

## STERIL CONTROL GST E6 ampoules

Biological indicators of steam sterilization processes with *G. stearothermophilus* spores contained in ampoules.

### DESCRIPTION

**STERIL CONTROL GST E6 ampoules** are biological indicators used for regular monitoring of steam sterilization cycles and monitoring of any steam autoclave functionality.

USP (United States Pharmacopoeia), EP (European Pharmacopoeia) and DAB (Deutsches Arzneibuch) standards recommend to use bioindicators during steam sterilization processes of pharmaceuticals, drugs in vials, culture media, medical instruments and more. Biological indicators **STERIL CONTROL GST E6 ampoules** are produced under strictly controlled conditions in order to satisfy the requirements in the USP current edition and in accordance with ISO 11138 and EN 866 standards.

### COMPOSITION

Each ampoule contains a spore suspension of *Geobacillus stearothermophilus* (ATCC® 7953) within a growth medium, also containing a pH indicator.

A certificate of analysis is included in the package providing the following data:

- Lot number
- Expiration date
- Species
- Certified population
- D-value (121°C)
- Z-value
- Survival time
- Kill time
- F<sub>BIO</sub> value

### PRINCIPLE

Spores in the ampoules are completely killed off after 15 minutes of sterilization at 121°C and therefore during the following incubation they are not able to grow and to modify the colour of the medium. At a lower temperature or at a shorter sterilization time, spores partially survive and will grow during the incubation time. The colour change of the medium is an indication of the acid production by the organisms.

### TECHNIQUE

1. Take one or more ampoules from the package.
2. Place the ampoules in the most challenging area for the autoclave, generally, on the bottom shelf, near the door and over the drain.
3. Remove the ampoules after sterilization and incubate at 55-60°C (131-140°F) for 24-48 hours or for a different time validated by user.
4. Incubate, at the same conditions of time and temperature, an ampoule not submitted to the sterilization cycle, belonging to the same batch, as spore growth control (positive control).
5. Examine ampoule colour and interpret results as per **EVALUATION TABLE**: a colour change of the medium from violet/clear to yellow/turbid indicates microbial growth and therefore an unsuccessful sterilization. On the contrary, the persistence of the initial colour of the medium (violet/clear) indicates absence of microbial growth and therefore a successful sterilization.

### INTERPRETATION OF RESULTS

*Geobacillus stearothermophilus* spores are killed off if the sterilization cycle has been efficient: in this case the colour of the ampoule remains violet/clear even after incubation at 55-60°C (131-140°F) for 24-48 hours or for a different time validated by user.

If the sterilization cycle has not been efficient, spores partially survive and the ampoule content turns yellow/turbid after incubation at 55-60°C (131-140°F) for 24-48 hours or for a different time validated by user.

The ampoule not submitted to the sterilization cycle and used as spore growth control has to turn yellow/turbid after incubation. On the contrary, the test must be repeated after having investigated the causes of the negative result.

EVALUATION TABLE		
MEDIUM COLOUR	SPORE	STERILIZATION
Clear / Violet	Killed off	Successful
Yellow / Turbid	Vital	Unsuccessful

### STORAGE

Store the product at 2-8°C: in these conditions it maintains its validity until the expiry date indicated on the label.

### WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is designed for professional use only and must be used by properly trained operators.



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#### DISPOSAL OF WASTE

Disposal of waste must be carried out according to the national and local regulations in force.

#### REFERENCES

1. United States Pharmacopoeia latest edition.
2. Deutsches Arzneibuch latest edition.
3. European Pharmacopoeia latest edition.
4. ISO 11138 and EN 866 latest edition
5. ISO 17665:2024.

### PRODUCT SPECIFICATIONS

#### NAME

**STERIL CONTROL GST E6 ampoules**

#### PRESENTATION

Glass ampoules containing a spore suspension of *Geobacillus stearothermophilus* (ATCC® 7953) within a growth medium

#### STORAGE

2-8°C

#### PACKAGING

Ref.	Content*	Packaging
91050	• 50 x 4 ml ampoules	50 ampoules in cardboard box
91210	• 20 x 4 ml ampoules	20 ampoules in cardboard box

\* Each package contains also an Instruction Sheet and the Certificate of Performance

#### TECHNICAL PROPERTIES

**Ampoule:** glass ampoule, body height 67±1 mm, body diameter 14±1 mm

**Species:** *Geobacillus stearothermophilus* ATCC® 7953

**Mean Population Recovery:** 1-5 x 10<sup>6</sup> spores per ampoule

**Purity:** bacterial contaminates less than 1% of the labelled population; this is the detection limit using the pour plate method with an aliquot that yields at least 100 Colony Forming Units (CFUs)

**Resistance data:** Decimal reduction time (D-value), Z-value, Survival time a Kill time, F<sub>BIO</sub> value.

#### Growth medium

pH 7.4 ± 0.1

Fill volume 4.0 ± 0.2 ml

**Growth promotion** meets U.S. Pharmacopeia Revision XXIII guidelines

**Appearance,** violet/clear (colour change to yellow/turbid indicates microbial growth)

#### USE

Biological indicators **STERIL CONTROL GST E6 ampoules** are used for regular monitoring of steam sterilization cycles and monitoring of any steam autoclave functionality.

#### TECHNIQUE

Refer to technical sheet of the product

#### SHELF LIFE

18 months

#### QUALITY CONTROL

- Control of general characteristics, label and print
- Purity < 1% contamination. No moulds
- Heat shocked population = 1-5 x 10<sup>6</sup> spores per ampoule
- D-value (121°C) = 1.5-4.5 minutes
- Z-value ≥ 6°C
- F<sub>BIO</sub> value ≥ 12 minutes
- Growth at 55-60°C for 24-48 hours

#### TABLE OF SYMBOLS

<b>LOT</b> Batch code	 Do not reuse	 Manufacturer	 Use by	 Fragile, handle with care
<b>REF</b> Catalogue number	 Temperature limitation	 Contains sufficient for <n> tests	 Caution, consult accompanying documents	



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