

Certificate of Analysis

Product name: LACTAMATOR™(Sterile Liquid)

Product code: # LCT-LQS100 (5 x 10 ml/vial)

Batch: 019.LQS100.00122

Mfg date: January 2022

Tests	Specifications	Results	Comment
Cephalosporinase Activity (IU/ml)	> 100	167	Passed
Penicillinase Activity (IU/ml)	> 1,000	2,537	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 %	86	Passed
Thermal stability Penicillinase (7 days at 42°C)	> 80 %	86	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 γ -irradiation.

The product does not contain animal derived components or additives.

Exp. Date: January 2025

Quality Assurance - Rosaria Cassese



¹ Sterility test according to EU.Ph.