



## Certificate of Analysis

**Product name: PENASE CONCENTRATE (Sterile Liquid)**

**Product code: # PEN-LQS**

**Batch: 017.LQS.00221**

**Mfg Date: May 2021**

Tests	Specifications	Results	Comment
Potency	>20000 LU/ml/min	<b>53478 LU/ml/min</b>	Passed
Thermal stability Penicillinase ( <u>7 days at 42°C</u> )	> 80 %	<b>87 %</b>	Passed
Sterility <sup>1</sup>	conform	<b>conform</b>	Passed

### Unit definition

Levy Unit (LU): amount of penicillinase that inactivates 59.3 IU (International Unit) of Sodium Penicillin G per hour at 25 °C and pH 7.0.

### 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: May 2025**

Quality Assurance

Rosaria Cassese

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