



This lot of product meets the accepted performance criteria recommended in the USP, ISO 11138-1 and ISO 11138-4.

Product Name: Dry Heat Ampule with Modified Growth Medium

Organism: *Bacillus atrophaeus* ATCC® 9372

LOT A25-0

REF AAD-06

For Monitoring: Dry Heat

2020-10-08

2022-10-08 (YYYY-MM-DD)

Quantity: 50 Ampules+ 50 Tubes of Medium

Population: 2.0 x 10⁶ per Ampule

Modified Growth Medium

LOT P102920-02

REF GGM-50

2022-04-29 (YYYY-MM-DD)

Resistance Characteristics

Dry Heat *D* value at 160°C: 3.6 minutes

z value: 49.3°C Based on *D* value determinations at 150°C, 160°C and 180°C.

The *D* value(s) were 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.

Recovery

Following exposure, remove the Ampule from the load and transfer to the laboratory for culturing. Ampules should be aseptically handled within a laminar flow hood. Open each Ampule by holding the base of the Ampule in one hand and firmly pressing the neck of the Ampule with the other hand to apply pressure to snap it open. Transfer contents of the Ampule to a tube of modified growth medium. Repeat until all Ampules have been transferred.

Incubate at 30°-40°C for a minimum of 72 hours. Examine tubes for growth, daily or as frequently as possible. Tubes showing typical growth of *Bacillus atrophaeus* will display a color change in the medium to Yellow and/or turbidity and formation of a pellicle at the top of the media which is orange in color. A passing sterilization cycle is indicated by the color of the growth medium remaining green and free of turbidity or visible evidence of growth.

Purity: Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the biological indicator.

Storage and Shelf Life			
	Room Temperature (15°-30°C)		Keep away from sunlight
	20% to 80% Relative Humidity		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 Approval

Date