Technical Data Sheet

QUALITY CONTROL SUSPENSION
Geobacillus stearothermophilus Cell Line 7953

True Indicating Codes: UT-01

Product Description

Geobacillus stearothermophilus Quality Control Suspensions consist of:

- Pure suspension of viable organisms with a known population of ≤100 Colony Forming Units (CFUs)
- Packaged in a vial with screw cap and septum for access with a syringe or pipette

Indications for Use

True Indicating Quality Control Suspensions are suspensions standardized to deliver ≤100 Colony Forming Units (CFUs)/0.1 mL for use for USP Growth Promotion Test, Monograph <71> Method of Suitability and other quality control applications.

Organism	*Geobacillus stearothermophilus* Cell Line 7953
Volume	10 mL
Packaging	Pharmaceutical grade glass vial with screw cap and septum
Classification	Biosafety Level 1

Physical Properties

Instructions for Use

For Growth Promotion Test Instructions, see current USP Release for Monograph <71>.

1. Use directly from refrigeration. Immediately place vial back into refrigerator after each use.
2. Manually shake or vortex Vial of Suspension.
3. Remove cap, insert pipette or insert syringe through cap septum and withdraw 0.1 mL of Suspension.
4. Deposit Suspension on Tryptic Soy Agar (TSA) plate for quantitative results or in a tube of Soybean Casein Digest Broth for a qualitative (growth/no growth) result. A control plate or tube from a previously qualified Lot should be inoculated.
5. For inoculation on an agar plate, spread the Suspension across the surface using a sterile cell spreader or glass rod.
6. Repeat process in steps 1 – 4 until the target number of plates or tubes is achieved.
7. Incubate plates or tubes at 55-60°C for 2 – 3 days.
8. For quantitative evaluation on agar plates, enumerate the number of colonies on each plate. For qualitative evaluation of broth, examine tubes for growth as evidenced by creamy-white crusty pellicle at top of the media with growth throughout the media growth.
9. Interpretation of Quantitative Results
   Control Plate: Test is valid if an average of ≤100 CFUs is obtained. If greater than 100 CFUs are obtained, the inoculum volume may need to be adjusted to <0.1 mL.

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Compliance

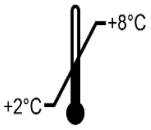
ISO 11138-1 sterilization of healthcare products - Biological indicators - Part 1: General requirements

USP

Performance Characteristics

Population	≤100 CFUs per 0.1 mL
Purity	Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the Suspension.

Storage and Shelf Life

	Refrigerate 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat and radioactive sources & sterilizing agents
Shelf Life	36 Months from the date of manufacture		
	Do not use damaged vials of Quality Control 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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