

**Biological indicators of steam sterilization processes with
Geobacillus stearothermophilus (ATCC® 7953) spores contained in ampoules.**

DESCRIPTION

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/E5/E4 ampoules** are used for regular monitoring of steam sterilization cycles and monitoring of any steam autoclave functionality.

Biological indicators **STERIL CONTROL GST E6/E5/E4 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.

PRINCIPLE

STERIL CONTROL GST E6/E5/E4 ampoules contain a nutritive broth, designed to this purpose, consisting of enzymatic digests of casein and soy bean, a pH indicator and a spore suspension of *Geobacillus stearothermophilus* (ATCC® 7953) in predefined concentrations: E6=1-5x10⁶CFU/ampoule; E5=1-5x10⁵CFU/ampoule; E4=1-5x10⁴CFU/ampoule.

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.

INSTRUCTIONS FOR USE

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.

EVALUATION

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

AMPOULE TREATMENT AFTER USE

After use, sterilize the positive ampoules (yellow/turbid) in autoclave at 121°C for at least 30 minutes and eliminate them in accordance with the procedures of the laboratory.

STORAGE

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

REFERENCES

- United States Pharmacopoeia latest edition.
- Deutsches Arzneibuch latest edition.
- European Pharmacopoeia latest edition.
- ISO 11138 and EN 866 latest edition.

PRESENTATION

PRODUCT	Ref.	PACKAGING	Spores: CFU / ampoule	D _{121°C}
STERIL CONTROL GST E6 ampoules	91210	20 Ampoules (4 ml)	1-5x10 ⁶	1.5-3.0 minutes
STERIL CONTROL GST E6 ampoules	91050	50 Ampoules (4 ml)	1-5x10 ⁶	1.5-3.0 minutes
STERIL CONTROL GST E6 ampoules	91040	50 Ampoules (1 ml)	1-5x10 ⁶	1.5-3.0 minutes
STERIL CONTROL GST E5 ampoules	91251	20 Ampoules (4 ml)	1-5x10 ⁵	1.5-3.0 minutes
STERIL CONTROL GST E5 ampoules	91052	50 Ampoules (4 ml)	1-5x10 ⁵	1.5-3.0 minutes
STERIL CONTROL GST E4 ampoules	91253	20 Ampoules (4 ml)	1-5x10 ⁴	1.5-3.0 minutes
STERIL CONTROL GST E4 ampoules	91054	50 Ampoules (4 ml)	1-5x10 ⁴	1.5-3.0 minutes

TABLE OF SYMBOLS

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

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