

# Penicillinase

## Catalogue No. PENI-70-1545 and PENI-70-1541

### SOURCE

Bacillus cereus 569/H9

### SPECIFICATIONS

Penicillinase is a freeze-dried product containing buffer salts and is active against penicillins only.

**TABLE 1** The Specifications of Penicillinase

Catalogue No.	Formulation	Units
1541	Freeze dried bulk powder	>15 Units/mg
1545	Sterile vials	>3000 Units/vial

Genzyme also provides a  $\beta$ -Lactamase product that is active against penicillins, cephalosporins and carbapenems (Cat. No. 1431, bulk powder and 1401, sterile vials).

### UNIT DEFINITION

One Genzyme (International) unit of Penicillinase ( $\beta$ -Lactamase I) activity is defined as the amount of enzyme that will catalyse the hydrolysis of 1.0 micromole of benzylpenicillin per minute at 25°C and pH 7.0.

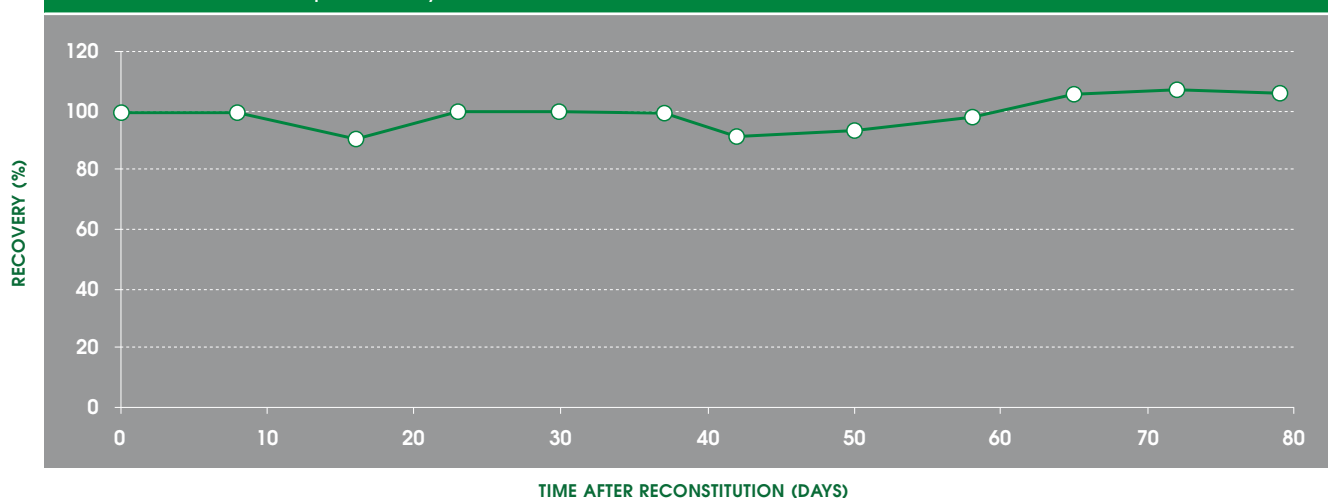
One Genzyme (International) Penicillinase unit is equivalent to 600 Levy Units, 75 Pollock Units or 91200 Kersey Kinetic Units.

### STERILITY

The Penicillinase vials are sterilised by gamma-irradiation. There is no detectable growth in Tryptone Soya Broth at 30-35°C for 14 days. The bulk powder is not sterile but has been filtered through a 0.45 micron filter prior to freeze drying.

### SHELF LIFE

Penicillinase bulk powder is stable for at up to 3 years at -20°C in the presence of a desiccant. Penicillinase vials are stable, when unopened, for up to 2 years at 2-8°C, and for at least 4 weeks at 2-8°C after reconstitution in water.

**FIG. 1** Penicillinase Liquid Stability

## APPLICATIONS

### 1. Testing sterility of blood cultures

Blood cultures are routinely prepared in order to test for bacterial infection. False negative results might be obtained where the blood sample contains antibiotics. Incorporation of  $\beta$ -Lactamase/ Penicillinase in the culture medium will overcome this problem when cephalosporins/penicillins are present.

### 2. Testing for contamination of drugs by antibiotics

US Code of Federal regulations states that "If a reasonable possibility exists that a non-penicillin drug product has been exposed to cross-contamination with penicillin, the non-penicillin drug product shall be tested for the presence of penicillin (21 CFR 211.176, Penicillin Contamination, FDA, BY-Lines No. 8 November 1977)

### 3. Environmental monitoring of antibiotic manufacturing areas

Contact plates, settle plates and air monitoring systems for testing of aseptic conditions in antibiotic manufacturing facilities need to be manufactured with agar medium for neutralisation of antibiotic. This is achieved by the addition of Penicillinase or  $\beta$ -Lactamase to the medium. In this way any antibiotic residues are hydrolysed and microbial contamination can be detected.

### 4. Sterility Testing of Bulk Antibiotics

US Pharmacopeia (USP) Chapter 71 and EP Section 2.6 describe sterility testing of bulk antibiotics, which should be shown to be free from microbial contamination. The testing requires the removal of significant amounts of active antibiotic from solution by combined filtration and the use of Penicillinase or  $\beta$ -Lactamase. The resulting solution is tested for the (lack of) growth of microbes. USP specifies that the amount of Penicillinase or  $\beta$ -Lactamase used in this removal process should be verified using a microbial challenge solution in a control sample.

EFFECTIVENESS

Genzyme Penicillinase has been demonstrated to inactivate the following penicillins; Amdinocillin, Amoxicillin, Ampicillin, Azlocillin, Benzylpenicillin, Carbenicillin, Cloxacillin, Flucloxacillin, Methicillin, Mezlocillin, Nafcillin, Oxacillin, Piperacillin, Ticarcillin.

Note: Genzyme Penicillinase is for in vitro use only.

- (1) Waterworth PM; An enzyme preparation inactivating all penicillins and cephalosporins. Jour Clin Path 26: 596, 1973
(2) Newsome SWB, Walsingham BM. The use of beta-lactamases in the clinical laboratory. Med. Microbiol. 1972 Jul;6:59-66
(3) Winley C et al ; Neutralisation of Beta Lactam Antibiotics in an environmental monitoring medium, PDA Jour Pharm Sci & Tech, 52 (6): 344-345, Nov-Dec 1998
(4) Serge Ohresser, Stéphanie Sacherer, Millipore Molsheim; Development of a culture media for microbiological air monitoring in antibiotic production area (http://mail.google.com/mail/html/load.htmlantibiotic production area; 2001.htm)

NOTES:

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