... 65,6	62.6 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 %	0.6 %
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 %

Amtsgericht Coesfeld
HRB-Nr. 10339
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