



Sani-Tech® SPT-60L Pump Tubing for High Accuracy Applications

Pump Tubing for Accurate Dispensing

Sani-Tech® SPT-60L is a premium platinum-cured silicone tubing designed for the most exacting pharma operations where low spallation, long pump life and high accuracy are required. Sani-Tech® SPT-60L provides best-in-class accuracy and precision assuring consistent filling performance and reducing the potential for costly over/under fills.

With an average pump life over *250 hours, Sani-Tech® SPT-60L tubing outperforms competitive extruded silicone tubing providing improved performance and reliability under various pumping conditions. (*Testing was performed on Sani-Tech® SPT-60L tubing using a four-roller peristaltic pump head operating at 400rpm with no backpressure at room temperature).

Filling Accuracy (Target) and Precision (Repeatability)

Sani-Tech® SPT-60L was assessed for accuracy (dispensing target fill volume) and precision (repeatability of delivered volume) against competitive pump tubing marketed for filling applications. Sani-Tech® SPT-60L provided a *4X improvement in filling accuracy and 2X improvement in precision over the closest performing competitor tubing. (*Supplemental data presented in white paper.)

Low Spallation

Sani-Tech® SPT-60L has the lowest spallation (number of particles and area of particles) across multiple dispensing cycles among the various silicone pump tubing evaluated.

Biocompatible

Sani-Tech® SPT-60L tubing is manufactured from platinum-cured silicone materials and tested to a variety of specifications including:

ADCF/BSE/TSE statements

USP <88> Class VI, and/or USP <87>, and/or ISO 10993-5

EP 3.1.9

Visit www.biopharm.saint-gobain.com to download the [Technical Dossier](#).

Features / Benefits

- Long Pump Life
- Low Spallation
- Accurate and Consistent Dispensing
- Full Extractables Report per BioPhorum Operations Group (BPOG) Protocol
- Technical Dossier Available
- Available with ValPlus™ Certification (See page 4 for more details)

Typical Applications

- Final Fill
- Extended Duration Pumping
- Precision Pumping



Sani-Tech® SPT-60L Pump Tubing Standard Size

Part Number	ID inch (mm)	OD inch (mm)	Wall Thickness inch (mm)	Burst Pressure (psi)	Burst Pressure (Bar)
SPT60L-020-2	0.020 (0.5)	0.146 (3.7)	.063 (1.6)	199	13.7
SPT60L-031-1	0.031 (0.8)	0.094 (2.4)	0.031 (0.8)	138*	9.5
SPT60L-031-2	0.031 (0.8)	0.156 (4.0)	0.063 (1.6)	160	11.1
SPT60L-047-157	0.047 (1.2)	0.157 (4.0)	0.055 (1.4)	168	11.6
SPT60L-047-2	0.047 (1.2)	0.172 (4.4)	0.063 (1.6)	174	12.0
SPT60L-063-1	0.063 (1.6)	0.125 (3.2)	0.031 (0.8)	113	7.8
SPT60L-063-157	0.063 (1.6)	0.157 (4.0)	0.047 (1.2)	142	9.8
SPT60L-063-2	0.063 (1.6)	0.188 (4.8)	0.063 (1.6)	167*	11.5
SPT60L-079-204	0.078 (2.0)	0.204 (5.2)	0.063 (1.6)	145	10.0
SPT60L-094-2	0.094 (2.4)	0.219 (5.6)	0.063 (1.6)	134	9.2
SPT60L-125-1	0.125 (3.2)	0.188 (4.8)	0.031 (0.8)	67	4.6
SPT60L-125-2	0.125 (3.2)	0.250 (6.4)	0.063 (1.6)	113	7.8
SPT60L-125-268	0.125 (3.2)	0.268 (6.8)	0.072 (1.8)	123	8.4
SPT60L-157-315	0.157 (4.0)	0.315 (8.0)	0.079 (2.0)	113	7.8
SPT60L-187-1	0.188 (4.8)	0.250 (6.4)	0.031 (0.8)	46	3.1
SPT60L-187-2	0.188 (4.8)	0.313 (7.9)	0.063 (1.6)	85	5.9
SPT60L-187-346	0.187 (4.7)	0.346 (8.8)	0.080 (2.0)	101	7.0
SPT60L-187-3	0.188 (4.8)	0.375 (9.5)	0.094 (2.4)	113	7.8
SPT60L-187-4	0.188 (4.8)	0.438 (11.1)	0.125 (3.2)	134	9.2
SPT60L-197-4	0.197 (5.0)	0.472 (12.0)	0.138 (3.5)	137	9.4
SPT60L-236-394	0.236 (6.0)	0.394 (10.0)	0.079 (2.0)	85	5.8
SPT60L-250-1	0.250 (6.4)	0.313 (7.9)	0.031 (0.8)	34	2.3
SPT60L-250-2	0.250 (6.4)	0.375 (9.5)	0.063 (1.6)	64*	4.4
SPT60L-250-3	0.250 (6.4)	0.438 (11.1)	0.094 (2.4)	167*	11.5
SPT60L-250-4	0.250 (6.4)	0.500 (12.7)	0.125 (3.2)	115*	7.9
SPT60L-313-2	0.313 (7.9)	0.438 (11.1)	0.063 (1.6)	54	3.7
SPT60L-313-3	0.313 (7.9)	0.500 (12.7)	0.094 (2.4)	78	5.4
SPT60L-315-472	0.315 (8.0)	0.472 (12.0)	0.079 (2.0)	66	4.6
SPT60L-313-488	0.313 (8.0)	0.488 (12.4)	0.088 (2.2)	73	5.0
SPT60L-375-2	0.375 (9.5)	0.500 (12.7)	0.063 (1.6)	50*	3.4
SPT60L-375-3	0.375 (9.5)	0.563 (14.3)	0.094 (2.4)	69*	4.8
SPT60L-375-4	0.375 (9.5)	0.625 (15.9)	0.125 (3.2)	84	5.8
SPT60L-438-3	0.438 (11.1)	0.625 (15.9)	0.094 (2.4)	57	4.0
SPT60L-500-2	0.500 (12.7)	0.625 (15.9)	0.063 (1.6)	33*	2.3
SPT60L-500-4	0.500 (12.7)	0.750 (19.1)	0.125 (3.2)	62*	4.3

*Actual tested burst pressure
 Burst pressure test method = ASTM D1599
 Test media = water

The values listed for burst pressures are derived from tests conducted under controlled laboratory conditions or calculated based on tested pressures and the hoop stress quotient. Many factors will reduce the tubing's ability to withstand pressures, including temperature, chemical attack, stress, pulsation and the attachment to fittings. It is imperative that the user conduct tests simulating the conditions of the application prior to specifying the tubing for use.

Typical Physical Properties

Property	ASTM Method	Target Values
Durometer, Shore A	D2240	60 nominal
Tensile Strength, psi	D412	> 900
Elongation, %	D412	> 300
Specific Gravity	D792	1.12 nominal

Unless otherwise noted, all tests were conducted at controlled room temperature. Values shown were determined on 0.075" thick extruded strip or 0.075" thick molded ASTM plaques or molded ASTM durometer buttons.

General Sterilization Methods

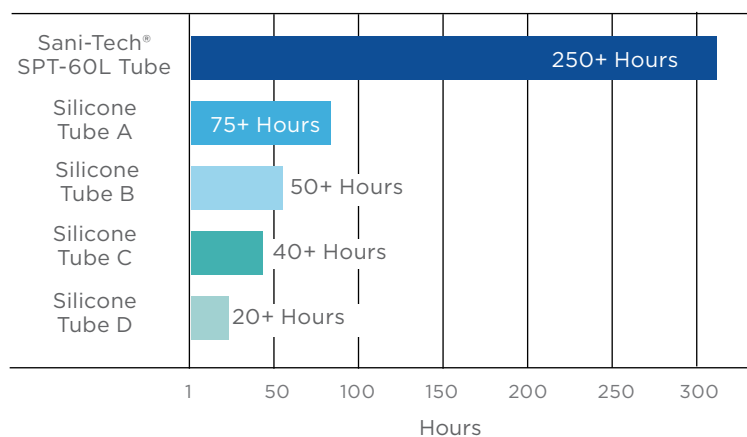
- Autoclavable
- Gamma Irradiation - up to 5.0 Mrad (50 kGy)
- Gas - Ethylene Oxide

Test data based on open source literature for material compatibility.

Peristaltic Pump Tubing Life

Due to its specific formulation, Sani-Tech® SPT-60L provides exceptional continuous pumping duration. As demonstrated in Table 1, Sani-Tech® SPT-60L provides over 3x the pump life compared to other extruded silicone tubing that are marketed for final fill applications.

Table 1



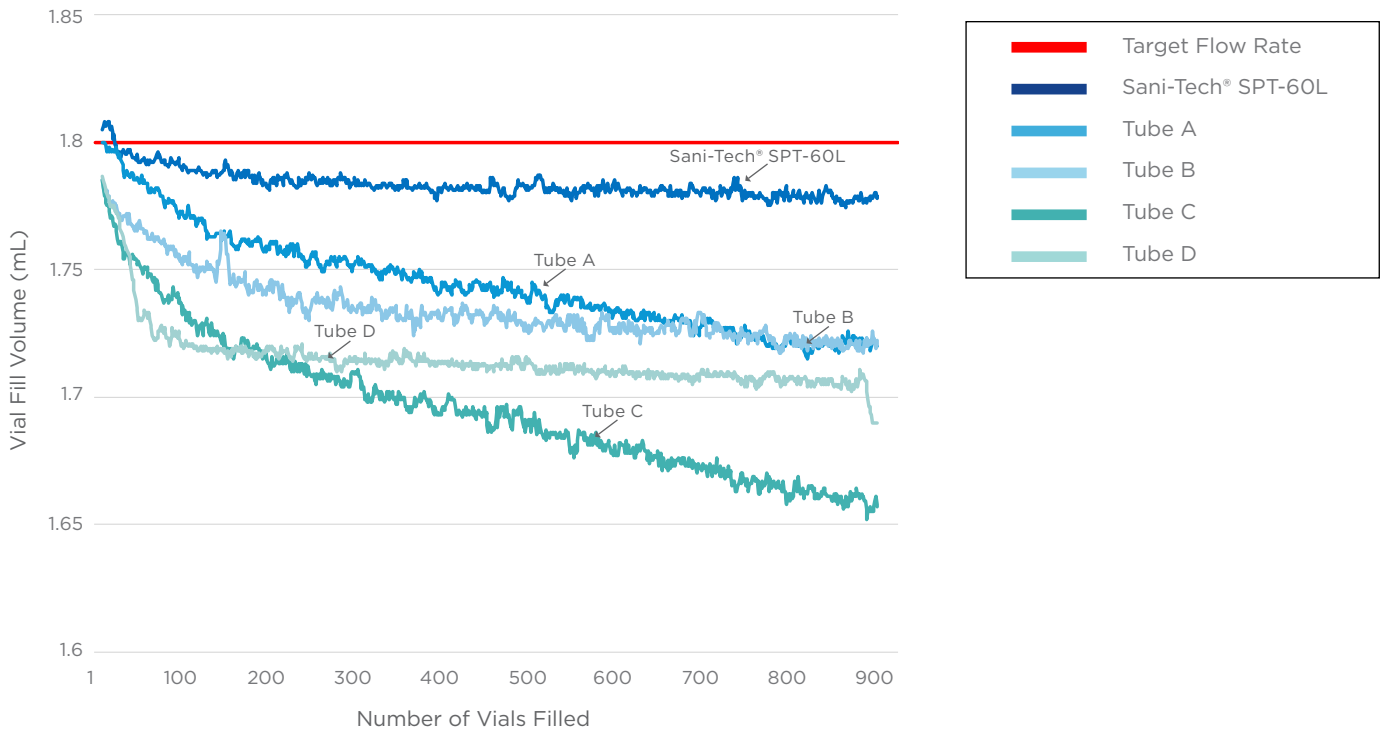
Pumping hours until tubing rupture for 1/16" x 3/16" ID x OD (1.6 x 4.8 mm) silicone tubing. A four-roller peristaltic pump head was utilized, operating at 400rpm (with no back pressure at room temperature).

Vial Fill Accuracy and Precision (Non-Irradiated Tubing)

Table 2 demonstrates the degradation in vial fill accuracy from the nominal (1.8 mL) target with the number of vial fills. Sani-Tech® SPT-60L maintains higher precision compared to competitors' tubing throughout the duration of the filling trial. (See white paper for more details.)

Table 2

10 Point Moving Average for Individual Vial Fill Readings Targeting 1.8ml

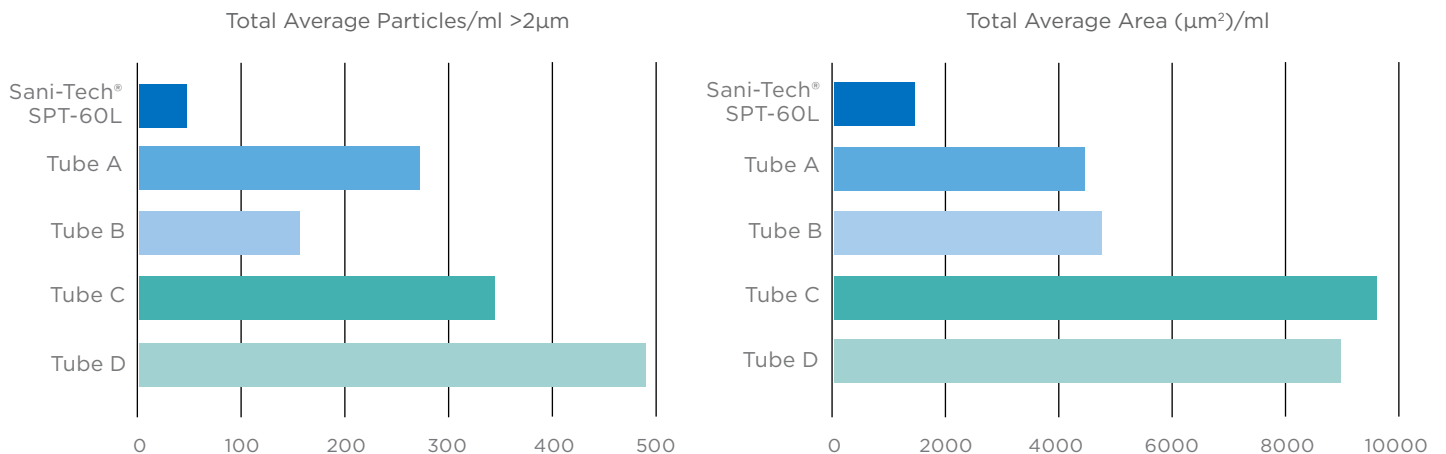


A 10 point moving average represents the trend in data. It smooths out data by averaging the first 10 data points (for example, 1-10, 2-11, 3-12, 4-13, etc.).

Spallation

Using flow-imaging microscopy, spallation within the fluid path was measured as the number of particles produced (number of particle/ml) and the relative size of the particles generated ($\mu\text{m}^2/\text{ml}$) over a number of simulated vial fills. The study was performed with Ultra-Pure water using a dual six-roller peristaltic pump, operating at 300 rpm (no back pressure at room temperature). The following table summarizes the spallation results for 1/16" x 3/16" ID x OD (1.6 x 4.8 mm) silicone tubing and represents the average sum of all particles produced after 3000 vial fills. The test was done in triplicate.

Sani-Tech® SPT-60L was tested against four final fill marketed silicone tubes and generated 50% less spallation (particles/ml) than the closest competitor.



2µm (micron) particle size was the minimum level of equipment detection.

Saint-Gobain Life Sciences – Bioprocess Solutions

Sani-Tech® SPT-60L Additional Resources:

- [Extractables Report](#)
- [Technical Dossier](#)
- [ValPlus™ Certification Available](#)

Sani-Tech® is a registered trademark.

ValPlus™ Certification

ValPlus™ provides customers with an industry first opportunity to mitigate risk and add value into their production process steps. This enhanced level of tubing validation certification offers a higher level of quality assurance in single-use fluid handling components. Saint-Gobain Life Sciences validates the fluid path of the tubing using a single, normal ANSI Level II sampling plan to meet the following standard industry requirements:

- USP <788> for Sub-visible Particulates
- USP <85> and <161> for Endotoxins
- ISO 11737-1 for Bioburden

For more information on ValPlus™, please visit www.biopharm.saint-gobain.com/valplus

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