

Quality Control Test Suspensions USP Growth Promotion Sterility Assurance & Antimicrobial Effectiveness Testing

Excelsior Code: GP-01E, GP-06E & GP-10E



Product Description

The QC Test Suspensions are ready-to-use microbial suspensions which require no rehydration or dilution prior to use. Each suspension contains a consistent number of microorganisms standardised to deliver <100 Colony Forming Units (CFUs) per 0.1 mL aliquot. Excelsior offers strains suitable for use in a variety of applications including:

- General Chapters: <71> Sterility Tests the USP Growth Promotion and the Method Suitability Tests
- ISO 11138-1 Sterilisation of healthcare products – Biological indicator – Part 1: General requirements Section 7.2.1 Growth Medium and Annex B Determination of growth inhibition by carriers and primary Packaging materials exposed to sterilisation processes.

Indications for Use

Strains of Test Microorganisms suitable for use in the Growth Promotion Test and the Method Suitability Test per **General Chapters:<71> Sterility Tests**

Organism	Strain (Cell Line)	Excelsior Code
Bacillus subtilis	6633	GP-01E

Strains for:

ISO 11138-1 Sterilization of healthcare products Biological indicators Part 1: General Requirements.

Organism	Strain (Cell Line)	Excelsior Code
Geobacillus stearothermophilus	7953	GP-06E
Bacillus atrophaeus	9372	GP-10E

Instructions for Use

Perform all manipulations of the suspension in a clean area such as a laboratory hood.

Select appropriate organism, based on the Indications for Use outlined in the table above.

Use a suitable sterile pipette or syringe to measure and deliver the volume of suspension to be utilised. Suspensions are standardised to deliver <100 Colony Forming Units (CFUs) per 0.1 mL. Adjust the volume accordingly based on use of suspension.

Manually shake vial before each use. Do not vortex suspension.

If a syringe is used, disinfect septum surface and pull syringe plunger halfway back. Insert needle through septum, push in plunger and slowly withdraw plunger to fill syringe to desired volume. If a pipette is used, remove cap and septum and insert pipette directly into suspension vial. Withdraw desired volume.

For quantitative testing, deposit inoculum (suspension) onto the growth medium agar. For qualitative testing, deposit inoculum (suspension) into growth medium broth. It is recommended that a control plate of a previously acceptable lot of growth medium is utilised with each new lot of medium being evaluated for growth promotion capabilities.

Incubate the plates at the optimal temperature and length of time as outlined below:

Organism	Excelsior Code	Incubation Temperature	Min. Incubation Period
Bacillus subtilus	GP-01E	20 - 25°C	48 Hours
Geobacillus stearothermophilus	GP-06E	55 - 65°C	16 Hours
Bacillus atrophaeus	GP-10E	30 - 35°C	16 Hours

After incubation, where applicable, enumerate colonies to determine number of CFUs obtained. The population may vary depending on type and lot of growth medium, user technique and method employed. As a result, while the concentration is standardized per 0.1 mL, the volume of inoculum may need to be adjusted to greater or less than 0.1 mL to obtain <100 CFU's to meet the "not more than 100 CFU"

Physical Properties

Organism	<i>Bacillus subtilis</i> Cell Line 6633 <i>Geobacillus stearothermophilus</i> Cell Line 7953 <i>Bacillus atrophaeus</i> Cell Line 9372
Volume per vial	10mL
Packaging	Pharmaceutical grade glass vial with screw cap and septum

Monitoring Frequency

For greatest control of growth medium, it is recommended that every lot purchased or manufactured in house demonstrate the ability to support growth of an inoculum less than 100 CFU of test organisms.

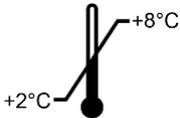
Performance Characteristics

Number of Passages from Source	≤ 5
Standardised Population	<100 Colony Forming Units (CFUs)
Purity	No evidence of contamination with other microorganisms

Compliance

United States Pharmacopeia (USP)
ISO 11138-1 Sterilization of healthcare products Biological indicators Part 1: General Requirements

Storage and Shelf Life

	Refrigerate at 2°C to 8°C		Do not freeze
	Protect from heat, radioactive sources		Do not use after expiration date
Shelf Life	Bacillus subtilis	GP-01E	14 Months
	Geobacillus stearothermophilus	GP-06E	24 Months
	Bacillus atrophaeus	GP-10E	18 Months

Disposal

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