β-Lactamase Extended Spectrum (ES) Vial
Cat: BELA-70-1461

Source: Bacterial

Introduction
β-Lactamase ES is an extended spectrum β-Lactamase product which completely degrades all classes of β-lactams. It is specifically developed to degrade all β-lactams which other commercially available β-lactamase products have struggled to degrade such as cefoxtin, cefonicid, cepime, moxalactam, cefuroxime and cefoperazone.

Intended Use
Environmental monitoring of antibiotic manufacturing areas: Contact plates; settle plates and air monitoring systems for testing of aseptic conditions in β-lactam antibiotic manufacturing facilities need to be manufactured with agar medium containing β-lactamase for neutralisation of antibiotics. This is effectively achieved by the addition of β-Lactamase ES to the medium to hydrolyse residual β-lactam antibiotic thus enabling growth, enumeration and identification of microbial contamination.

Sterility Testing of Bulk Antibiotics: Antibiotics must be shown to be free from microbial contamination. US Pharmacopeia (USP) Chapter 71 and the US Code of Federal Regulations 21 CFR 436.20 outline the testing that is required on bulk antibiotics. The testing requires the removal of significant amounts of active antibiotic from solution by combined filtration and the use of β-Lactamase ES.

Testing sterility of blood cultures: Blood cultures are routinely used to test for bacterial infection. Incorporation of β-Lactamase ES in the culture medium will overcome false negative results in the blood samples containing β-lactam (cephalosporins and penicillin) antibiotics.

Testing for β-lactam contamination of drugs: 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". The 21 CFR 211.176, Penicillin Contamination; and FDA, BY-Lines No. 8 November 1977 methods rely on the inactivation of a test solution by a β-Lactamase to provide evidence of the presence of a residual β-Lactam antibiotic and to distinguish the activity produced by this residue from the antimicrobial activity that may be produced by other non-penicillin and non-cephalosporin active agents.

Specification

Format:	Vacuum sealed Irradiated vials
Activity (pH 7.0, 25ºC):	> 50 Units/Vial

Characteristics

pH Activity Range :	Active at pH 6.5 to 9.8
Temperature Stability:	> 90% at 50ºC for 4 hours
Vial stability:	Stable until expiration date at 4ºC
Solubility:	>10 U/mL in water
Reconstituted stability (sterile filtered):	3 months at 2-8ºC

Preparation: Reconstitute at 10 U/mL with sterile water, Sterile-filter through a 0.45mM Supor® PES membrane filter into sterile media. For agar media, add to liquid agar medium at >40ºC just prior to pouring agar plates.

Potency in Agar Medium: Use at 0.5 U/mL in agar plates for complete (100%) hydrolysis of all β-lactams (at up 256 μg/disc or e-strip).

Advantages
- Full inactivation of a broad range of β-Lactams including the more resistant cephalosporins: Cefepime, Cefoxitin, Cefradine and Ceftazidime which other commercially available enzymes do not degrade as efficiently.
- Highly stable, retaining >90% of its activity after 4 hours at 50°C, means no need to compensate for loss of enzyme activity during media preparation for applications using sterile plates.

References

1. Testing for contamination of drugs by antibiotics http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=211.176
2. FDA, BY-Lines No. 8 November 1977 http://www.fda.gov/cder/dmpq/penicillin.pdf
3. 21 CFR 436.20 http://www.access.gpo.gov/nara/cfr/waisidx_98/21cfr436_98.html

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