

Sterile Polyester Spun Swab Sterilization and Shelf-Life Information

General Information

Trade Name: SteriPack Swab

Common Name: Sterile Polyester & Narrow Spun Swab

Catalogue number(s):

SP Ref	GTIN /GS1/UPC Ref	Description
60564	860004112716	Sterile Polyester Spun Swab [bulk shipper]
60567	860004112723	Sterile Polyester Narrow Spun Swab [bulk shipper]
60577	860004112754	Sterile swab v2, single unit [bulk shipper]

Note: bundled versions are available, i.e. the individually packaged swab is grouped/bundled together

Sterilization Cycle and monitoring

- Sterilization type: Gamma
- Routine sterilization:
 - o Standard Cycle: Gamma, 20 – 50 kGy
 - o 2000 units per shipper box
 - o Random product/package orientation in box
 - o Shipper box/product dimensions: 23.25"x15.5"x7.5"
 - o 30 shipper boxes per carrier
- Frequency of QDA (Ver/Low dose and bioburden): every 3 months

Shelf-life

- The expiry date was established in phases.
 - o Initially, 12 months expiry date.
 - o Upon completion of additional studies, the expiry date was approved up to 36 months.
 - o The expiry date is identified on product label.

1.0 SUMMARY OF RESULTS

Test Description	Method	Status	Items Tested	Qty Defective
Aging Conditioning				
Accelerated Aging – 1 Year (T1)	ASTM F1980-16	Complete	89 Pouches	N/A
Accelerated Aging – 3 Year (T3)	ASTM F1980-16	Complete	89 Pouches	N/A
Accelerated Aging – 5 Year (T5)	ASTM F1980-16	In Progress	89 Pouches	N/A
Integrity Testing – T1				
Visual Inspection	Visual	Complete	59 Pouches	0
Package & Seal Integrity	Visual, ASTM F1886	Complete	59 Pouches	0
Seal Width	ASTM F2203	Complete	59 Pouches	0
Bubble Leak	ASTM F2096	Complete	59 Pouches	0
Seal Strength	ASTM F88	Complete	30 Pouches	0
Integrity Testing – T3				
Visual Inspection	Visual	Complete	59 Pouches	0
Package & Seal Integrity	Visual, ASTM F1886	Complete	59 Pouches	0
Seal Width	ASTM F2203	Complete	59 Pouches	0
Bubble Leak	ASTM F2096	Complete	59 Pouches	0
Seal Strength	ASTM F88	Complete	30 Pouches	0