Technical Data Sheet

SPORE SUSPENSIONS
Bacillus subtilis Cell Lines 6633

True Indicating Codes: UB6-06, UB6-07 and UB6-08

Product Description
Pure suspensions of viable spores with a known population.

Indications for Use

True Indicating Spore Suspensions are standardised suspensions of spores appropriate for direct inoculation onto samples for sterility, bio burden and bacteriostasis testing. Dilution of the Spore Suspensions to deliver <100 Colony Forming Units (CFUs) allows for use for USP Growth Promotion Test and the Method of Suitability Test[1].

Physical Properties

Organism	*Bacillus subtilis* Cell Line 6633
Suspended Volume	10 mL suspended in water for injection (WFI)
Packaging	Pharmaceutical grade glass vial with screw cap and septum

Instructions for Use—Sterility
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 vial 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 utilised.
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. Run exposure.

Culturing: After sterilization cycle is complete, aseptically transfer the exposed test samples into Soybean Casein Digest Broth (SCDB) as soon as possible following the exposure.

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

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

Turbidity = Growth = non-sterile Clear Medium = no growth = sterile

[1] Product Code UB6-01 is standardized to deliver <100 CFU per 0.1 mL thus requires no dilution.

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Interpretation: Tubes which demonstrate turbidity with cream colored sediment are considered positive for growth of *Bacillus subtilis*. Tubes which remain clear and without sediment formation are considered negative for growth.

Performance Characteristics

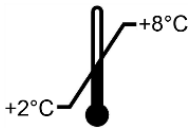
Population	≥1.0 x 10^6 - 10^8 spores per 0.1 mL
Post Market Criteria	Population: 50% to 300% of certified population

Compliance

ISO 11138-1 sterilization of healthcare products—Biological indicators—Part 1: General requirements

USP

Storage and She If Life

	Refrigerate 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat and radioactive sources & 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.		

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

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