Technical Data Sheet

SPORE SUSPENSIONS
For Monitoring Radiation Processes

True Indicating Code: UBP-06, UBP-07, UBP-08

Product Description

Spore suspensions for monitoring Radiation processes consist of pure suspensions of *Bacillus pumilus* Cell Line 27142 with a known population and resistance to radiation sterilization processes.

Indications for Use

True Indicating Spore Suspensions are standardized suspensions of spores appropriate for direct inoculation onto samples for sterility, bio burden and bacteriostasis testing.

Physical Properties

Organism	*Bacillus pumilus* (Cell Line 27142)
Suspended Volume	10 mL suspended in water for injection (WFI)
Packaging	Pharmaceutical grade glass vial with screw cap and septum

Instructions for Use

1. Perform inoculation operations in a clean area which is remote from the sterility testing area.
2. Samples to be inoculated should be representative of product being sterilized.
3. For most purposes, inoculation of product with targeted population level of spores to provide a suitable challenge. Note: Suspensions are standardized on the basis of number of spores per 0.1 mL of Suspension; a 10 mL yields 100 doses of 0.1 mL.
4. Use a suitable sterile pipette or syringe to accurately measure and deliver the volume of suspension to be utilized.
5. Manually shake or vortex vial before each use.
6. If a syringe is used, disinfect septum surface and pull syringe plunger halfway back. Insert needle through the septum, push the plunger in, and slowly withdraw plunger to fill syringe to desired volume.
7. If a pipette is used, remove cap and septum and insert pipette. Withdraw desired volume.
8. Deposit suspension onto product. The area to be inoculated should be the one most difficult to sterilize. Return vial(s) of remaining suspension to refrigerator storage (2°C to 8°C) after use.
9. Allow product to dry at room temperature (15°C to 30°C) for approximately 24 hours (or until visibly dry). Some devices with small lumens may take longer to dry.
10. Package inoculated product exactly like product being sterilized and identify prominently as “Inoculated Test Samples.”
11. Distribute “Inoculated Test Samples” throughout the sterilizer load, as outlined in associated validation protocol or work instruction specific to your process.
12. After sterilization cycle is complete, test the inoculated products as soon as possible by aseptically transferring into Soybean Casein Digest Broth (SCDB).

Incubation: incubated at 30°C to 35°C. for up to 7 days or for a validated incubation period.

Monitoring: Examine the tubes daily, when ever possible during incubation. Record observations.

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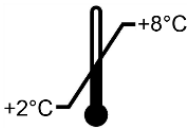
Interpretation: Tubes which demonstrate turbidity are considered positive for growth of Bacillus pumilus. Tubes which remain clear and without pellicle formation are considered negative for growth.

Performance Characteristics

Population	≥1.0 x 10^6 - 10^8 spores per 0.1 mL
Radiation Resistance	*D* value (Cobalt-60) 0.10 to 0.20 Mrads (1.0 to 2.0 kGy)
Post Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value

Storage and Shelf Life

	Refrigerate 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat, radioactive sources and sterilizing agents
Shelf Life	24 months from the date of manufacture		
	Do not use damaged vials of Spore Suspensions. Do not use after the expiration date. The Spore Suspensions contain live cultures and should be handled with care.		

Compliance
ISO 11138-1 Sterilization of health care products –Biological indicators Part 1: General requirements

USP

Disposal

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

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