



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

PRODUCT NAME: Spore Suspension

FOR USE IN MONITORING: Dry Heat Processes

ORGANISM: *Bacillus atrophaeus*, ATCC® 9372

DILUENT: Water for Injection (WFI)

VOLUME: 10 mL each vial

LOT	A00-1		2021-01-01		2024-01-01
REF	UA-06DH	POPULATION:		2.0x10 ⁶ /0.1 mL	
Resistance Characteristics					
<i>D</i> value		Survival		Kill	
Dry Heat, 160°C: 2.0 minutes		8.7 minutes		20.6 minutes	
<p>The <i>D</i> value was determined on paper carriers packaged in glassine envelopes 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.</p> <p>Survival-kill times are calculated based on the formulae outlined in USP and ISO 11138-1.</p>					
z value: 50.0°C Based on <i>D</i> value determinations at 150°C, 160°C and 180°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 at 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat, radioactive sources, & sterilizing agents
Shelf-life	36 Months from the date of manufacture		
	Do not use damaged vials of Spore Suspension. Do not use after expiration date. Spore Suspensions contain live cultures and should be handled with care.		

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

QUALITY ASSURANCE APPROVAL

January 9, 2022
DATE