

MINI SPORE AMPULES For Monitoring Steam Processes

Product Code: BI-MSA-ATM06



Product Description

Mini Spore Ampules are Self-Contained Biological Indicators (SCBIs) consisting of a hermetically sealed glass ampule which contains modified Tryptic Soy Broth (TSB) with a pH indicator and *Geobacillus stearothermophilus* Cell Line 7953 at a population level of 10^6 . The modified TSB will transition from the initial Purple color to Yellow and/or demonstrate turbidity in the presence of bacterial growth.

Negative Control Ampules are manufactured with the modified TSB with a pH indicator from the same lot as the Spore Ampules providing a consistent Purple color prior to and post-incubation. Each Negative Control Ampule contains a single glass bead to ensure they are easily distinguishable from the Mini Spore Ampules.

Indications for Use

The Mini Spore Ampules may be utilized to monitor Steam sterilization processes at 121°C to 137°C. The Spore Ampules are ideal for monitoring liquid steam sterilization cycles but may also be utilized in monitoring dry loads. Mini Spore Ampules are labeled for laboratory/industrial use only.

Physical Properties

Process	Steam
Dimensions	40 mm x 6.5 mm
Packaging	Mini Spore Ampules: 200 per box Negative Control Ampules: 20 per Box
Volume	0.7 mL

Monitoring Frequency

For greatest control of sterilized goods, it is recommended that one or more Mini Spore Ampules be included with every load.

Instructions for Use

Exposure: Mini 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 Mini 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 Mini Spore Ampules with care as contents are extremely hot. Once Spore Ampules are cooled and able to be handled, remove from sterilizer immediately. Leaving the Mini Spore Ampules in the sterilizer post-exposure may have a negative impact on the product's performance. As such, Mini Spore Ampules left in the chamber for extended periods of time (24 hours) post-exposure should be discarded.

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

Incubation: Place the processed Mini Spore Ampules, one Negative Control Ampule and one Positive Control (unprocessed Mini Spore Ampule) in a vertical position in an incubator at 60°C to 65°C for a minimum of 48 hours.

Monitoring: Examine the Mini Spore Ampules daily during incubation. Record observations. All positive Mini Spore Ampules should be disposed of immediately. Do not continue to incubate a positive Ampule. Continued growth 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 than a sterile unit. These should be considered as positive for growth (turbidity will be present).

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

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

Test Mini Spore Ampules: A passing sterilization cycle is indicated by a test Spore Ampule which retains its original Purple color and is free from turbidity. A failed sterilization cycle is indicated by turbidity and/or a color change to Yellow.

For unexpected positives, it is recommended that a Gram stain be performed. Gram positive rods are indicative for the indicator organism.

Compliance

ISO 11138-1 Sterilization of health care products - Biological indicators - Part 1: General requirements

ISO 11138-3 Sterilization of healthcare products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes.

USP <55> Biological Indicators - Resistance Performance Tests

True Indicating has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin which outlines the recommended methodology.

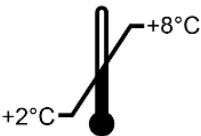
Disposal

Autoclave for not less than 30 minutes at 121°C or per validated disposal cycle prior to discard.

Performance Characteristics

Population	$\geq 1.0 \times 10^6$ ampule
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	D value at $121^\circ\text{C} \pm 0.5^\circ\text{C}$ ≥ 1.5 minutes The Steam D value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food & Drug Administration (FDA). Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1 and guidance issued by the FDA. z value $\geq 6^\circ\text{C}$ Determined based on three temperatures in the range of 110°C to 138°C. True Indicating typically utilizes D values determined at 118°C, 121°C and 130°C for z value calculation.
Post-Market Criteria	Population: 50% to 300% of certified population D value: $\pm 20\%$ of the certified D value Survival Time: All Spore Ampules result in growth at the certified survival time Kill Time: All Spore Ampules result in no growth at the certified kill time

Storage and Shelf Life

	Refrigerate at 2°C to 8°C		Keep away from Sunlight
	Do not freeze		Protect from heat, radioactive sources & sterilizing agents
Shelf Life	24 months from the date of manufacture		
	Do not use damaged Mini Spore Ampules or Mini Spore Ampules which demonstrate turbidity or have transitioned to a Yellow color. Do not use after expiration date. The Mini Spore Ampules contain live cultures and should be handled with care.		