TS 263 – β LACTAMASE MIXTURE SUPPLEMENT W/ (>500 β I UNITS/VIAL) & (>50 β II UNITS/VIAL)

INTENDED USE

For inactivation of Penicillins and Cephalosporins of first, second, third, fourth generation and Carbopenems.

PRODUCT EXPLANATION AND SUMMARY

β –Lactamase II supplement is an β -Lactamase product which completely degrades β -lactam. It is specifically developed to degrade β -lactam which other commercially available β -lactamase products have struggled to degrade such as cefoxtin, cefonicid, cepime, moxalactam, cefuroxime and cefoperazone.

Cephalosporinases are defined as a group of enzymes with varying specificity for hydrolysis of β- lactam compounds. The use of β-lactamase is specified by the US Pharmacopoeia (USP) in chapter 71 for monitoring of cephalosporin manufacturing facilities and sterility testing of bulk cephalosporins. USP has been harmonised with the European and Japanese pharmacopoeias.

There are following uses of this preparation of enzymes.

1. Testing sterility of blood culture:

β Lactamase enzymes helps in inactivation of beta-lactam antibiotics in blood or other tissue samples prior to microbiological estimate of aminoglycosides or other non-lactam antibiotics and routine microbiological examination.

2. Environmental monitoring of antibiotic manufacturing areas:

In manufacturing facilities where antibiotics are produced, β-lactamase enzymes such as cephalosporinase are contained in the monitoring media to inactivate β-Lactam antibiotics. Produced antibiotics must also be inactivated prior to sterility testing to allow for the detection of potential contaminants which are sensitive to the antibiotic. Also, help in Assessment of the susceptibility of new beta-lactam antibiotics to inactivation by lactamase.

3. Testing for contamination of drugs by antibiotics:

β-lactamase enzymes help to check contamination of drugs by antibiotic such non cephalosporin drug shall be tested for the presence of cephalosporin.

4. Sterility Testing of Bulk Antibiotics:

US Pharmacopeia (USP) Chapter 71 and EP Section 2.6 describes sterility testing of bulk antibiotic, which should be free from microbial contamination.

COMPOSITION

Ingredients	Concentration
Penicillinase (β Lactamase I)	> 500 IU activity
Cephalosporinase (β Lactamase II)	> 500 IU activity

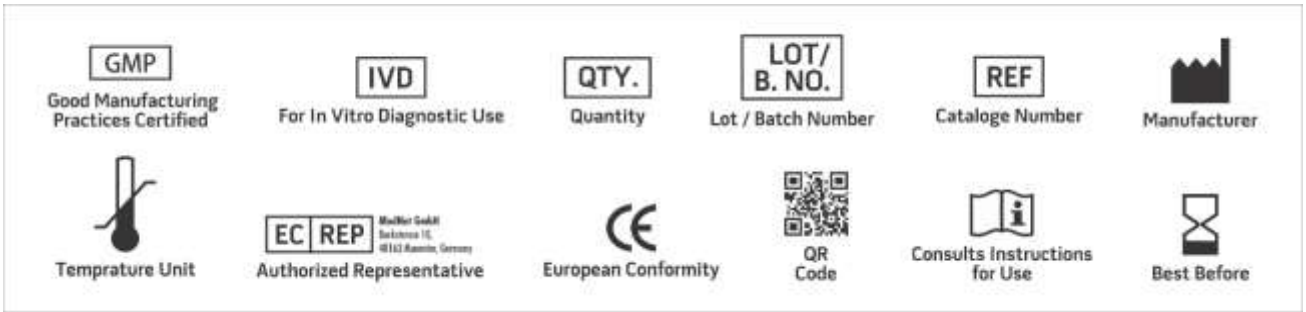
(*1 IU is defined as the amount of enzyme needed to hydrolyze 1µmole of Penicillin G (Penicillinase) or 1µmole of Cephalosporin C (Cephalosporinase) per minute at 25ºC and pH 7.0. 1 IU of Penicillinase corresponds to 600 Levy Units or 75 Pollock Units or 91200 kersey Kinetic Units.)

INSTRUCTION FOR USE

- Rehydrate the contents of 1 vial with 5 ml of sterile distilled water.
- After reconstitution, filter sterilize the solution with 0.2 micron syringe filter.
- Add appropriate amount of solution depending upon the specific application.
- Remaining solution can be stored at 2-8º C for 4 weeks.

STORAGE

Store the supplement vials at 2-8°C in its original packaging. If opened and not completely utilized, be certain that aseptic dispensing procedures are followed to maintain sterility of the solution. β-lactamase vials are stable for 4 weeks at 2-8℃ after reconstitution in water. Repeated freezing and thawing should be avoided. However, it is not advisable to store solution for long period and to keep container tightly closed to protect from contamination.



NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**

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