

CERTIFICATE OF ANALYSIS

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: Vaporized Hydrogen Peroxide Processes

ORGANISM: Geobacillus stearothermophilus, ATCC® 7953

VOLUME: 10 mL each vial **DILUENT**: Water for Injection (WFI)

LOT	S710-1	W	2021-01-01			2024-01-01	
REF	UTH-06			POPULATION:	1.0x10 ⁶ /0.1 mL		
Resistance Characteristics							
Hydrogen Peroxide D value				Survival		Kill	
2.3 ± 0.4 mg/L, 55° ± 5°C: 1.0 minutes				4.0 minutes		10.0 minutes	

The *D* 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.

Survival-Kill times calculated using USP and ISO survival time and kill time formulae.

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

Storage and Shelf Life							
+2°C	Refrigerate at 2°C to 8°C	类	Keep away from sunlight				
1	Do not freeze	**	Protect from heat, radioactive sources & sterilizing agents				
Shelf-life	36 Months from the date of manufacture						
\triangle	Do not used 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 DATE

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