

## Certificate of Analysis

**Product name: LACTAMATOR™(Sterile Liquid)**

**Product code: # LCT-LQS40**

**Batch: 019.LQS40.00122**

**Mfg date: June 2022**

Tests	Specifications	Results	Comment
Cephalosporinase Activity (IU/ml)	> 200	<b>261</b>	Passed
Penicillinase Activity (IU/ml)	> 2,000	<b>3,473</b>	Passed
Cephalosporinase Activity (IU/vial)	> 4,000	<b>5,220</b>	Passed
Penicillinase Activity (IU/vial)	> 40,000	<b>69,460</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>96</b>	Passed
Thermal stability Penicillinase ( <b>7 days at 42°C</b> )	> 80 %	<b>83</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: June 2025**

**Quality Assurance -Rosaria Cassese**



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