

ENZYMES

β-Lactamase ES (Extended Spectrum)

ORIGIN *Bacillus cereus* 569/H9

CAT# BELA-70-1491, BELA-70-1461
 EC# 3.5.2.6

► SPECIFICATIONS

β-Lactamase ES is a freeze-dried product containing buffer salts and zinc. It has an extended spectrum activity of complete inactivation of a broad range of cephalosporins and penicillins.

TABLE 1: THE SPECIFICATIONS OF β-LACTAMASE

FORMULATION	UNITS	CAT#
Freeze dried bulk powder	>2 BII Units/mg	BELA-70-1491
Sterile product in vials	>50 BII Units/vial	BELA-70-1461

► UNIT DEFINITION

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.

► EFFECTIVENESS

SEKISUI Diagnostics β-Lactamase ES has been demonstrated to inactivate the following:

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

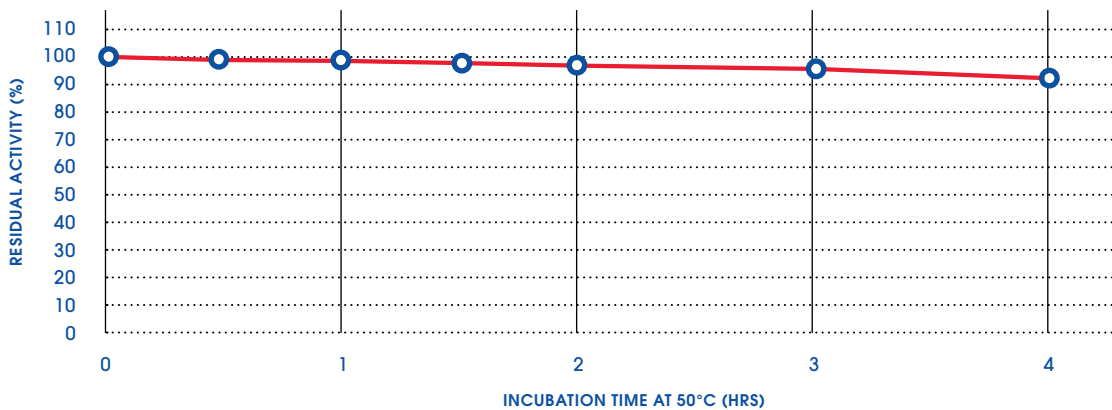
EFFECTIVENESS (continued)

Cephalosporins:

- First generation: Cefadroxil, Cefalexin, Cefaloridine, Cefazolin.
- Second generation: Cefaclor, Cefamandole, Cefmetazole, Cefonicid, Cefotetan, Cefoxitin, Cefprozil, Cefuroxime.
- Third generation: Cefdinir, Cefixime, Cefoperazone, Cefopodoxime, Cefotaxime, Cefsulodin, Ceftazidime, Ceftibuten, Ceftiofur, Ceftizoxime, Ceftriaxone, Moxalactam.
- Fourth generation: Cefepime, Cefpirome.
- Fifth generation: Ceftobiprole.

Carbapenems: Ertapenem, Imipenem, Meropenem.

FIGURE 1: B-LACTAMASE ES THERMAL 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 B-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 nonpenicillin drug product shall be tested for the presence of penicillin" (21 CFR 211.176, Penicillin Contamination, FDA, BY-Lines No. 8 November 1977).

APPLICATIONS (continued)

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.

OTHER AVAILABLE PRODUCTS

CAT#	FORMULATION	SPECIFICATIONS	
BELA-70-1431	Freeze dried bulk powder	>2 BIU Units/mg	Active against both penicillins and a narrower range of cephalosporins
BELA-70-1401	Sterile product in vials	>500 BI Units/vial >50 BIU Units/vial	
PENI-70-1541	Freeze dried bulk powder	>15 BI Units/mg	Active against penicillins only
PENI-70-1545	Sterile product in vials	>3000 BI Units/vial	

THE AMERICAS

SEKISUI Diagnostics,
One Wall Street,
Burlington, MA 01803
Phone: 800 332 1042
Fax: 800 762 6311

INTERNATIONAL

SEKISUI Diagnostics (UK) Limited,
Liphook Way, Allington
Maidstone, Kent, ME16 0LQ, UK
Phone: +44 1622 607800
Fax: +44 1622 607801



Because every result matters™

info@sekisui-dx.com
sekisuidiagnostics.com