

PharmaPure® Low Spallation Pump Tubing



PharmaPure® combines unsurpassed pump life with ultra-low particle spallation, making it the peristaltic pump tubing of choice.

PharmaPure® Flexibility

PharmaPure® is a premium, low spallation, biologically compatible peristaltic pump tubing developed especially for pharmaceutical, biotechnology, and laboratory applications. This tubing meets the demanding challenges of providing unsurpassed pump life with ultra-low particulate spallation and very low permeability.

PharmaPure® Characteristics

The superior flex life characteristics of PharmaPure® simplify the manufacturing process by reducing production downtime due to pump tubing failures.

Its excellent wear properties allow the product to provide extremely low rates of spallation as compared to silicone and other alternate materials.

Because PharmaPure® has low permeability and superior absorption characteristics, it is ideal for protecting sensitive cell cultures and for fermentation, separation, purification, process monitoring, and sterile fill applications.

Biocompatibility

PharmaPure® tubing complies fully with the requirements of USP Class VI and European Pharmacopeia 3.2.9 and FDA 21 CFR Part 177.2600 criteria, and is entirely non-cytotoxic, non-pyrogenic, and non-hemolytic.

To confirm the superior characteristics of PharmaPure® the following tests were also performed: Genotoxicity Tests, Bacteriostasis – Fungistasis Tests, Physiochemical Testing for Elastomeric Closures (USP <381>), Physiochemical Testing for Plastics (USP <661>), Total Extractables (per 21 CFR 177.2600), and full Preservative Absorption Test Protocol evaluating benzyl alcohol, phenol, meta-cresol, methyl paraben, and propyl paraben. PharmaPure® tubing has a Master File with the U.S. Food and Drug Administration.

BIOPHARMACEUTICAL PRODUCTS

High-Performance Peristaltic Pump Tubing

Features/Benefits

- Ultra-low particulate spallation
- Outlasts silicone tubing in peristaltic pumps by up to 30 times
- Provides an excellent barrier with very low permeability
- Withstands repeated autoclaving and sterilization
- Meets all USP Class VI and FDA criteria
- Custom mold and design capabilities

Typical Applications

- Cell harvest and media process systems
- Vaccine manufacturing
- Bioreactor process lines
- Sterile filling
- Diagnostic test products
- Production filtration and fermentation



PharmaPure® Tubing Inventory Sizes

Part Number	I.D. (inches)	O.D. (inches)	Wall Thickness (inches)	Length (feet)	Minimum Bend Radius (inches)	Max. Suggested Working Pressure at		Vacuum Rating In. of Mercury at	
						73°F (psi)	180°F (psi)	73°F	180°F
AL242606	1/32	5/32	1/16	25	1/2	38	23	29.9	29.9
AL242002	1/16	1/8	1/32	25	1/2	20	13	29.9	29.9
AL242003	1/16	3/16	1/16	25	1/2	27	18	29.9	29.9
AL242005	3/32	7/32	1/16	25	1/2	27	13	29.9	29.9
AL242006	1/8	3/16	1/32	25	3/4	10	8	29.9	10
AL242007	1/8	1/4	1/16	25	3/4	24	12	29.9	29.9
AL242012	3/16	5/16	1/16	25	3/4	20	10	29.9	25
AL242017	1/4	3/8	1/16	25	1-1/4	15	7	29.9	15
AL242019	1/4	1/2	1/8	25	1-1/4	26	13	29.9	29.9
AL242022	5/16	7/16	1/16	25	1-1/2	13	7	29.9	10
AL242027	3/8	1/2	1/16	25	1-3/4	10	6	15	5
AL242029	3/8	5/8	1/8	25	1-1/2	19	10	29.9	29.9
AL242038	1/2	3/4	1/8	25	2-1/2	15	7	29.9	20
AL242046	5/8	7/8	1/8	25	2-3/4	12	6	25	10
AL242053	3/4	1	1/8	25	3-3/4	10	4	15	5

*Working pressures are calculated at a 1.5 ratio relative to burst pressure using ASTM D1599.

Product Characteristics

Opacity	Opaque
FDA Approved for Food Contact	Yes
USP Class VI	Yes
Sterilization	Autoclavable/Gas/Radiation*

*Okay at 2.5 MRad (25 kilogray)

Typical Physical Properties

Property	ASTM Method	Value or Rating
Durometer Hardness Shore A, 15 Sec.	D2240-00	65
Tensile Strength, psi (MPa)	D412-98	700 (4.8)
Ultimate Elongation, %	D412-98	400
Tensile Stress @ 100% psi (MPa)	D412-98	375 (2.6)
Tensile Set % @ 75% of Ultimate Elongation	D412-98	38
Color	—	Off White
Tear Resistance, lb-f/inch (kN/m)	D1004-94	110 (19.3)
Compression Set	D395-98	36
Constant Deflection, % @ 158°F (70°C) for 22 hours	Method B	
Specific Gravity	D792-00	0.92
Water Absorption, %, 24 hours @ 73°F (23°C)	D570-98	0.04
Brittle Temperature, °F (°C)	D746-98	-89 (-67)
Low Temperature Flexibility @ -40°F (-40°C)	D380-94	Passed (Still Flexible)
Flame Resistance Classification	UL 94-HB	Passed
Maximum Recommended Operating Temp., °F (°C)	—	275 (135)
Dielectric Strength, v/mil (kV/mm)	D149-97a	567 (22.3)

Unless otherwise noted, all tests were conducted at room temperature (73°F). Values shown were determined on 0.075" thick extruded strip or 0.075" thick molded ASTM plaques or molded ASTM durometer buttons.

PHARMAPURE® TUBING IS NOT INTENDED FOR USE AS AN IMPLANT MATERIAL

PharmaPure® is a registered trademark.

BIOPHARMACEUTICAL PRODUCTS

Come through clean.™

Saint-Gobain Performance Plastics

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IMPORTANT: It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics tubing for all intended uses. Laboratory and clinical tests must be conducted in accordance with applicable regulatory requirements in order to determine the safety and effectiveness for use of tubing in any particular application.

For a period of 6 months from the date of first sale, Saint-Gobain Performance Plastics Corporation warrants this product to be free from defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price thereof. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse, or inability to use, this product. THIS WARRANTY IS IN LIEU OF THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. No deviation is authorized.

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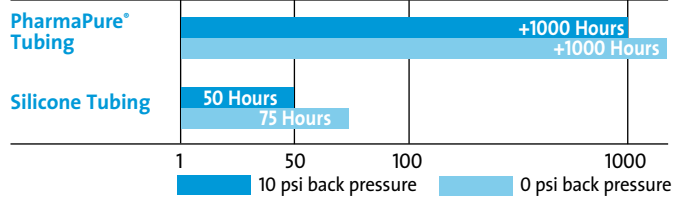
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Comparative Peristaltic Pump Tubing Life

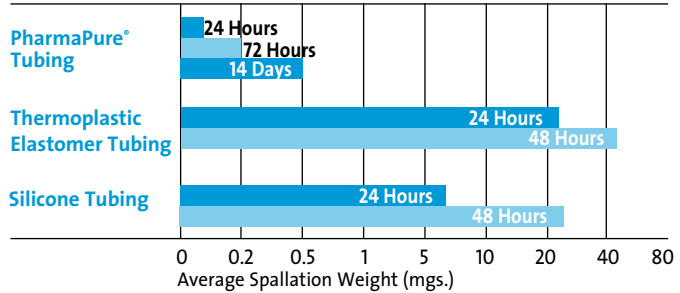
The table below depicts hours until failure of 1/4" ID x 3/8" OD tubing. In each case, a 3-roller pump head was utilized operating at 600 RPM under room temperature (73°F). Tubing failure is measured in hours of use prior to rupture.



The performance of tubing in peristaltic pumping applications is affected by the conditions of use and equipment utilized, along with size and wall thickness of the tubing tested. The data above is presented for information only and should not be utilized for specification purposes.

Spallation Rate Tubing Comparison

The following test data summarizes the spallation results of select tubing used in a peristaltic pump. In each case 1/4" ID tubing was used in a 3-roller pump head operating at 600 RPM under room temperature (73°F). Results from a minimum of 5 samples were averaged to obtain values.



Relative Chemical Resistance Properties

Acids			Bases			Salts	Alcohols	Ketones
conc.	med.	weak	conc.	med.	weak			
U	F	F	F	E	E	E	F	U

E = Excellent F = Fair U = Unsatisfactory

*All tests conducted at room temperatures.

