



SPORE SUSPENSIONS

Bacillus subtilis Cell Line 5230

Crosstex Codes: US52304, US52305, US52306, US52307, US52308

Product Description

Pure suspensions of viable spores with a known population and resistance to Steam sterilization processes.

Intended Use

Crosstex Spore Suspensions are standardized suspensions of spores appropriate for direct inoculation onto samples for sterility, bioburden, and bacteriostasis testing. Spore Suspensions are labeled For Industrial Use Only.

Instructions for Use

Perform inoculation operations in a clean area which is remote from the sterility testing area.

Samples to be inoculated should be representative of product being sterilized.

For most purposes, inoculate 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.

Shake vial vigorously 10 times or vortex for 30 seconds before each use. Excessive vortexing or shaking may cause adhesion of spores to the vial and result in reduced recovery. Do not sonicate.

- Use a suitable sterile pipette or syringe to accurately measure and deliver the volume of suspension to be utilized.
- 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.
 - If a pipette is used, remove cap and septum and insert pipette. Withdraw desired volume.

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.

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.

Package inoculated product exactly like product being sterilized and identify prominently as “Inoculated Test Samples.”

Exposure: Distribute the test samples throughout the sterilizer load, as outlined in associated validation protocol or work instruction specific to your process. Crosstex can assist with the development of your sterilization validation. Run the cycle.

After sterilization or exposure, remove the product from the sterilizer.



Culturing: Aseptically transfer the exposed test samples into Soybean Casein Digest Broth (SCDB) as soon as possible following the exposure.

Incubation: Incubate the tubes at 30°C to 40°C for seven days or per a validated incubation period.

Monitoring: Examine test samples in SCDB daily during incubation. Record observations.

Interpretation: Containers of SCDB which demonstrate turbidity with a cream-colored pellicle are considered positive for growth of *Bacillus subtilis*. Containers of SCDB which remain clear and without pellicle formation are considered negative for growth.

Physical Properties

Organism	<i>Bacillus subtilis</i> Cell Line 5230
Suspension Volume	10 mL Diluent contains 20% ethanol
Packaging	Pharmaceutical grade glass vial with screw cap and septum

Performance Characteristics

Population	1.0 to 5.0 x 10 ⁴ – 10 ⁸ spores per 0.1 mL
Steam Resistance	<i>D</i> values at 115°C, 118°C and 121°C
Post-Market Criteria	Population: 50% to 300% of certified population <i>D</i> value: ± 20% of the certified <i>D</i> value

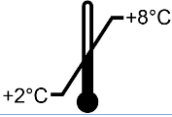




Compliance

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

USP (where applicable)

Crosstex has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin entitled *Population Verification of Spore Suspensions* to ensure consistent methodologies are being utilized when performing verification testing.

Storage and Shelf Life

	Refrigerate at 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat, radioactive sources, & sterilizing agents
<p>Shelf Life</p>	15 Months from the date of manufacture		
	Do not use damaged vials of Spore Suspension. Do not use after expiration date. Spore Suspensions contain live cultures and should be handled with care.		

Disposal

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