



Certificate of Analysis

Product name: PENASE CONCENTRATE (Sterile Liquid)

Product code: # PEN-LQS

Batch: 017.LQS.00421

Mfg Date: December 2021

Tests	Specifications	Results	Comment
Potency	>20000 LU/ml/min	43404 LU/ml/min	Passed
Thermal stability Penicillinase (<u>7 days at 42°C</u>)	> 80 %	82 %	Passed
Sterility ¹	conform	conform	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 γ -irradiation.

The product does not contain animal derived components or additives.

Exp. Date: December 2025

Quality Assurance

Rosaria Cassese

¹ Sterility test according to EU.Ph.