

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

Excelsior Code: GP-01E, GP-02E, GP-03E, GP-04E, GP-05E, GP-06E, GP-07E, GP-08E, GP-09E & 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
- General Chapters: <51> Antimicrobial Effectiveness Testing for Inoculum Preparation
- 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**

	Strain (Cell Line)	Organism	Excelsior Code
	6538	<i>Staphylococcus aureus</i>	GP-08E
Aerobic Bacteria	6633	<i>Bacillus subtilis</i>	GP-01E
	9027	<i>Pseudomonas aeruginosa</i>	GP-07E
Anaerobic Bacteria	11437	<i>Clostridium sporogenes</i>	GP-02E
Fungi	10231	<i>Candida albicans</i>	GP-03E
	16404	<i>Aspergillus brasiliensis</i>	GP-04E

Strains for Inoculum preparations per **General Chapters:<51> Antimicrobial Effectiveness Testing**

Organism	Strain (Cell Line)	Suitable Medium	Excelsior Code
<i>Escherichia coli</i>	8739	Soybean-Casein Digest Broth Soybean-Casein Digest Agar	GP-09E
<i>Pseudomonas aeruginosa</i>	9027	Soybean-Casein Digest Broth Soybean-Casein Digest Agar	GP-07E
<i>Staphylococcus aureus</i>	6538	Soybean-Casein Digest Broth Soybean-Casein Digest Agar	GP-08E
<i>Candida albicans</i>	10231	Sabouraud Dextrose Agar Sabouraud Dextrose Broth	GP-03E
<i>Aspergillus brasiliensis</i>	16404	Sabouraud Dextrose Agar Sabouraud Dextrose Broth	GP-04E

Strains for:

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

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

Instructions for Use

Use vials of suspension directly from refrigeration and immediately return to refrigerator after each 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.

Organism	Excelsior Code	Incubation Temperature	Incubation Period
<i>Bacillus subtilis</i>	GP-01E	30 - 35°C	2-3 days
<i>Clostridium Sporogenes</i>	GP-02E	30 - 35°C	2-3 days (Anaerobically)
<i>Candida albicans</i>	GP-03E	30 - 35°C	2-3 days
<i>Aspergillus brasiliensis</i>	GP-04E	30 - 35°C	2-3 days
<i>Geobacillus stearothermophilus</i>	GP-06E	55 - 60°C	2-3 days
<i>Pseudomonas aeruginosa</i>	GP-07E	30 - 35°C	2-3 days
<i>Staphylococcus aureus</i>	GP-08E	30 - 35°C	2-3 days
<i>Escherichia coli</i>	GP-09E	30 - 35°C	2-3 days
<i>Bacillus atrophaeus</i>	GP-10E	30 - 35°C	2-3 days

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" verbiage in USP <71> Sterility Tests. No volume of inoculum is specified in the USP.

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 standardised 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" verbiage in USP <71> Sterility Tests. No volume of inoculum is specified in the USP.

Physical Properties

Organism	<i>Bacillus subtilis</i> Cell Line 6633 <i>Clostridium sporogenes</i> Cell Line 11437 <i>Candida albicans</i> Cell Line 10231 <i>Aspergillus brasiliensis</i> Cell Line 16404 <i>Geobacillus stearothermophilus</i> Cell Line 7953 <i>Pseudomonas aeruginosa</i> Cell Line 9027 <i>Staphylococcus aureus</i> Cell Line 6538 <i>Escherichia coli</i> Cell Line 8739 <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.

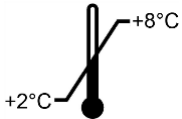



Performance Characteristics

Number of Passages from Source	≤ 5
Standardised Population	<100 Colony Forming Units (CFUs) per 0.1 mL
Purity	No evidence of contamination with other microorganisms

Compliance

United States Pharmacopeia (USP), JP & EP.
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	<i>Bacillus subtilis</i>	GP-01E	24 Months
	<i>Clostridium sporogenes</i>	GP-02E	12 Months
	<i>Candida albicans</i>	GP-03E	2 Months
	<i>Aspergillus brasiliensis</i>	GP-04E	6 Months
	<i>Geobacillus stearothermophilus</i>	GP-06E	24 Months
	<i>Pseudomonas aeruginosa</i>	GP-07E	3 Months
	<i>Staphylococcus aureus</i>	GP-08E	3 Months
	<i>Escherichia coli</i>	GP-09E	3 Months
	<i>Bacillus atrophaeus</i>	GP-10E	24 Months

Disposal

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