

INSTRUCTIONS FOR USE



EZ-Accu Shot™ Starved Cells

INTENDED USE

EZ-Accu Shot™ Starved Cells microorganisms are lyophilized, enumerated microorganism preparations to be used in industrial laboratories growth promotion testing of R2A media for pharmaceutical water testing according to the Japanese Pharmacopeia. These microorganism preparations are traceable to the American Type Culture Collection (ATCC®) or other authentic reference culture collections.

FORMULA COMPONENTS

The lyophilized preparation consists of:

- An enumerated microorganism population
- Skim milk (Bovine – USA origin)
- Carbohydrate
- Gelatin (Porcine – USA or Canada origin)
- Ascorbic acid

The gelatin serves as a carrier for the microorganism. Skim milk, ascorbic acid, and a carbohydrate protect the microorganism by preserving the integrity of the cell wall during freeze-drying and storage.

EZ-Accu Shot™ Starved Cells conform with Article 5 of EC 1069/2009 as they have reached the end point in the manufacturing chain and are no longer subject to the requirements of EC 1069/2009. The products are considered derived products per Article 36 of EC 1069/2009 and do not pose any significant risk to public or animal health.

SPECIFICATIONS AND PERFORMANCE

EZ-Accu Shot™ Starved Cells are packaged in a kit configuration. Each kit consists of:

- 5 vials each containing 1 lyophilized pellet of an individual microorganism strain
- Instructions for Use

Processed as directed, **EZ-Accu Shot™ Starved Cells** will provide a challenge concentration of 50-200 CFU per inoculum on R2A media.

Pellet Concentration	Examples of Concentration in Specified Volume of Sterile Water	
	1 ml Sterile Water	10 ml Sterile Water
500-2000 CFU	50 – 200 CFU per 0.1 ml	50-200 CFU per 1 ml

Quality control documentation includes, but is not limited to, an online Certificate of Analysis stating:

- The identity of the microorganism
- The traceability of the microorganism to a reference culture
- That the microorganism preparation is ≤ 3 passages from the reference culture
- The mean assay value for the microorganism preparation



INSTRUCTIONS FOR USE ---

A. 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.

B. Hydration

1. Remove 1 foil pouch containing the lyophilized pellet from refrigerated storage. Allow the unopened pouch to equilibrate to room temperature (about 30 minutes).
2. Obtain or aliquot an appropriate amount of sterile water for rehydration.
3. Tear open the foil pouch and remove the vial containing 1 lyophilized pellet.
4. Remove the cap from the pellet vial. Tip 1 pellet into sterile water. Only 1 pellet must be used to obtain the challenge concentration of 50-200 CFU per inoculum on R2A media. Immediately recap the water.
5. Vortex the hydrated material until the pellet has completely dissolved and the suspension is homogeneous.
6. With a sterile pipette, transfer desired volume of the hydrated suspension to the R2A media.
7. Discard any remaining hydrated material in accordance with the laboratory protocol for disposal of biohazard materials.

PRECAUTIONS AND LIMITATIONS ---

- Not intended for clinical use.
- Not intended for human, animal or pet consumption.
- **EZ-Accu Shot™ Starved Cells** do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located at **www.microbiologics.com** or by contacting Technical Support at **1.320.229.7045**
- These devices, and growth of these microorganisms, are considered biohazard material.
- These devices contain viable microorganisms that may 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.
- Only trained laboratory personnel should use these devices.
- Agencies and statutes regulate the disposal of all biohazard materials. Each laboratory must be aware of, and comply with, the proper disposal of biohazard materials.
- **EZ-Accu Shot Starved Cells** are not made with natural rubber latex.

TECHNICAL NOTES ---

Mean Assay Value

- The mean assay value obtained at Microbiologics is based on well proven statistical methods. As part of Microbiologics' quality control procedure, pellets from each **EZ-Accu Shot™ Starved Cells** microorganism lot are hydrated in sterile water. Replicate colony counts are performed on non-selective agar media and enumerated using an automated colony counting device. Results may differ from the mean assay value that Microbiologics obtained due to different materials and methods used.

- Variability of hydrating fluid, sampling, different inoculation and colony counting techniques, incubation and the use of selective agar media will produce colony counts that vary from the stated mean assay value.
- Inoculating wet media may result in clumping or spreading colonies. For best results, dry media for 48 hours at room temperature or for 15 minutes under a laminar flow hood before inoculating.
- When inoculating a spread plate with high volumes, such as 1 ml, the microbial suspension may spread to the edge of the plate, and colonies may grow in the space between the agar and petri dish or appear to grow inside the agar. These colonies grow more slowly than the colonies on the surface of the agar, and consequently may require the entire seven days to be countable.

Shelf Life and Stability

- Product warranty is limited to specifications and performance of the **EZ-Accu Shot™ Starved Cells** stored properly in the sealed pouch.
- Exposure to heat, moisture, and oxygen can adversely affect the stability of the mean assay value. Expiration dating, reproducibility and stability are predicated on proper storage of the lyophilized pellets in the original desiccant-containing pouch.

STORAGE AND EXPIRATION

Store the **EZ-Accu Shot™ Starved Cells** pouches at 2°C–8°C in their original, sealed packages. Stored as directed, the lyophilized microorganism preparation will retain, until the last day of the month of the expiration date stated on the device label, its specifications and performance within the stated limits.

EZ-Accu Shot™ Starved Cells should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The expiration date has passed

MATERIALS REQUIRED BUT NOT PROVIDED

Sterile Pipettes: Sterile pipettes are required to inoculate the medium/media to be challenged.

KEY OF SYMBOLS



Batch Code (Lot)



Biological Risks



Catalog Number



Caution, Consult Accompanying Documents



Manufacturer



Temperature Limitation



Use By

PRODUCT WARRANTY ---

These products are warranted 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
- The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature
- If the resuscitated culture is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

WEBSITE ---

Visit www.microbiologics.com for current technical information, product availability, biohazard cleanup, growth requirements, and Certificate of Analysis.

ACKNOWLEDGEMENTS ---



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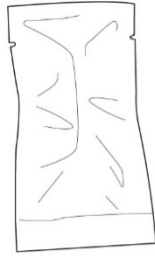
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ILLUSTRATED INSTRUCTIONS

Dry media before inoculating (see Technical Notes) to prevent clumping or spreading colonies.

1

Remove one foil pouch containing the lyophilized pellet from refrigerated storage. Allow the unopened pouch to equilibrate to room temperature (about 30 minutes).



2

Obtain or aliquot an appropriate volume of sterile water for rehydration.



3

Tear open the foil pouch and remove the vial containing one lyophilized pellet



4

Remove the cap from the pellet vial. Tip one pellet into the sterile water. Only 1 pellet must be used to obtain the challenge concentration of 50-200 CFU per inoculum on R2A media. Immediately recap the water.



5

Vortex the hydrated material until the pellet has completely dissolved and the suspension is homogeneous.



6

With a sterile pipette, transfer desired volume of the hydrated suspension to the R2A media.

