

Bacillus pumilus Biological Indicator Spore Strip Product Comparison

This document refers to standard spore strips of *Bacillus pumilus*, ATCC® 27142 NAMSA Product Codes: STP-02, STP-03, STP-04, STP-05, STP-06, STP-07 and STP-08 in comparison to Crosstex's equivalent replacement Product Codes: PM-102, PM-103, PM-104, PM-105, PM-106, PM-107 and PM-108.

Product Code Reference and Shelf Life

Product Description	NAMSA		Crosstex	
	Product Code	Shelf Life	Product Code	Shelf Life
<i>Bacillus pumilus</i>				
10 ² Spore Strip	STP-02	24 months	PM-102	24 months
10 ³ Spore Strip	STP-03	24 months	PM-103	24 months
10 ⁴ Spore Strip	STP-04	24 months	PM-104	24 months
10 ⁵ Spore Strip	STP-05	24 months	PM-105	24 months
10 ⁶ Spore Strip	STP-06	24 months	PM-106	24 months
10 ⁷ Spore Strip	STP-07	24 months	PM-107	24 months
10 ⁸ Spore Strip	STP-08	24 months	PM-108	24 months

Product Lot Comparison: NAMSA STP-06 versus Crosstex PM-106

Product Characteristic	NAMSA			Crosstex		
	Lot Number			Lot Number		
	P01992	P019110	P019114	P69	P72	P76
Population per strip	1.3x10 ⁶	4.2x10 ⁶	1.5x10 ⁶	1.7x10 ⁶	2.2x10 ⁶	1.7x10 ⁶
Radiation <i>D</i> value (Cobalt 60) In kGy	1.4	1.4	1.4	2.0	2.2	2.2

Crosstex is a FDA registered facility (registration number 1319130). Based on a product comparison and review of best practices, the Biological Indicator Spore Strips manufactured by Crosstex are equivalent to those manufactured by NAMSA Products Division and offer the following advantages:

- An improved peel area which allows for the Spore Strip to be more easily accessed and removed from the glassine packaging.
- Natural glassine material which does not contain dye.

	NAMSA	Crosstex
Glassine Material	30# Blue	25# White
<p>Worldwide sources for glassine material are limited; thus, the material utilized by NAMSA and Crosstex-SPSmedical are the same with the exception of a blue dye. It is this dye which causes the glassine material NAMSA has utilized to appear blue, whereas Crosstex-SPSmedical utilizes the natural form of the material without the addition of the dye. Crosstex-SPSmedical switched from the dyed material to the natural white version several years ago without any negative impact to the product or its performance.</p>		
Peel Area	Not Applicable – STP products packaged in glassine envelope which did not offer an option to peel open.	Edges of glassine material are offset, creating an obvious peel area which requires no indication.
Lot Number	6-7 Digits printed on glassine	4 Digits printed on glassine
Expiration Date	DD-MMM-YYYY	YYYY-MM-DD
Strip Dimension	6 mm x 30 mm	7 mm x 38 mm
Quantity	Boxes of 100	Boxes of 100
Population	1.0 to 6.0 x 10 ^x	1.0 to 5.0 x 10 ^x

The ordering information associated with the products, during and post transition, will remain the same.

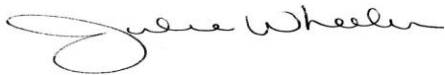
Ordering Information	
Telephone	1 (800) 860-1888
Fax	1 (419) 666-1715
Email	productorders@crosstex.com

We understand that our clients have different needs based on your internal quality system requirements or Standard Operating Procedures (SOP's). Because of this, if there is something specific that is required, such as completion of specific forms or documents, samples, etc., please do not hesitate to let us know.

Thank you for being a valued client and we look forward to continuing to serve you.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Julie Wheeler
Director Industrial Markets
jwheeler@crosstex.com
419-304-6535