

# Macrocluster



## THE PRODUCT

**MACRODUSTER™** is an innovative enzyme-based product developed by CPC Biotech specifically designed for the inactivation of a wide range of macrolids antibiotics.

**MACRODUSTER™** efficiently inactivates Erythromycin, Azithromycin, Clarithromycin and Roxithromycin.

## FORMULATION AND PACK SIZE

Freeze dried **MACRODUSTER™** is available in the following pack size:

- cod. MCD-40: pack size of 5 vials of > 40 IU (International Units) of macrolidase per vial plus 5 vials of diluent solution

1 IU of macrolidase is defined as the amount of enzyme needed to inactivate 1  $\mu$ mole of Erythromycin at 25°C and pH 6.7

## APPLICATION

**MACRODUSTER™** finds its application in macrolids sterility testing, total count, environmental monitoring and media fill. According to USP <71>, <61>, <1116>, microbiological test (sterility test, total count and environmental monitoring) carried out on compounds having anti-microbial activity (like macrolids) should be performed adding to the culture medias inactivating agents of the same compounds. **MACRODUSTER™** efficiently inactivates Erythromycin, Azithromycin, Clarithromycin and Roxithromycin representing an effective agent for their inactivation. **MACRODUSTER™** can be used for the inactivation of macrolids from blood or tissue sample prior to routine microbiological examination. Due to its very broad specificity range **MACRODUSTER™** can also be used in the assessment of the susceptibility of new macrolids antibiotics to inactivation by macrolidases.

## USAGE

### Freeze dried formulation

cod. MCD-40: reconstitute each vial with 8 ml of diluent solution supplied in the pack obtaining a solution having > 5 IU/ml of macrolidase. After reconstitution sterile filter the solution using a suitable device.



## Example of Usage in sterility testing by filtration

Following a general procedure for sterility testing is reported. The amount of macrolidase to be used, however, could be different depending on the amount of antibiotic residue to be inactivated.

Add 10 IU of macrolidase (2 mls of the sterile reconstituted powder at 5 IU/ml) to 1 l of sterile Fluid A (Diluting and rinsing Fluids for membrane filtration).

Dissolve the antibiotic powder in a suitable amount of the Fluid A containing the macrolidase enzyme as described above.

Filter the antibiotic solution in the canisters (or alternative devices).

Rinse two-three times the filter with Fluid A containing the macrolidase enzyme.

Add 10 IU of macrolidase (2 mls of the sterile reconstituted powder at 5 IU/ml) to 100 ml of TSB medium and transfer the medium into the canister.

Add 10 IU of macrolidase (2 mls of the sterile reconstituted powder at 5 IU/ml) to 100 ml of TGM medium and transfer the medium into the canister.

Incubate the canisters.

## Usage of Macrocluster™ in Environmental Monitoring, total count and media fill

**MACRODUSTER™** can be efficiently used in agarised media for environmental monitoring as well as for total count on non-sterile macrolids and media fill.

For such applications please contact us ([info@cpcbiotech.it](mailto:info@cpcbiotech.it)) to get suggestion on usage and procedures.

## STABILITY OF REAGENTS

Freeze dried **MACRODUSTER™** has a stability of three years from manufacturing date if stored at +2/8°C.

After reconstitution with diluent solution and sterile filtration, the solution can be stored at least for three weeks at +2/8°C.

## ADDITIONAL INFORMATION

**MACRODUSTER™** DOES NOT CONTAIN ANIMAL DERIVATIVES and it's certified as a TSE/BSE free product.



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