

Penase



THE PRODUCT

Penase concentrate is a highly purified enzyme-based product specifically designed for the inactivation of Penicillins. The product does not contain animal derivatives thus is TSE/BSE free and is non-toxic. **Penase concentrate** is certified as a sterile product by γ -irradiation and it has passed a sterility test. The process has not been validated to the level required for an injectable drug.

Before use or preparation observe the product for signs of deterioration. The recommendation of CFR 436 Subpart B, "Sterility Test Methods" should be followed, i.e. "Prior to use, or at the time of test, a representative number of the tubes containing added penicillinase are incubated at 30°-32°C for 24 to 48 hours and are examined for sterility".

FORMULATION AND PACK SIZE

Penase concentrate is available in the following pack size in glass vials with flip-off cap:

Pack size

- cod. 6 PEN-LQS20: pack of 6 x 20 ml bottle
- cod. PEN-LQS: pack of 1 x 100 ml bottle

Potency

20,000 Levy Units/ml/min
equivalent to 10,000,000 IU Pen G/ml

APPLICATION

Penase concentrate is a product specifically designed for the inactivation of penicillins, thus finds its application in beta-lactams (Penicillins) sterility testing (either environmental and antibiotics sterility testing). **Penase concentrate** can be used for the inactivation of beta-lactams from blood or tissue sample prior to routine microbiological examination.

For this last application **Penase concentrate** is intended only for IVD manufacturer.

USAGE

Penase concentrate is an optimized ready to use solution that can be directly added to the test samples. The amount of product to be added to the test sample should be determined and set-up case by case depending on the application, concentration of antibiotic that should be inactivated, and depending on the specific beta-lactam that should be inactivated.

Before to sample the product disinfect the cap septum with a suitable disinfectant.

PRECAUTION

Penase concentrate is intended for in vitro use only.

STABILITY OF REAGENTS

Penase concentrate has a stability of 48 months from manufacturing date. The product should be stored at +2°C/+8°C.

ADDITIONAL INFORMATION

Penase concentrate DOES NOT CONTAIN ANIMAL DERIVATIVES and it's certified as a TSE/BSE free product.



CPC Biotech S.r.l.

Office: Via L. Galvani, 1 | 20875 | Burago di Molgora (Monza Brianza) Italy

T: +39.039.6898029 | F: +39.039.6899774 | info@cpcbiotech.it | www.cpcbitech.it