STERITEST-12

Biological indicator of steam sterilization process with Certificate of functionality

ATTENTION: to get the results of sterility tests performed on cylinders returned to LTA you need to register on the web site www.ltaonline.it

TEST SUMMARY

The assurance of the sterilization occurs when it can be determined that: 1) an appropriate temperature has been reached at any point of the autoclave; 2) this temperature was maintained for as long as necessary; 3) the air of the autoclave has been replaced completely by water vapor.
The implemented of these conditions may be hampered by several factors: incomplete removal of the air, the formation of "pockets" where steam penetration is hampered, imperfect operation of pressure gauges or thermometers, etc. ....
From these considerations it becomes necessary to make sure controls of the functionality of steam autoclaves.
While it is easy to determine, with the use of substances or fuses alloys to known temperature if it has been reached or not predetermined temperature, the harder it is to ascertain if this temperature has been maintained for a sufficient time and if the replacement of steam to air is was complete in every point of the autoclave.
For this investigation - the only one that can give you the assurance of the sterilization - you may want to use biological control. Is used to demonstrate that with the conditions of operation of the autoclave has obtained the death of bacterial spores surely equipped with high heat resistance. This biological control is indicated by the monograph 5.1.2. European Pharmacopoeia 6.0.
the Steritest-12 is Biological indicator of steam sterilization process (121°C – 134°C) with Certificate of functionality containing spores of Bacillus stearothermophilus ATCC 7953, which survive after autoclaving with steam for 5 minutes at 121 ° C ± 0.5 ° C (1 atm), while die when the exposure lasts for 12 minutes at 121 ° C ± 0.5 ° C (1 atm). The Seritest-12 has been studied to monitor and monthly certify the efficiency of the sterilization process.

HOW USE

In box Steritest-12 there are twelve metallic cylinders each containing a vial of spores of *Bacillus stearothermophilus*. Each of these is marked by a number.
For each sterilization process tested take one of the cylinders, and put it in the autoclave.

We recommend the use of cylinders in numerical order, starting with the cylinder No. 1 to No. 12.
In case it is necessary to monitor more than one autoclave use a box for each autoclave in order to have uniformity in the certificate of analysis.

After use, remove the cylinder from the steam autoclave , write the date of the sterilization process on the label, place it in one of the envelopes provided in the package and send it to:
LTA srl Via Milano 15 / F, 20063 Bussero (MI) - Italy.
Alternatively, return it to the company that provides the service.

ATTENTION: the first cylinder of each box must be sent back to together with the module, provided in the package, correctly filled in all the spaces reserved for the user.

The execution of the analysis of bacteriological sterility for the cylinders received will be notified by e-mail and its result will be available for viewing and printing on the site **www.LTAonline.it** in his private area after registration by the user.

REAGENTS

Cylinders:	Medium with suspension containing spores of Bacillus stearothermophilus ATCC 7953, an indicator of pH, carbohydrate.

RESULTS INTERPRETATION

If the contents of the vials of Steritest-12 is sterile, it must be concluded that the sterilizing action of heat is efficient: it has caused the death of bacterial spores.

If the contents of the vials of Steritest-12 is not sterile, it must be concluded that the sterilizing action has been insufficient: this has allowed the survival of bacterial spores.

STORAGE

Keep the Stericolor-test at 4-30°C up to expiration date indicated on the package.

NOTE

- If it is deemed appropriate to the cylinders can be placed at the points where it is suspected that the sterilizing action of the steam is insufficient (the central part of sacks, baskets, parcels, etc..).
- The metal cylinders of Steritest-12 should never be opened.
- If the sender's address is not readable and / or is absent in the space provided on the module included in the package will be impossible to carry out the analysis and in this case LTA srl disclaims all responsibility.
- Product manufactured according to Italian Official Pharmacopoeia and European Pharmacopoeia

PACKAGING

CODE AT00500 (12 Cylinders)	
Cylinders from no.1 to no.12	12 x 1 test
Envelopes for the return	12 pieces
Module Steritest-12	1

REFERENCES

Brewer J.H., McLaughlin C.B. . Bact. Proc. Am. Soc. Micr., 54th General Meeting – Pitsburg, 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.

MANUFACTURER

LTA s.r.l.
Via Milano 15/F
20060 Bussero (Milano) - ITALY
tel. +39 02 95409034
fax. +39 02 95334185
e-mail. info@LTAonline.it
website. http://www.LTAonline.it

SYMBOLS

LOT	Lot f manufacturing
REF	Code number
	Storage temperature interval
	Expiration date (year – month)
	Warning, read enclosed documents
	Read the directions
	Biological risk

Mod. 01.06 (ver. 1.5 – 22/05/2018)