

## Biological indicators of steam sterilization processes with *Geobacillus stearothermophilus* (ATCC 7953) spores self-contained

### DESCRIPTION

USP (United States Pharmacopoeia) and EP (European Pharmacopoeia) standards, recommend to use bioindicators during steam sterilization processes of pharmaceuticals, drugs in vials, culture media, medical instruments and more.

**STERILtest GST E6/E5 self-contained** are made of a thermoplastic tube, with a cup permeable to steam, that contains an ampoule with a nutrient broth with a pH indicator and a disc impregnated with *Geobacillus stearothermophilus* (ATCC 7953) spores in predefined concentrations (E6 =  $1-5 \times 10^6$  UFC/disc; E5 =  $1-5 \times 10^5$  UFC/disc).

These bioindicators are used for regular control of steam sterilization cycles (for i.e. 15 minutes at 121 °C) and control of any steam autoclave functionality. Biological indicators **STERILtest GST E6/E5 self-contained** are produced under strictly controlled conditions in order to satisfy the requirements indicated in the USP current edition and in accordance with ISO 11138 and EN 866 standards.

### PRINCIPLE

**STERILtest GST E6/E5 self-contained** contains, inside a thermoplastic tube, a paper disc impregnated with *Geobacillus stearothermophilus* (ATCC 7953) spores in predefined concentrations (E6=  $1-5 \times 10^6$  UFC/disc; E5 =  $1-5 \times 10^5$  UFC/disc).

The tube contains also a small glass ampoule with nutrient broth with a pH indicator. Spores are completely killed off after 15 minutes of sterilization at 121 °C and therefore during the following incubation in the culture medium contained inside the ampoule, they are not able to grow and to modify the medium's colour. At a lower temperature or at a shorter sterilization time, spores partially survive and therefore during the incubation are able to grow and to modify the medium's colour.

### INSTRUCTION FOR USE

- Take one or more **STERILtest GST E6/E5 self-contained** from the package.
- Put the **STERILtest GST E6/E5 self-contained** on the bottom, in the centre, inner sides and on the critical points of the autoclave or in positions decided by user.
- For autoclaves with capacity up to 250 litres put two **STERILtest GST E6/E5 self-contained** for each selected point of the autoclave. For autoclaves with capacity higher than 250 litres put six or more **STERILtest GST E6/E5 self-contained** in each selected point.
- Remove the **STERILtest GST E6/E5 self-contained** after sterilization cycle, and activate them by breaking the glass ampoule through pressure to permit contact between culture medium and spores.
- Incubate the activated **STERILtest GST E6/E5 self-contained** at 55-60 °C (131-140 °F) for at least 48 hours or for a different time validated by user.
- Incubate, at the same conditions of time and temperature, a **STERILtest GST E6/E5 self-contained**, activated by breaking the glass ampoule through pressure, not submitted to the sterilization cycle and belonging to the same batch, as spore growth control (positive control).
- Examine **STERILtest GST E6/E5 self-contained** colour and interpret results as per **evaluation TABLE**: a change of medium's colour from violet/clear to yellow/turbid indicates a microbial growth and therefore an unsuccessful sterilization. On the contrary, the persistence of the medium's initial colour (violet/clear) indicates absence of microbial growth and therefore a successful sterilization.

### EVALUATION

*Geobacillus stearothermophilus* (ATCC 7953) spores are killed off if the sterilization cycle has been efficient: in this case the broth contained in **STERILtest GST E6/E5 self-contained** remains violet/clear even after incubation at 55-60 °C (131-140 °F) for at least 48 hours or for the selected time. If the sterilization cycle has not been efficient, spores partially survive and the broth contained in **STERILtest GST E6/E5 self-contained** turns yellow/turbid after incubation at 55-60 °C (131-140 °F) for at least 48 hours or for the selected time. The broth contained in **STERILtest GST E6/E5 self-contained** 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
Violet / clear	Killed off	Successful
Yellow / turbid	Vital	Unsuccessful

### VIALS TREATMENT AFTER USE

After use, sterilize the positive **STERILtest GST E6/E5 self-contained** (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.










### BIBLIOGRAPHY

- United States Pharmacopoeia latest edition.
- European Pharmacopoeia latest edition.
- ISO 11138 e EN 866 latest edition.

### PRESENTATION

PRODUCT	CODE	PACKAGING	Spores: UFC / disc	D <sub>121</sub> °C
<b>STERILtest GST E6 self-contained</b>	91100	100 unities	$1-5 \times 10^6$	1,5-3,0 minutes
<b>STERILtest GST E5 self-contained</b>	91101	100 unities	$1-5 \times 10^5$	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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