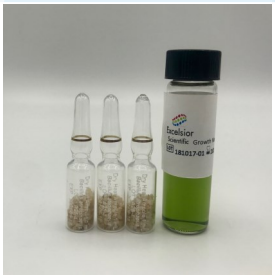
AMPOULES
For monitoring Dry Heat and Depyrogenation processes
ISO 11113-1 & ISO 11138-4 Compliant



Excelsior Code: AAD-06E

Product Description

Excelsior Dry Heat Ampoules are appropriate for use in high temperature processes including direct air exposure, submersion in oils and other liquids where traditional BIs of paper are not suitable for use. The Dry Heat Ampoules are a snap top glass ampoule containing silica material inoculated with *Bacillus atrophaeus* Cell Line 9372 Spores with a known population and resistance. The Ampoules are sold with tubes of growth medium specially formulated for *Bacillus atrophaeus* and modified with a pH indicator that offers a reduced incubation time of 72 hours. When Spores have survived the process, the growth medium transitions from Green to Yellow.

All materials are compatible with extremely high temperatures such as those in dry heat tunnels or ovens used for sterilisation or depyrogenation in manufacturing of aseptically filled pharmaceutical liquids.

Indications for Use

The indicators are for use in high temperature dry heat sterilisers, ovens and tunnels operating at 160°C (or higher) or depyrogenation processes operating up to 250°C.

The Ampoules are labelled for industrial use only.

Instructions for Use

Identify the Ampoule with pertinent process or load location information. Position the Ampoule inside the product or product packaging and place in the most difficult to sterilise location. Expose the load to the validated sterilisation cycle/conditions.

Following exposure, remove the Ampoule from the load and transfer to the laboratory for culturing. Ampoules should be aseptically handled within a laminar flow hood.

Open each Ampoule be holding the base of the Ampoule in one hand and firmly pressing the neck of the Ampoule with the other hand to apply pressure to snap it open.

Wear safety goggles.
Avoid scored area of the Ampoule once snapped as the Ampoule base will be sharp where the neck has been removed.

Transfer contents of the Ampoule to a tube of growth medium. Repeat until all Ampoules have been transferred.

Controls: Use of a Positive Control Ampoule is recommended. Transfer the contents of an unexposed Ampoule (in the same manner as the Test Ampoules) to a tube of growth medium. Label the tube with “Positive Control”.

Incubation: Place the tubes containing the contents of the Test Ampoules and the Positive Control, if applicable, in a vertical position in an incubator at 30°C - 40°C for a minimum of 72 hours.

Monitoring: Examine the Spore Ampoules daily during incubation. Record observations. All positive tubes should be disposed of immediately. Do not continue to incubate a positive as continued growth may result in metabolism of amino acids in the absence of sugars, causing the pH to rise and result in colour reversion to a share of blue-green that is visibly different than a sterile unit. These should be considered positive for growth (turbidity and pellicle formation in the tube will be present).

Interpretation:

Positive Control: The Positive Control should exhibit a colour change to Yellow and/or demonstrate turbidity. Utilise the Positive Control as a colour comparison for the tubes containing the Test Ampoules.

Test Ampoules: A passing sterilisation cycle is indicated by the colour of the growth medium remaining green and free of turbidity or visible evidence of growth. A failed sterilisation cycle is indicated by a colour change in the medium to Yellow and/or turbidity.

Physical Properties

Process	Dry Heat or Depyrogenation
Dimensions	Ampoule: 58 mm x 10.6mm
Packaging	50 Ampoules + 50 Tubes of Growth Medium
Volume	4.5 mL

Monitoring Frequency

For greatest control of sterilised goods, it is recommended that one or more Ampoules be included with every load.

Performance Characteristics

Population	≥ 1.0 x 10^6 per ampoule
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Dry Heat Resistance	*D* value at 160°C ≥ 2.0 minutes The dry heat *D* value is based on the requirements outlined in ISO 11138-4. Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1 and guidance issued by the FDA. *z* value ≥ 20°C Determined based on three temperatures in the range of 150°C to 180°C. Excelsior Scientific typically utilises *D* values determined at 150°C, 160°C and 180°C for *z* value calculation.
Post-Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value Survival Time: All Ampoules result in growth at the certified survival time Kill Time: All Ampoules result in no growth at the certified kill time

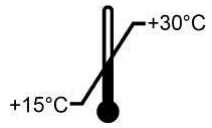
Compliance

ISO 11138-1 Sterilization of health care products – Biological Indicators- Part 1:General Requirements

ISO 11138-4 sterilisation of healthcare products—Biological Indicators — Part 4: Biological Indicators for dry heat sterilization processes.

Excelsior Scientific has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin entitled “Population Verification for Spore Ampoules” to ensure consistent methodologies are being utilised when performing verification testing.

Storage and Shelf Life

	15°C to 30°C		Keep away from Sunlight
	20% to 80% Relative Humidity		Keep Dry
Shelf Life	24 months from the date of manufacture.		
	Do not use damaged Ampoules or Ampoules which have transitioned to a yellow colour. Do not use after expiration date.		

Disposal

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

For additional product information:
Please visit us at
www.excelsiorscientific.com
Email us at sales@excelsiorscientific.com

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