



Certificate of Analysis

Product name: LACTAMATOR™ (Sterile Liquid)

Product code: # LCT-LQS20 Batch: 019.LQS20.00123

		Mfg date: July 2023	
Tests	Specifications	Results	Comment
Cephalosporinase Activity (<i>IU/mI</i>)	> 10	26	Passed
Penicillinase Activity (IU/ml)	> 100	404	Passed
Cephalosporinase Activity (IU/vial)	> 200	520	Passed
Penicillinase Activity (IU/vial)	> 2,000	8,080	Passed

Unit definition

- One Cephalosporinase International Unit of activity is defined as the amount of enzyme that catalyze the hydrolysis of 1.0 micromole of cephalosporin C per minute at 25 °C at pH 7.0.
- One Penicillinase International Unit of activity is defined as the amount of enzyme that catalyze the hydrolysis of 1.0 micromole of benzylpenicillin per minute at 25 °C at pH 7.0.
- One Penicillinase International Unit corresponds approximately to 600 Levy Units or 75 Pollock Units.

Tests	Specifications	Results	Comment
Thermal stability Cephalosporinase (7 days at 42°C)	> 80 %	89	Passed
Thermal stability Penicillinase (7 days at 42°C)	> 80 %	84	Passed
Sterility ¹	conform	conform	Passed

Appearance

Yellowish liquid clear solution. Small white particles maybe present in suspension without affecting on the performance of the product.

Storage

Store from +2°C to +8°C

The product is sterile by $_{v}$ -irradiation.

The product does not contain animal derived components or additives.

Exp. Date: July 2026

Quality Assurance – Rosaria Cassese

Page 1 of 1

CPC BIOTECH S.r.l.

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Registro Imprese di Monza e Brianza Cap. Soc. € 114.000,00 i.v.

www.cpcbiotech.it

 $^{^{\}rm 1}\,{\rm Sterility}$ test according to EU.Ph.