Quanti-CultiControl™

Freeze-dried bacterial strains

INTENDED USE

The Quanti-CultiControl™ are lyophilized, quantitative microorganism preparations to be used in industrial laboratories for Quality Control purposes. Processed as directed, these preparations provide a challenge of <100 CFU per 0.1 mL, which is a concentration usually suitable for several pharmaceutical applications, including growth promotion testing of culture media to be employed in sterility testing. These microorganism preparations are derived from the American Type Culture Collection (ATCC®) or other authentic reference culture collection.

The Quanti-CultiControl™ are suitable for the Growth Promotion Test recommended by the international Pharmacopoeiae, without need of intermediate dilution steps, since each rehydrated suspension generates less than 100 UFC for 0.1 mL inoculum. Each suspension (1 mL) allows 10 inocula.

SUMMARY AND HISTORY

Many laboratory Quality Control testing procedures need a specified concentration of the challenge strain and that the challenge strain only be passed or subcultured from a reference culture a limited number of times to prevent mutation and subtle performance changes. Traditional methods for preparing challenge strains at specified concentrations are time consuming and labor-intensive. Laboratories will purchase a designated strain, grow the strain, prepare the dilutions, perform colony counts on each dilution to determine the concentration to be employed in the challenge procedure, and subsequently prepare dilutions of the challenge strain for actual use. Also, at each subculture step, phenotypic tests (biochemical activity and morphological examinations) are performed to provide assurance that no mutations or alterations have taken place.
Quanti-CultiControl™ microorganisms are a cost-effective alternative to labor-intensive dilution/colony count procedures. They do not require the equipment necessary for processing and preserving in-house concentrations of challenge strains, and routine quality control is performed which documents the absence of mutations and alterations.

PRINCIPLE

CultiControl™ microorganisms incorporate a lyophilization method reported by Obara et.al. which uses a suspending medium consisting of gelatin, skim milk, ascorbic acid, dextrose, and charcoal. The gelatin serves as a carrier for the microorganism. Skim milk, ascorbic acid, and dextrose protect the microorganism by preserving the integrity of the cell wall during freeze-drying and storage. The charcoal is included to neutralize any toxic substances formed during the lyophilization process.

PRODUCT DESCRIPTION

- The lyophilized preparation consists of:
- A quantified microorganism population
- Gelatin
- Skim milk
- Ascorbic acid
- Dextrose
- Charcoal

The Hydrating Fluid is a working solution of pH 7.2 Phosphate Buffer. The fluid contains:
- Monobasic potassium phosphate
- Sodium hydroxide
- Deionized water
- Magnesium chloride as required

Quanti-CultiControl™ microorganisms are packaged as a kit that consists of:
- One vial containing one lyophilized pellet of an individual microorganism strain.
- One Hydrating Fluid vial containing 1 mL of hydrating fluid.
- Detailed instructions.
- Certificate of Assay.

Processed as directed, Quanti-CultiControl™ microorganisms deliver a challenge concentration of < 100 CFU per 0.1 mL.
Quality control documentation includes, but is not limited to, a Certificate of Assay stating:
- The Identity of the microorganism.
- The traceability of the microorganism to a reference culture.
- That the microorganism preparation has been removed four (4) passages from the reference culture.
- The mean assay value for the microorganism preparation.

MATERIALS REQUIRED BUT NOT PROVIDED

A sterile forceps or tweezers is required for the transfer of the lyophilized pellets into the Hydrating Fluid.
Sterile pipettes are required for inoculating the medium/media to be challenged.

INSTRUCTIONS FOR USE

Material Preparation

All the materials required for the challenge procedure and the materials to be challenged must be ready for use immediately following the hydration step. Following the hydration of the lyophilized strain, challenge inoculation(s) MUST be completed within 8 hours.
The remaining suspension must be refrigerated between use to avoid a change in the challenge suspension concentration.

Hydration
The instructions and Hydrating Fluid provided in the kit must be used in the hydration procedure. The Hydrating Fluid is formulated to optimize the hydration, pellet matrix dissolution, and the uniform suspension of the lyophilized microorganism.
Remove the Hydrating Fluid vial and vial of lyophilized strain preparation from refrigerated storage.
Allow the lyophilized strain preparation to equilibrate to room temperature. Warm the Hydrating Fluid to 36±2 °C prior to use.
With a sterile forceps, remove one pellet and place into the 1 mL vial of Hydrating Fluid. Do not remove the desiccator from the vial.
One pellet obtains the challenge concentration of <100 CFU per 0.1 mL.
Immediately replace the rubber stopper, recap the vial, and return the remaining lyophilized material to refrigerated storage (2°C to 8°C).
Immediately recap the vial with the hydrated material and place into a 36±2 °C incubator for 30 minutes to assure complete hydration.
Immediately following incubation, vortex the hydrated material to achieve a homogeneous suspension.
With a sterile pipette, remove the desired volume (i.e. 0.1 mL) from the hydrated microorganism suspension and transfer the inoculum to the medium/media to be challenged. Proceed with the challenge procedure according to laboratory protocol.
Discard any remaining hydrated material in accordance with the laboratory protocol for disposal of biohazard materials.

STORAGE AND EXPIRATION

Store the Quanti-CultiControl™ microorganisms and Hydrating Fluid at 2°C to 8°C in their original, sealed vials.
Stored as directed, the lyophilized microorganism preparation will retain, until the expiration date stated on the device label, its specifications and performance within the stated limits.
Quanti-CultiControl™ microorganisms should not be used if stored improperly, if there is evidence of excessive exposure to heat or moisture, if the expiration date has passed.

QUALITY CONTROL

This product is developed, manufactured, and distributed in conformity with ISO 9001:2000
Quality control functions may include, but are not limited to: Purity and growth characteristics, Morphological features, Biochemical activity, Assay value, The identity of the microorganism and traceability to a reference culture, The number of passages the microorganism preparation has been removed from the reference culture. The decision to perform additional quality control is the responsibility of each individual laboratory.

PRECAUTIONS AND LIMITATIONS

These products are for in-vitro use only.
These devices, and subsequent growth of these microorganisms on culture media, are considered to be biohazard material. These devices contain viable microorganisms that may, under certain circumstances, produce disease. Proper techniques must be employed to avoid exposure and contact with any microorganism growth.
The microbiology laboratory must be equipped, and have the facilities to receive, process, maintain, store and dispose of biohazard material.
The microbiology laboratory personnel using these devices must be trained, experienced and demonstrate proficiency in processing, maintaining, storing and disposing of biohazard material.
Agencies and statutes do regulate the disposal of all biohazard materials. Each laboratory must be aware of, and comply with, the proper disposal of biohazard materials.

PRODUCT WARRANTY

These products are covered under warranty to meet the specifications and performance printed and illustrated in product inserts, instructions, and supportive literature. The warranty, expressed or implied, is limited when: the procedures employed in the laboratory are contrary to printed and illustrated directions and instructions or the products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature.

REFERENCES

The following reference cites the basis for the lyophilization method employed on these microorganism preparations.
1. Y. Obara, S. Yamai, T. Nikkawa, Y. Shimoda, and Y. Miyamoto. 1981. J. Clin. Microbiol. 14:61-66.

TABLE OF SYMBOLS

Consult Instructions for Use	Biological risk	Manufacturer	Contains sufficient for <n> tests	Temperature limitation	Do not reuse
REF Catalogue number	Fragile, handle with care	Use by	Caution, consult accompanying documents	LOT Batch code	

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