



# **Certificate of Analysis**

## Product name: LACTAMATOR™ Product code: # LCT-LQS10 (Sterile Liquid) Batch: 019.LQS.00123

		Mfg Date: February 2023	
Tests	Specifications	Results	Comment
Cephalosporinase Activity (IU/ml)	> 10	19	Passed
Penicillinase Acitivity (IU/mI)	> 100	254	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 %	93	Passed
Thermal stability Penicillinase (7 days at 42°C)	> 80 %	82	Passed
Sterility <sup>1</sup>	conform	conform	Passed

### **Appearance**

Yellowish liquid clear solution. Small white particles maybe present in suspension.

#### **Storage**

Store from +2°C to + 8°C The product does not contain animal derived components or additives.

Exp. Date: February 2027

Quality Assurance Rosaria Cassese

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

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