



This lot of product meets the accepted performance criteria recommended in the USP.

**PRODUCT NAME:** Quality Control Suspensions

**FOR USE IN MONITORING:** Growth Capabilities

**ORGANISM:** *Bacillus subtilis*, ATCC® 6633

**Diluent:** Water for Injection (WFI)

**Volume:** 10 mL each vial

<b>LOT</b>	B61-1		2018-10-25		2019-12-25
<b>REF</b>	UB6-01	<b>POPULATION:</b>		≤100 Colony Forming Units/0.1 mL	
Number of Passages: 2		Verified Population		89 CFU/0.1 mL	

**Instructions for Use**

1. Manually shake or vortex Vial of Suspension.
2. Remove cap, insert pipette or insert syringe through cap septum and withdraw 0.1 mL of Suspension.
3. Deposit Suspension on Tryptic Soybean Agar (TSA) plate or other media plate for quantitative results or in a tube of broth for a qualitative (growth/no growth) result. A control plate of TSA, previously determined to support low levels of growth should be inoculated.
4. For inoculation on an agar plate, spread the Suspension across the surface using a sterile cell spreader or glass rod.
5. Repeat process in steps 1 – 4 until the target number of plates or tubes until the target number is achieved.
6. Incubate plates or tubes at 20-25°C for 2 – 3 days.
7. 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 turbidity and/or formation of cream sediment in the tube.
8. Interpretation of Results: Control Plate: Test is valid if an average of ≤100 CFU's is obtained. If greater than 100 CFU's are obtained, the inoculum volume may need to be adjusted to <0.1 mL.  
Agar plates: An average of ≤100 CFU's confirms media is able to support low levels of growth.

**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
<b>Shelf-life</b>	14 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.		

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

November 8, 2018

QUALITY ASSURANCE APPROVAL