



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

**PRODUCT NAME:** Spore Suspension

**FOR USE IN MONITORING:** Steam Processes

**ORGANISM:** *Bacillus subtilis*, ATCC® 35021

**DILUENT:** Water for Injection (WFI)

**VOLUME:** 10 mL each vial

<b>LOT</b>	B57-EXAMPLE		2024-02-15		2026-02-15
<b>REF</b>	UB5-06	POPULATION:		1.0x10 <sup>6</sup> /0.1 mL	
<b>Resistance Characteristics</b>					
<i>D</i> value		Survival		Kill	
Steam, 110°C: 12.8 minutes		51.2 minutes		128.0 minutes	
Steam, 115°C: 4.5 minutes		18.0 minutes		45.0 minutes	
Steam, 118°C: 1.5 minutes		6.0 minutes		15.0 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 calculated using USP and ISO survival time and kill time formulae.</p> <p>z value: 8.8°C      Based on <i>D</i> value determinations at 110°C, 115°C and 118°C.</p> <p>Purity: Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the product.</p>					

<b>Storage and Shelf Life</b>			
	Refrigerate at 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat, radioactive sources, & sterilizing agents
<b>Shelf-life</b>	24 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.

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QUALITY ASSURANCE APPROVAL

March 2, 2026  
DATE

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