

## 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/ml</i> )	> 10	<b>26</b>	Passed
Penicillinase Activity ( <i>IU/ml</i> )	> 100	<b>404</b>	Passed
Cephalosporinase Activity ( <i>IU/vial</i> )	> 200	<b>520</b>	Passed
Penicillinase Activity ( <i>IU/vial</i> )	> 2,000	<b>8,080</b>	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 ( <b>7 days at 42°C</b> )	> 80 %	<b>89</b>	Passed
Thermal stability Penicillinase ( <b>7 days at 42°C</b> )	> 80 %	<b>84</b>	Passed
Sterility <sup>1</sup>	conform	<b>conform</b>	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  $\gamma$ -irradiation.

The product does not contain animal derived components or additives.

**Exp. Date: July 2026**

**Quality Assurance –  
Rosaria Cassese**



<sup>1</sup> Sterility test according to EU.Ph.