



BIOLOGICAL INDICATOR – SPORE SUSPENSION

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: Radiation


Organism: *Bacillus pumilus*

LOT BP1-1

REF UBP-06

Volume 10 mL

 2018-10-25

 2020-10-25 (YYYY-MM-DD)

Diluent: Water for Injection (WFI)

Derived from: Cell Line 27142

Population: 2.0×10^6 per 0.1 mL

Resistance Characteristics

D value

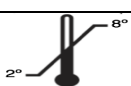


Radiation (Cobalt 60): 1.5 kGy

The *D* value was determined in 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 are calculated based on the formulae outlined in USP and ISO 11138-1.

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

Storage and Shelf Life

	Refrigerate (2 - 8°C)		Keep away from sunlight
	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