



Certificate of Analysis

Product name: CARBAMATOR™ Plus (BROAD RANGE β-LACTAMASE)

Product code: # CRK MP-Bulk

Batch: 029.MP.00123

Mfg Date: April 2023

Tests	Specifications	Results	Comment
Cephalosporinase Specific Activity (IU/mg of powder)	≥ 20	48	Passed
Carbapenemase Specific Activity (IU/mg of powder)	≥ 5	13	Passed

Unit definition

One International Unit of Cephalosporinase 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 International Unit of Carbapenemase activity is defined as the amount of enzyme that catalyze the hydrolysis of 1.0 micromole of imipenem per minute at 25 °C at pH 7.0.

Thermal stability Test (7 days at 42°C)

Tests	Specifications (%)	Results (%)	Comment
Thermal stability Cephalosporinase	100 ±15	92	Passed
Thermal stability Carbapenemase	100 ±15	97	Passed

Storage and use conditions.

The enzyme is supplied as lyophilized formulation and should be stored between -25°C and +8 °C.

Dissolve the powder in distilled water. After dissolution insoluble particulates may be appear without affecting the performance of the product.

The product is not sterile. If necessary, sterilize by filtration. After dissolution, filter using sterile 0.20 µm filters with low protein binding under sterile conditions.

Appearance: Yellowish powder.

The product does not contain animal derived components or additives.

Exp. Date: April 2027

Quality Assurance
Rosaria Cassese

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