



BIOLOGICAL INDICATOR – SPORE AMPULE

This lot of product meets the accepted performance criteria recommended in the USP, ISO 11138-1 and ISO 11138-3.

Product Name: Mini Spore Ampule + Negative Controls

For use in Monitoring: Steam

Organism: *Geobacillus stearothermophilus* ATCC®7953

LOT S701-0

REF ATM-06

Ampule Volume: 0.7 mL

2021-01-01

2023-01-01

Population: 2.0 x 10⁶ per ampule

Negative Controls

Tryptic Soybean Broth

LOT NC010121-01

2021-01-01

2023-01-01

LOT 136758

Resistance Characteristics		
<i>D</i> value Steam 121°C:	1.5 minutes	The <i>D</i> value was determined per the fraction negative method and are reproducible only when exposed and cultured under the exact conditions used to obtain results reported above. The user would not necessarily obtain the same results, therefore, should determine the suitability for their particular use.
Survival	6.5 minutes	Survival-Kill times are calculated based on the formulae outlined in USP and ISO 11138-1.
Kill	15.4 minutes	
<i>z</i> value:	10.0 °C	Based on <i>D</i> value determinations at 118°C, 121°C and 130°C
Purity: Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the product.		

Storage and Shelf Life			
	Refrigerate (2° - 8°C)		Keep away from sunlight
	Protect from heat, radioactive sources, and sterilizing agents	Shelf Life	24 Months from the date of manufacture

Disposal: Autoclave, steam at 121°C for not less than 30 minutes, or incinerate (standard microbial waste; non-pathogenic species).

QUALITY ASSURANCE APPROVAL

January 4, 2022
DATE



Exposure:

Spore Ampules may be placed inside representative materials (containers of liquid) or within the chamber directly. Package or wrap product as usual, if applicable. Locate product or Spore Ampules in most difficult location to sterilize, as outlined in your specific sterilization validation protocol or according to standard operating procedure. Run the cycle.



Handle Spore Ampules with care as the contents are extremely hot post-exposure. Always employ proper PPE when handling hot materials; remove Ampules from sterilizer as quickly and safely as possible post-exposure. Leaving the Spore Ampules in the sterilizer post-exposure may have a negative impact on the product's performance. As such, Spore Ampules left in the chamber for extended periods of time (24 hours) post-exposure should be discarded.

After sterilization or exposure, remove Spore Ampules or product from sterilizer. Allow product or Spore Ampules to cool to the touch. No activation is required.

Controls:

Use a Negative Control Ampule in conjunction with the Spore Ampules, where a negative control is required. If a Positive Control is needed, label one unprocessed Spore Ampule as "Positive Control".

Incubation:

Place the processed Spore Ampules, the Negative Control and the Positive Control in a vertical position in an incubator at 60°C to 65°C for a minimum of 48 hours.

Monitoring:

Examine the Spore Ampules daily, whenever possible during incubation. Record observations. All positive Spore Ampules should be disposed of immediately. Do not continue to incubate a positive Spore Ampule. Continued incubation of positive Ampules may result in metabolism of amino acids in the absence of sugars, causing the pH to rise and result in color reversion that is visibly darker (Dark Purple- Brown) than a sterile unit. These should be considered as positive for growth (turbidity and sediment in the Ampule will be present).

Interpretation:

Negative Control: The Negative Control Ampule should remain Purple and not exhibit a color change to Yellow and/or demonstrate turbidity. Utilize the Negative Control as a color comparison for the exposed Spore Ampules, where applicable.

Positive Control:

The Positive Control Spore Ampule should exhibit a color change to Yellow and/or demonstrate turbidity. Utilize the Positive Control as a color comparison for the exposed Spore Ampules, where applicable. If the positive control does not demonstrate a Yellow color and/or turbidity, the results for test Spore Ampules should not be considered valid. Verify incubation conditions were met throughout the incubation period.

Test Spore Ampules:

A passing sterilization cycle is indicated by a test Spore Ampule remaining Purple in color and is free from turbidity. A failed sterilization cycle is indicated by turbidity and/or a color change to Yellow.