

DOW CORNING® Pharma Tubing

FEATURES

- Excellent flexibility
- Low extractables
- Contains no peroxide by-products, chlorophenyls or PCBs
- No organic plasticizers, phthalates or latex additives
- Easily sterilized
- Available in three durometers to match performance requirements
- Stable over a wide temperature range
- High resiliency
- No imparted taste or odor
- Non-wetting (hydrophobic) surface
- Made from SILASTIC® BioMedical Grade elastomer that exceeds United States Pharmacopeia (USP®) Class VI Plastics Test requirements
- Meets European Pharmacopoeia monograph 3.1.9. "Silicone elastomer for closures and tubing"
- Manufactured to the principles of FDA 21 CFR 210/211 cGMPs for Pharmaceutical products
- Produced in an FDA-registered (CFN 1816403) and inspected healthcare facility

BENEFITS

- Reduces risk of contaminating ultra-pure liquids
- Complete traceability
- Consistent performance
- Rigorous change control

COMPOSITION

- Platinum-cured silicone tubing

Pharmaceutical grade silicone tubing for transferring of ultra-pure liquids, air or steam in pharmaceutical and biotechnological manufacturing processes

APPLICATION

- DOW CORNING Pharma Tubing is designed for applications that require the transfer of high purity fluids where contamination is a concern.

TYPICAL PROPERTIES

Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales representative or your global Dow Corning connection prior to writing specifications on this product.

CTM*	ASTM*	Test	Unit	Value		
				Pharma-50 ¹	Pharma-65 ²	Pharma-80 ³
0099	D2240	Durometer hardness, shore A ⁴		50	65	80
0137A	D412	Tensile strength at break, die D ⁵	MPa psi	8.7 1265	6.8 990	7.0 1025
0137A	D412	Elongation at break, die D ⁵	%	795	775	570
0137A	D412	Modulus at 200%, die D ⁵	MPa psi	2.1 310	2.8 415	3.9 570
0159A	D624	Tear strength, die B ⁴	kN/m ppi	47.3 270	45.5 260	42 240

1. 9.53mm x 15.875mm (ID x OD; 0.375" x 0.625").
2. 3.35mm x 4.65mm (ID x OD; 0.132" x 0.183").
3. 1.63 mm x 2.21 mm (ID x OD; 0.064" x 0.087").

4. Typical properties for the elastomer.
5. Typical properties of the extruded tubing.

* CTM: Corporate Test Method, copies of CTMs are available on request.

* ASTM: American Society for Testing and Materials.

DESCRIPTION

DOW CORNING Pharma Tubing is a translucent silicone tubing made from tear-resistant SILASTIC® brand BioMedical Grade platinum-cured elastomer. It is designed for use in pharmaceutical and biotechnological manufacturing processes.

DOW CORNING Pharma Tubing is available in three durometers (hardnesses) to meet burst or processing requirements:

- 50 Shore A: Medium
- 65 Shore A: Medium-High
- 80 Shore A: High

For more demanding applications, the increased hardness of DOW CORNING® Pharma-65 and Pharma-80 Tubing offers greater pressure and kink resistance.

MANUFACTURING ENVIRONMENT

DOW CORNING Pharma Tubing is manufactured under quality control guidelines. The Healthcare Industries Materials Site in Hemlock, Michigan, is dedicated to the production of silicone materials for healthcare applications. It is registered with the U.S. Food and Drug Administration (FDA) as a Drug Establishment (CFN 1816403). The site quality system is based on principles of current Good Manufacturing Practices for both Bulk Pharmaceutical Products and Medical Devices. The site is ISO 9001-registered.

QUALITY ASSURANCE

Dow Corning manufactures DOW CORNING Pharma Tubing in a totally integrated process from raw materials to the final extruded tubing. The tubing is manufactured in an ISO registered facility, requiring appropriate documentation and traceability. Critical properties are controlled all along the complete manufacturing process, to provide quality of the raw materials, the elastomer, and the finished tubing.

STERILIZATION CONSIDERATIONS

It is the user's responsibility to validate a sterilization process for silicone tubing. The user should conduct testing if sterilization conditions vary and/or if minor property changes could affect application performance. Common sterilization procedures include:

Autoclave (Steam Sterilization)

Silicone tubing can be effectively sterilized by steam in an autoclave. Silicone materials are more difficult to heat than materials such as thermoplastics because they have thermal insulating properties. Steam sterilization has been accomplished in a standard gravity steam sterilization cycle (30 minutes at 1 bar /15 psi and 121°C/250°F) and in a high-speed flash steam sterilization cycle (15 minutes at 2 bar/30 psi and 132°C/270°F).

Gamma Radiation Sterilization

Gamma radiation studies of the effects on the physical properties of the silicone elastomer used to produce DOW CORNING Pharma Tubing have shown that doses of radiation up to 2.5 Mrad (25kGy) do not adversely affect durometer, elongation, modulus, tensile or tear strength. Repeated gamma sterilization or processing at higher doses of radiation and for longer dosing periods may change some of the physical properties of the elastomer.

Ethylene Oxide Sterilization

Ethylene oxide (ETO) has been used to sterilize silicone tubing with no degradation of physical properties. Sterilization by this method is only recommended if procedures allow sufficient time for complete out-gassing of residual ETO and ETO by-products.

REGULATORY STATUS

DOW CORNING Pharma Tubing is manufactured using SILASTIC BioMedical Grade silicone elastomer that meet or exceed the test requirements of USP Class VI Plastics <87> and <88>.

DOW CORNING Pharma Tubing meets the requirements of 21 CFR 177.2600 and USP <661> (Physico-chemical Tests - Plastics), and its elastomer stock complies with selected 3-A Sanitary Standards. The tubing meets the requirements of European Pharmacopoeia (Ph. Eur. or "EP") 3.1.9. "Silicone elastomer for closures and tubing."

To support use in validated processes, contact Dow Corning to obtain a Qualifications Guide for Dow Corning Pharma Tubing. This manual summarizes key tubing performance and regulatory data.

USABLE LIFE AND STORAGE

When stored in the original unopened containers, DOW CORNING Pharma Tubing has a usable life of 36 months from the date of production.

TUBING SIZE CAPABILITIES AND PACKAGING

To serve our customers better, we can provide DOW CORNING Pharma Tubing in a variety of dimensions, including the most commonly used sizes shown in Table 1. Standard package is a 15-meter (50 foot) coil, double bagged in separately sealed polyethylene bags contained in a cardboard box.

SPECIAL NEEDS

Dow Corning has the capabilities to customize products to your specifications. Customization includes sizes, tolerances, cut lengths, bulk packaging and spooling. For easy identification, DOW CORNING Pharma Tubing is also available marked with product name and size. Please contact your Dow Corning representative to discuss your specific requirements.

LIMITATIONS

This product has not been tested or approved for any hospital or patient care use such as for temporary insertion or any in vivo procedures.

This product is not to be used in human implantation, or human contraceptive, reproductive, obstetrical or gynecological applications. The user shall hold Dow Corning harmless from any and all damages resulting from use of this product. It is the sole responsibility of the user to determine the safety and efficacy of this product for any specific use.

ORDERING

DOW CORNING Pharma Tubing is available direct from Dow Corning or through many pharmaceutical or laboratory distributors. For order information or to discuss specific requirements, please contact Dow Corning at 1-800-248-2481 (USA) or +44-(0)1676-528000 (Europe & Middle East) or consult www.dowcorning.com.

HEALTH AND ENVIRONMENTAL INFORMATION

To support Customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance (PS&RC) specialists available in each area.

For further information, please see our website, www.dowcorning.com or consult your local Dow Corning representative.

LIMITED WARRANTY INFORMATION - PLEASE READ CAREFULLY

The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customers' tests to ensure that Dow Corning's products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

Dow Corning's sole warranty is that the product will meet the Dow Corning sales specifications in effect at the time of shipment.

Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.

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Table 1: Common tubing product sizes. Capability exists for these and many other sizes.

Imperial (inches)			Metric (mm)		
<i>Inside diameter</i>	<i>Outside diameter</i>	<i>Wall</i>	<i>Inside diameter</i>	<i>Outside diameter</i>	<i>Wall</i>
0.125	0.250	0.063	3.175	6.350	1.588
0.188	0.313	0.063	4.775	7.950	1.588
0.188	0.375	0.094	4.775	9.525	2.375
0.250	0.375	0.063	6.350	9.525	1.588
0.250	0.438	0.094	6.350	11.113	2.381
0.250	0.500	0.125	6.350	12.700	3.175
0.313	0.500	0.094	7.950	12.700	2.375
0.375	0.500	0.063	9.525	12.700	1.588
0.375	0.563	0.094	9.525	14.300	2.388
0.375	0.625	0.125	9.525	15.875	3.175
0.500	0.688	0.094	12.700	17.463	2.381
0.500	0.750	0.125	12.700	19.050	3.175
0.625	0.875	0.125	15.875	22.225	3.175
0.750	1.000	0.125	19.050	25.400	3.175

Table 2: Burst Properties.

Values stated are typical values only and are not intended for writing specifications. The user is responsible for validating the suitability of DOW CORNING Pharma Tubing for their process.

Imperial (inches)		Metric (mm)		Burst pressure ¹		
<i>Inside diameter</i>	<i>Outside diameter</i>	<i>Inside diameter</i>	<i>Outside diameter</i>	<i>Pharma-50 psi (bar)</i>	<i>Pharma-65 psi (bar)</i>	<i>Pharma-80 psi (bar)</i>
0.125	0.250	3.175	6.350	80 (5.5)	123 (8.5)	191 (13.2)
0.188	0.375	4.775	9.525	101 (7.0)	157 (10.8)	246 (17.0)
0.250	0.500	6.350	12.700	85 (5.9)	147 (10.1)	254 (17.5)
0.375	0.625	9.525	15.875	59 (4.1)	112 (7.7)	192 (13.2)
0.500	0.750	12.700	19.050	48 (3.3)	90 (6.2)	147 (10.1)
0.625	0.875	15.875	22.225	37 (2.6)	67 (4.6)	123 (8.5)
0.750	1.000	19.050	25.400	33 (2.3)	63 (4.3)	107 (7.4)

1. Test method described in Dow Corning Form 52-1047-01, Burst Strength Testing of DOW CORNING Pharma Tubings.