B-Lactamase

Catalogue No. BELA-70-1401, BELA-70-1431and 70-1431-01

SOURCE

Bacillus cereus 569/H9

SPECIFICATIONS

β-Lactamase is a freeze-dried product containing buffer salts and zinc and is has a broad range of activity against both penicillins (βI activity) and cephalosporins (βII activity).

TABLE 1 The Specifications of β-Lactamase

Catalogue No.	Formulation	Units
1431	Freeze dried bulk powder	>2 βII Units/mg (also contains approx. 20 βI Units/mg)
1401	Sterile product in vials	>500 βI Units/vial >50 βII Units/vial

Sekisui Diagnostics also provides a Penicillinase product that is active against penicillins only (Cat. No. 1541, bulk powder and 1545, sterile vials).

UNIT DEFINITION

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

One Sekisui (International) unit of Cephalosporinase (β-Lactamase II) activity is defined as the amount of enzyme that will catalyse the hydrolysis of 1.0 micromole of cephalosporin C per minute at 25°C and pH 7.0.

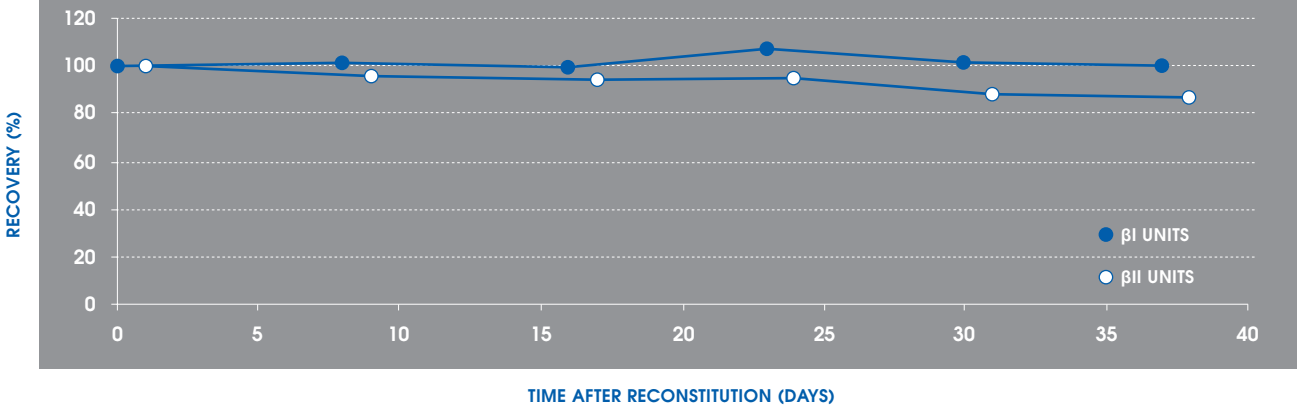
STERILITY

The β-Lactamase 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

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

FIG.1 β-Lactamase 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 β-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 β-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 β-Lactamase. The resulting solution is tested for the (lack of) growth of microbes. USP specifies that the amount of Penicillinase or β-Lactamase used in this removal process should be verified using a microbial challenge solution in a control sample.

EFFECTIVENESS

Sekisui Diagnostics β-Lactamase has been demonstrated to inactivate the following;

Penicillins: Amdinocillin, Amoxicillin, Ampicillin, Azlocillin, Benzylpenicillin, Carbenicillin, Cloxacillin, Flucloxacillin, Methicillin, Mezlocillin, Nafcillin, Oxacillin, Piperacillin, Ticarcillin.

Cephalosporins: Cefaclor, Cefadroxyl, Cefalexin, Cefaloridine, Cefalothin, Cefamandole, Cefazolin, Cefdinir, Cefixime, Cefonicid, Cefoperazone, Cefotaxime, Cefpodoxime, Cefprozil, Cefsulodin, Ceftazidime, Ceftiofur, Ceftizoxime, Ceftriaxone, Cefuroxime.

Sekisui Diagnostics β-Lactamase has also been demonstrated to inactivate Carbapenems

Note: Sekisui Diagnostics β-Lactamase 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 β-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)
(5) Haberer K, Schulz H, Romeyke Y, Sauer D. Validation of enzymatic inactivation of cephalosporins adhering to enviromental monitoring samples. Eur. J. Parenteral Sciences 1996;3:79-81.

NOTES:

SEKISUI DIAGNOSTICS

THE AMERICAS
Sekisui Diagnostics, LLC
31 New York Avenue
Framingham, MA 01701-9400
Phone: 800 332 1042
Fax: 800 762 6311
Email: questions@sekisuidiagnostics.com

INTERNATIONAL
Sekisui Diagnostics (UK) Limited
50 Gibson Drive
Kings Hill, West Malling, Kent, ME19 4AF, UK
Phone: +44 (0) 1732 220022
Fax: +44 (0) 1732 220024
Email: info@sekisuidiagnostics.com