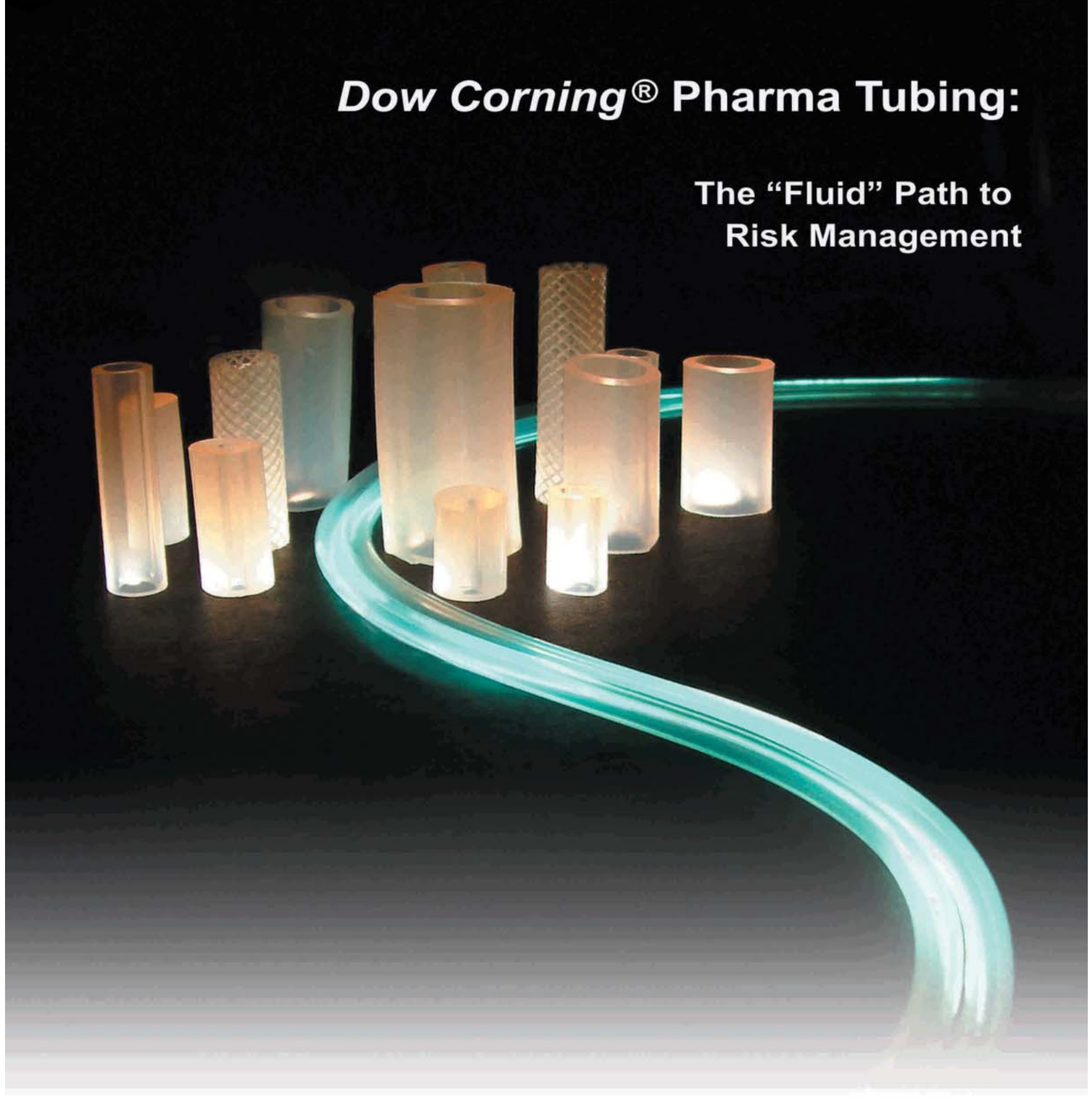
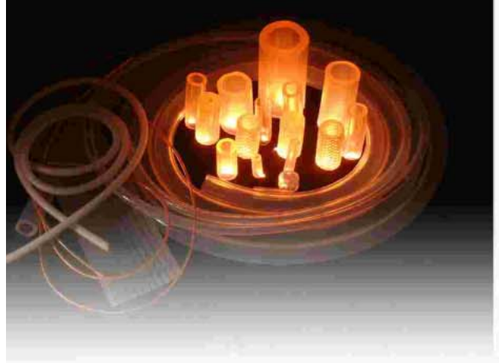


Healthcare
Solutions

DOW CORNING



How Much Risk Are You Willing to Take?

What if… your product becomes contaminated during processing and you need to identify the source of contamination?

What if… a product made with one batch of tubing yields different results than another batch?

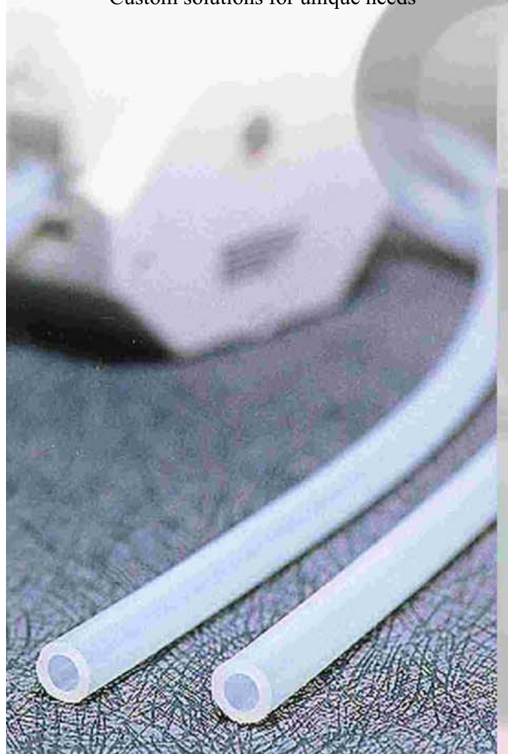
What if… the FDA challenges you about the qualification and validation of your tubing during an audit?

Dow Corning® Pharma Tubing can help you avoid these potential "road blocks" with ease.

Avoid Unnecessary Detours

Dow Corning Pharma Tubing was developed specifically to meet the stringent performance and regulatory requirements of pharmaceutical and biotech applications.

- High purity BioMedical Grade platinum-catalyzed silicone
- Strict contamination control in manufacturing facilities dedicated to healthcare products
- Unparalleled change control resulting from a vertically-integrated supply chain
- Expert technical and regulatory support to accelerate your process validation
- Global supply of products and services
- Custom solutions for unique needs

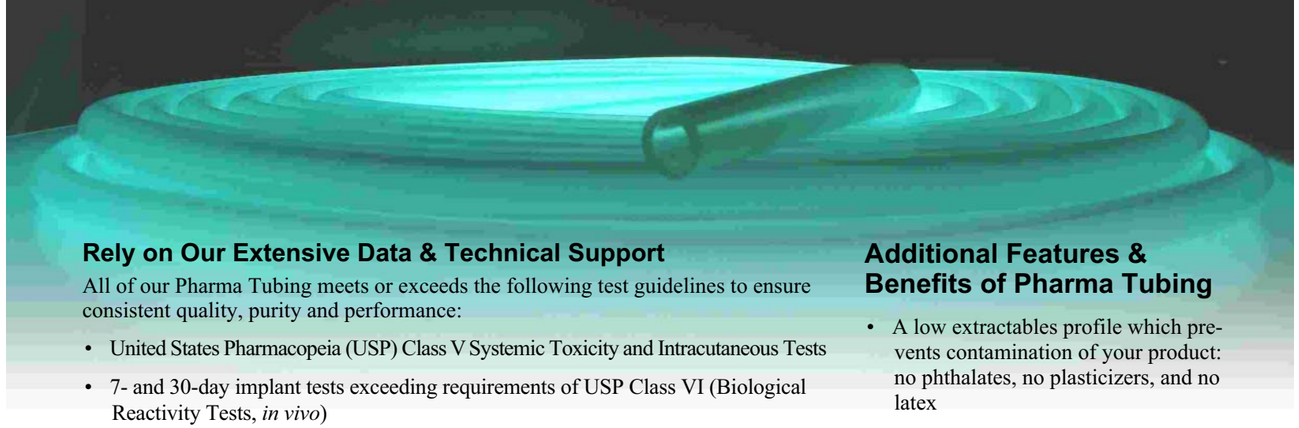


Trace the Path of Dow Corning Pharma Tubing

It's important to know about the manufacturing process that's used to make your tubing, especially at audit time. Dow Corning's unique vertically-integrated supply chain allows every step of the Pharma Tubing manufacturing process to be accounted for – from silicon metal to silicone tubing. With integration of manufacturing from raw materials to final product, changes at any step can be identified, evaluated and controlled.

Dow Corning Pharma Tubing is available to meet your specific performance needs:

- Pharma 50 – for standard tubing transfer and filling operations
- Pharma 65 and 80 – cost-effective alternatives to reinforced tubing in many applications
- Pharma Advanced Pump Tubing – for longer life in peristaltic pump applications
- Pharma Reinforced Tubing – where especially high or low pressure-resistance is required



Rely on Our Extensive Data & Technical Support

All of our Pharma Tubing meets or exceeds the following test guidelines to ensure consistent quality, purity and performance:

- United States Pharmacopeia (USP) Class V Systemic Toxicity and Intracutaneous Tests
- 7- and 30-day implant tests exceeding requirements of USP Class VI (Biological Reactivity Tests, *in vivo*)
- FDA Food Grade (21 CFR 177.2600)
- European Pharmacopoeia 3.1.9.
  (Silicone elastomer for closures and tubing)
- Japanese Pharmacopoeia
  (Section 11: Plastic Containers for Pharmaceutical Products)
- USP‹661›(Physiochemical Tests – Plastics)

In addition, Dow Corning Pharma Tubing has been qualified per USP‹381›(Elastomer Closures for Injection – Physiochemical Test Procedures); it also fulfills the requirements of selected Sanitary 3-A standards, and it may be used in compliance with ANSI/NSF Standard 51.

Datasheets can be found at www.dowcorning.com/healthcare, and Qualification Data Summaries are available upon request. We have also developed special literature to answer your questions on burst performance, pharmaceutical GMPs, and extractables. Our team of regulatory and technical professionals can address any product concerns you may have and provide you with complete technical and validation support.

Additional Features & Benefits of Pharma Tubing

- A low extractables profile which prevents contamination of your product: no phthalates, no plasticizers, and no latex
- A hydrophobic surface – to cut fluid loss
- Smooth inner bore
- Stability over a wide range of conditions – suitable for diverse applications
- Available in many standard sizes and formats, including double-bagged, in coils or on spools
- Customizable marking, packaging, length, shapes, sizes, and tolerances – which can be specially designed for your process needs
- Easily sterilized

Pharma Tubing Properties*

Size ID x OD		Pharma 50				Pharma 65				Pharma 80				Advanced Pump			
		Burst[1]		Vacuum**		Burst		Vacuum		Burst		Vacuum		Burst		Vacuum	
inches	mm	psi	bar	in Hg	mm Hg	psi	bar	in Hg	mm Hg	psi	bar	in Hg	mm Hg	psi	bar	in Hg	mm Hg
0.125 x 0.250	3.175 x 6.350	80	5.5	29.2	741	123	8.5	29.2	742	191	13.2	29.0	735	79	5.4	29.3	743
0.188 x 0.375	4.775 x 9.525	101	7.0	29.2	741	157	10.8	29.5	749	246	17.0	28.8	732	69	4.8	29.1	739
0.250 x 0.500	6.350 x 12.700	85	5.9	28.8	732	147	10.1	28.7	728	254	17.5	29.1	739	75	5.2	29.3	744
0.375 x 0.625	9.525 x 15.875	59	4.1	29.5	750	112	7.7	29.0	737	192	13.2	29.3	744	50	3.4	29.3	743
0.500 x 0.750	12.700 x 19.050	48	3.3	15.1[a]	384	90	6.2	28.0[b]	712	147	10.1	28.5	724	37	2.6	17.4[a]	441
0.625 x 0.875	15.875 x 22.225	37	2.6	8.6[a]	218	67	4.6	26.6[b]	649	123	8.5	29.7	754	33	2.3	12.1[a]	309
0.750 x 1.000	19.050 x 25.400	33	2.3	9.3[a]	236	63	4.3	13.7[a]	349	107	7.4	23.2[a]	590	24	1.7	7.9[a]	201

Pharma Reinforced Tubing Properties*

Size (ID x OD)		Burst[1]		Vacuum**	
inches	mm	psi	bar	in Hg	bar
0.125 x 0.365	3.175 x 9.271	893	61.6	28.7	729
0.187 x 0.447	4.749 x 11.353	787	54.3	29.4	746
0.250 x 0.520	6.350 x 13.208	837	57.7	29.6	753
0.312 x 0.592	7.924 x 15.036	629	43.4	29.7	754
0.375 x 0.655	9.525 x 16.637	597	41.2	29.6	752
0.500 x 0.800	12.700 x 20.320	546	37.7	29.1	738
0.625 x 0.965	15.875 x 24.511	470	32.4	29.6	752
0.750 x 1.100	19.050 x 27.940	310	21.4	29.3	744
0.875 x 1.235	22.225 x 31.369	308	21.2	29.2[b]	741
1.000 x 1.360	25.400 x 34.544	208	14.3	23.5[c]	597

[1] Methods described in Dow Corning form 52-1047-01, "Burst Strength Testing for DOW CORNING® brand Pharma Tubings."

* Values stated are typical values only and are not intended for writing specifications.

** Experiments performed at 22-23°C, 31-71% RH. Data are the results of at least three replicates (different pieces of tubing). Unless noted, value given is the maximum vacuum the pump could pull for tubing samples that did not deform or collapse.

[a] Tubing collapsed completely at this pressure, although it began to deform at a lower reading.

[b] Some of this tubing collapses, and some resists the maximum pull. Value given is the average of maximum readings and readings at collapse. When tubing did not collapse, readings maintained for at least 10 min.

[c] Tubing did not collapse, but did deform.

Production Facility

Dow Corning is ISO-registered and is the global leader in silicone technology. Our FDA-registered Healthcare Industries Materials Site is dedicated to the production of silicone materials for the medical device and pharmaceutical markets, and has over 30 years of extrusion experience. Our in-house lab routinely performs qualification assays on elastomer and tubing, and can also provide specialized testing services as needed, such as batch-to-batch EP testing.

During the manufacturing process, strict contamination control policies are followed in accordance with appropriate principles of GMPs to ensure consistent product purity and quality. Frequent monitoring of air, critical surfaces and equipment verifies compliance to these policies.

- Microbial air analysis includes aerobic, yeast and mold organisms with guidelines of <5.7 CFU/ft^3 of air.
- Criteria for airborne particulate concentrations comply with Classification 9 per ISO 14644-1.
- Surface monitoring is performed using RODAC (Replicate Organism Detection and Counting) agar plates with guidelines of <10 CFU/cm^2.

Contamination control, batch traceability and change control all converge to one point: improved risk management. Clearly, for the pharmaceutical and biotechnology industries, Dow Corning Pharma Tubing is the best path to follow.

For More Information:

Contact your Dow Corning representative, or visit www.dowcorning.com/healthcare.

Dow Corning has sales offices, manufacturing sites, as well as science and technology laboratories around the globe. Telephone numbers of locations near you are available at www.dowcorning.com.

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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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