



M.H.S.C.T. MOIST HEAT STERILITY COLOUR TEST

1 - INTENDED USE

Biological indicator for the validation and routine monitoring of moist heat sterilization process.

2 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

M.H.S.C.T. (Moist Heat Sterility Colour Test) is a biological indicator containing *Geobacillus stearothermophilus* ATCC 7953 spores suspended into a culture medium containing a pH indicator and a carbohydrate.

The M.H.S.C.T vial is used to monitor the effectiveness of autoclave steam sterilization cycles (usually at 121°C or 134°C).

The *Bacillus stearothermophilus* ATCC 7953 is considered a biological indicator of absolute tranquillity and security due to its bacteriological and biological characteristics.

This strain is not pathogenic, is not toxic, has not pyrogens activity and, compared with other microorganism, doesn't give any contamination of laboratory.

Product manufactured according to Italian Official Pharmacopoeia and European Pharmacopoeia.

3 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
M.H.S.C.T.	Spores suspension	9100110	24 vials x 1 mL; Ø 10.75 mm

4 - TEST PROCEDURE

To control the sterilization process the M.H.S.C.T vial must be placed inside the autoclave in the sites where the sterilization conditions are considered critical (for example: on the bottom of the autoclave where air pockets are suspected, all inside of packages of clothes, racks, etc.)

For the control of the sterilization process of material contained in recipients with dimensions greater than the indicator vials, the best method of use is by inserting the M.H.S.C.T vial inside the containers (bottle, bottle, etc.).

The number of vials to be used is at the discretion of the operator based on the size of the autoclave, its characteristics and the reliability of the required analytical result.

Set the duration of the sterilization control cycle by referring to the killing time values indicated on the certificate of each batch.

At the end of the sterilization process the M.H.S.C.T vials should be recovered and incubated at 57°C (55°C - 60°C) for 24-48 hours, using an unsterilized vial as a control.

Handle with Care To avoid breakage of the vials, with consequent contamination of the environment.

5 - READING AND INTERPRETATION

The turning of the medium to yellow colour and the presence of turbidity into the M.H.S.C.T vial incubated as described above, shall be interpreted as a failure of the sterilization process.

The maintenance of the original colour and the absence of bacterial growth shall be interpreted as a correct sterilization process.

M.H.S.C.T vial used as control and not exposed to moist heat must show a colour change of the medium to yellow and a turbidity.

In the absence of color change, incubate for up to 48 hours.

6 - LIMITATIONS OF THE METHOD

Different batches of spores may have different killing times. This depends on the natural variability of the biological material. Take this into account when setting the duration of the control cycle to avoid invalid results.

7 - PRECAUTIONS AND WARNINGS

- Handle with Care To avoid breakage of the vials, with consequent contamination of the environment.
- M.H.S.C.T. vials showing bacterial growth and/or a colour change of the medium must be sterilized before being eliminated to avoid dispersion of spores into the environment.
- The Certificates of Analysis and the Safety Data Sheets are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

8 - STORAGE CONDITIONS

Store M.H.S.C.T. at a temperature of 4-30°C













9 - REFERENCES

- Brewer J.H., McLaughlin C.B. . Bact. Proc. Am. Soc. Micr., 54th General Meeting – Pittsburg, May 2-7-1954, pag. 28.
- Brewer J.H., Mckayghlin C.B.: J. Pharm. Sc., 50, 171, 1961.
- Developments in Biological Standardization vol. 23 – International Symposium on Sterilization and sterility testing of biological substances – Editors: R.H. Ragamey (Geneva), F.P. Gallardo (Madrid) and W. Hennessen (Marburg/Lahn).
- Lena e coll.: Il farmaco, Ed. Pr., 32, 172, 1977.
- USP XX, 1038, 1979.





TABLE OF APPLICABLE SYMBOLS

 or REF Catalogue number	 Batch code	 Manufacturer	 This side up	 Store in a dry place	 Fragile
 Temperature limitation	 Content sufficient for <n> tests	 Consult Instructions for Use	 Use by	 Biological Risk	 For single use only

REVISION HISTORY

Version	Description of changes	Date
Revision 3	Content update	2025/03

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

