

STERILtest BAT E6 self-contained

Self contained biological indicators for ethylene oxide sterilization processes containing *Bacillus atrophaeus* (ATCC 9372) spores

DESCRIPTION

Biological indicators STERILtest BAT E6 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.

STERILtest BAT E6 self-contained are made of a thermoplastic tube, with a cup permeable to ethylene oxide, that contains an ampoule with a growth medium with a pH indicator and a disc impregnated with *Bacillus atrophaeus* (ATCC 9372) spores in predefined concentrations.

The medium is validated for use with disc and meets U.S.Pharmacopoeia Revision XXIII growth promotion guidelines.

Each package contains also a Certificate of Performance that indicates a certified population, D-value (121°C), survival time, kill time, species, lot number and expiration date.

COMPOSITION

Discs contain *Bacillus atrophaeus* (ATCC 9372) spores in concentrations: 1-5 x 10⁶CFU/disc

Ampoule contains 0,7 +/- 0.1 mL of a sterile modified soybean casein digest broth with a pH indicator.

PRINCIPLE

Spores are completely killed off during the ethylene oxide sterilization process if the process has been efficient. 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.

On the contrary if the sterilization process has not been efficient, spores partially survive and therefore during the incubation are able to grow and to modify the medium's colour.

TECHNIQUE

1. Take one or more STERILtest BAT E6 self-contained from the package.
2. Put the STERILtest BAT E6 self-contained on the bottom, in the centre, inner sides and on the critical points of the sterilizer.
3. For sterilizer with capacity up to 250 litres put two STERILtest BAT E6 self-contained for each selected point of the sterilizer. For sterilizers with capacity higher than 250 litres put six or more STERILtest BAT E6 self-contained in each selected point.
4. Remove the STERILtest BAT E6 self-contained after sterilization/aeration cycle, and activate them by breaking the glass ampoule through pressure to permit contact between culture medium and spores.
5. Incubate the activated STERILtest BAT E6 self-contained at 30-35 °C (86-95 °F) for 7 days or for a different time validated by user.
6. Incubate, at the same conditions of time and temperature, a STERILtest BAT E6 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).
7. Examine STERILtest BAT E6 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

Bacillus atrophaeus (ATCC 9372) spores are killed off if the sterilization cycle has been efficient: in this case the broth contained in **STERILtest BAT E6 self-contained** remains violet/clear even after incubation at 30-35 °C (86-95 °F) for the selected time. If the sterilization cycle has not been efficient, spores partially survive and the broth contained in **STERILtest BAT E6 self-contained** turns yellow/turbid after incubation at 30-35°C (86-95°F) for the selected time. The broth contained in **STERILtest BAT E6 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

STORAGE

Store the product at 10-25 °C: in these conditions it maintains its validity until the expiry date indicated on the label.

WARNING and PRECAUTIONS

The product is not classified as hazardous by current legislation and does not contain harmful substances in concentrations of ≥1%. The product and must be used only by properly trained operators.

DISPOSAL of WASTE

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

REFERENCES

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



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PRODUCT SPECIFICATIONS

NAME

STERILtest BAT E6 self-contained

PRESENTATION

Thermoplastic tube, with a cup permeable to steam, that contains an ampoule with a growth medium and a disc impregnated with *Bacillus atropheus* (ATCC 9372) spores in predefined concentrations.

STORAGE

10-25°C.

PACKAGING

CODE	CONTENT	PACKAGING
91150	100 unities 1 Instruction sheet 1 Certificate of Performance	100 unities in thermically soldered envelope 1 envelope in cardboard boxes

TECHNICAL PROPERTIES

DISC

Spore carrier type: filter paper

Spore carrier: 6,1 +/- 0,1 mm diameter disc

Species: *Bacillus atropheus* (ATCC 9372)

Mean Population Recovery: 1×10^6 - 5×10^6 spores/ disc

Purity: Bacterial contaminates less than 1 percent of the labeled population; this is the detection limit using the pour plate method with an aliquot that yields at least 100 colony forming units (CFU).

Resistance data: decimal reduction time (D-Value), survival time and kill time.

GROWTH MEDIUM

pH: 7, 4 +/- 0.1

Fill volume: 0,7 +/- 0,1 mL

Tube: glass tube ; height approximately 45 +/-1 mm

Growth promotion: meets U.S.Pharmacopoeia Revision XXIII guidelines

Color : violet (color change to yellow and/or turbidity indicates bacterial growth)

Thermoplastic tube : dimensions : 47 +/- 1 mm height and 7 +/-1 mm diameter.

Cap: dimensions: approximately 12+/- 1 mm diameter; steam permeable cap with three holes and inner tyvek disc.

USE

Biological indicators **STERILtest BAT E6 self-contained** are used for validation, re-validation and process monitoring of ethylene oxide sterilizers.

TECHNIQUE

Refer to technical sheet of the product.

APPEARANCE

Discs are white in colour. The medium is violet, clear.

QUALITY CONTROL

- Control of general characteristics, label and print
- Purity : < 1 % contamination. No moulds
- Heat shocked population : $1-5 \times 10^6$ Spores/ disc
- D_{EO} (600±30 mg/l, 60%±10% RH, 54±1°C) : 2,6-4,5 minutes
- Growth: 30-35°C for 18-24 hours; medium change color from violet/clear to yellow/turbid

SHELF LIFE

1 year

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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