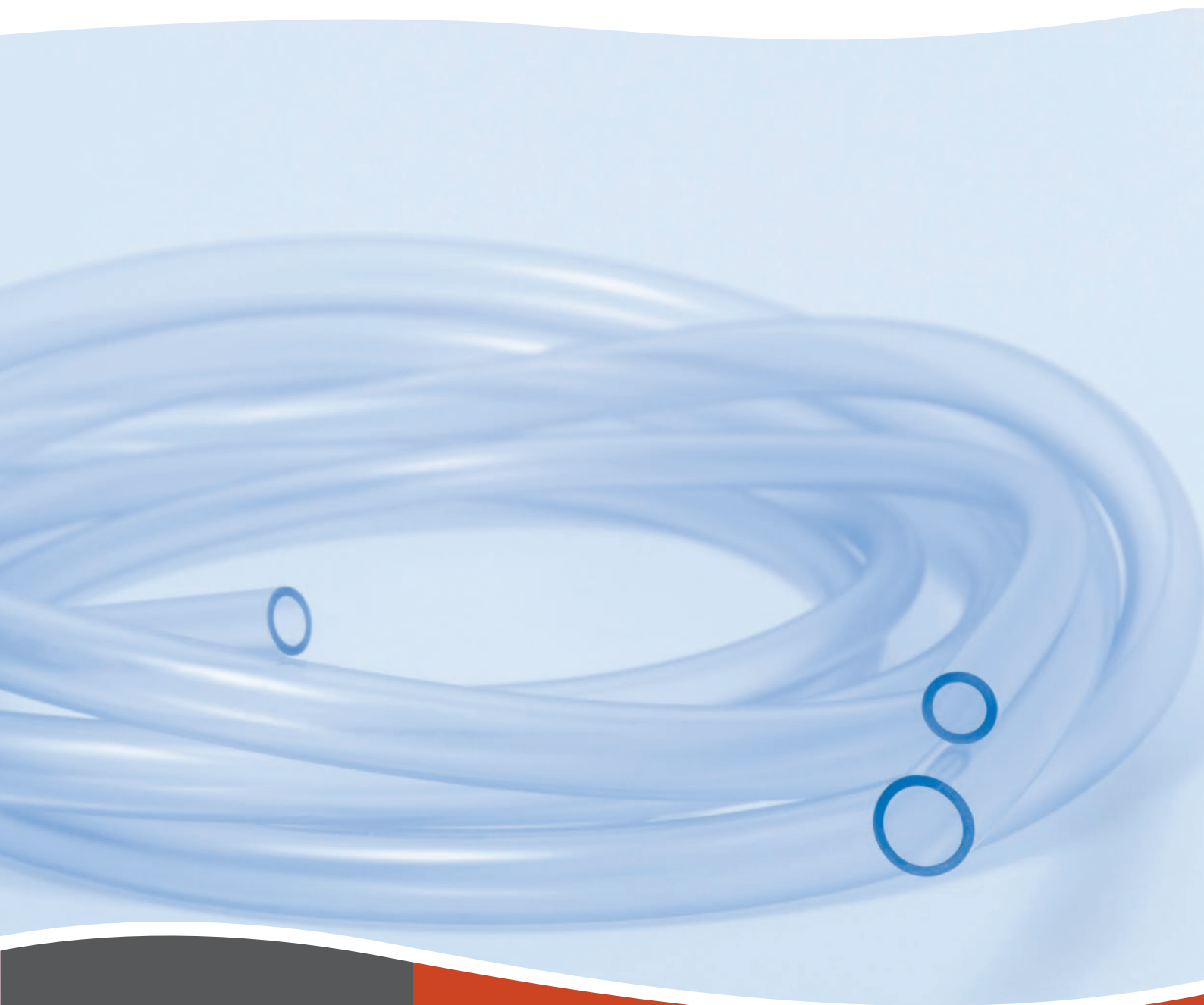




Technology and Production
Production Site
Properties
Silicone Tubing Offering
Quality
Purity
Regulatory
Performance Testing
Stability to Sterilisation

Silicone Tubing

Dow Corning™ Silicone Tubing



Dow is a unique tubing supplier with over 50 years of extrusion and healthcare experience. Dow provides the expertise, support and comprehensive services needed to address today's Pharmaceutical and Medical Device challenges. In combination with full lot traceability, change control, reliability and a stable quality a unique selling proposition has been established in the market.

Dow Corning™ Silicone Tubing are thoroughly qualified, including compliance with European Pharmacopoeia 3.1.9, USP Class VI, Japanese Pharmacopoeia and other standards which makes them specially suitable for BioPharma Processing and Medical Device applications. They are fully traceable and comprehensively documented, substantially reducing the risk of contamination.

Technology and Production

Dow Corning™ platinum-cured Silicone Tubing are made of Silastic™ BioMedical Grade elastomer which is recognised for its high purity.

These high consistency silicone rubbers are available as two-part products which are mixed at the point of use, for example using a two-roll mill, before extrusion at room temperature followed by continuous curing in high temperature ovens.

Different dies and mandrels are used to produce single lumen tubing of various size and wall thickness (defined by their outside diameter/inside diameter, with specific tolerances).

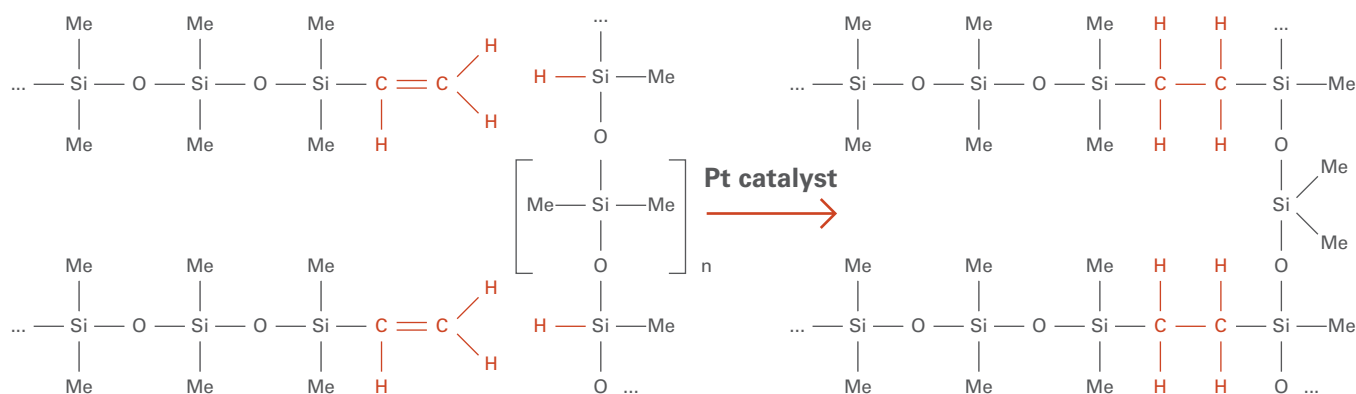
Production Site (HIMS)

- FDA 21CFR 210/211 cGMP
- ISO 9001:2008 certified
- ISO 14001:2004 certified
- Production equipment dedicated solely to healthcare products
- Strictly controlled and monitored clean environment, class 9

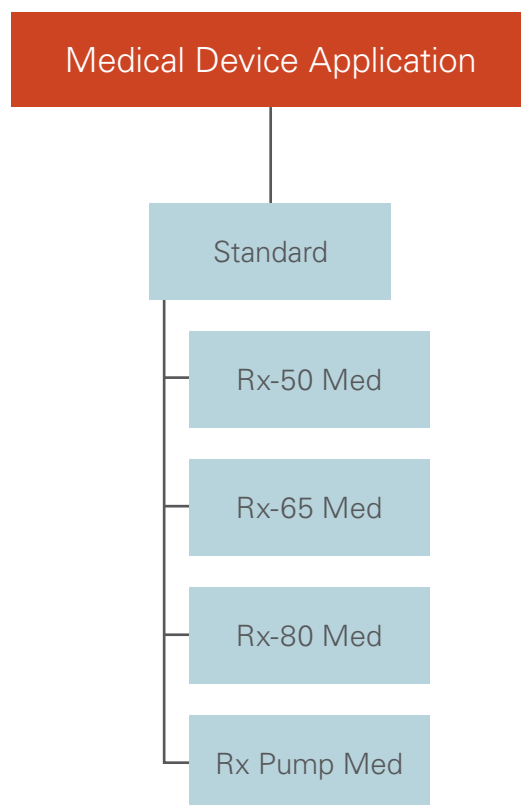
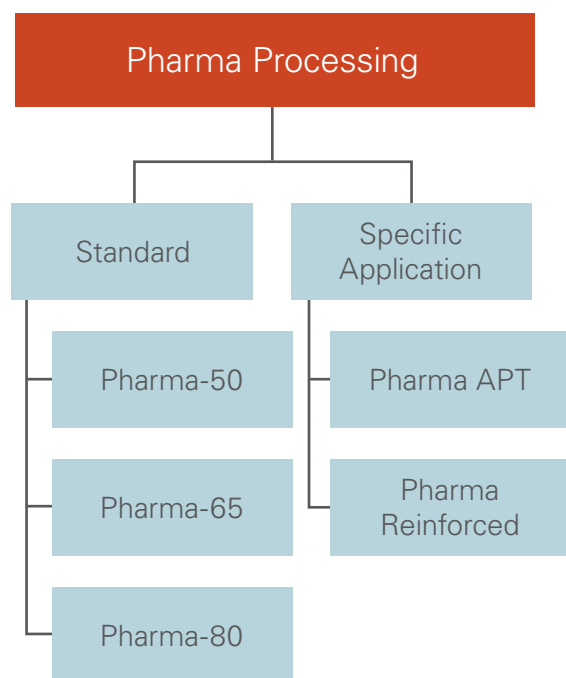
Tubing extrusion floor will be classified as ISO 7 manufacturing environment in 2019

Properties

- Biocompatible
- Non-reactive
- Hydrophobic and smooth surface
- Thermally and chemically stable
- UV stable
- High flexibility without plasticisers
- Kink-resistant



Silicone Tubing Offering



Product	Description	Special Features	Application
Dow Corning™ Pharma Tubing	Durometers 50, 65, 80 Shore A Shelf life: 5 years	Pharma 80 Tubing: Durometer unique in the market Cost effective alternative to Reinforced Tubing for moderate to high pressure or vacuum applications, highest kink resistance.	• Ultra-pure fluid transfer • Steam or gas transfer • BioPharma processing • Filling and packaging systems • Drug production
Dow Corning™ Pharma Advanced Pump Tubing	Durometer 50 Shore A Shelf life: 3 years (extension to 5 years in 2018)	Outstanding performance in peristaltic pumps: • Reduced particle generation during pumping/squeezing • Increased pump life by 4-6 times compared to Pharma 50 Tubing	• Ultra-pure fluid transport • Filling and packaging systems • Peristaltic pumps
Dow Corning™ Pharma Reinforced Tubing	Durometer 65 Shore A Shelf life: 3 years	Reinforced with polyester fibers (Dacron® braid) Improved kink, high pressure, and vacuum resistance	• Ultra-pure fluid transfer • Steam or gas transfer • Filling machines • High pressure or high vacuum applications
Silastic™ RX Medical Grade Tubing	Durometers 50, 65, 80 Shore A Shelf life: 3 years	Radiopaque options available	• Medical devices • Infusion therapy • Medical catheters • Pharmaceutical instruments
Silastic™ RX Pump Medical Grade Tubing	Durometer 50 Shore A Shelf life: 3 years		• Medical devices • Infusion therapy • Medical catheters

Quality

- Dow owns its entire supply chain, from chemical building blocks to finished tubing
- Unparalleled change control resulting from a vertically-integrated supply chain
- Traceability at every step of the manufacturing process
- Production equipment dedicated solely to healthcare products
- Strict contamination control
- Elastomer produced under principles of pharmaceutical GMPs, in an FDA-registered facility

Purity

Dow Silicones Corporation has developed its own set of comprehensive testing protocols and aligned to industry standards to ensure its solutions meet the highest reliability. Their latest testing package includes:

Endotoxins: All Dow Corning™ brand Pharma Tubing is tested according to USP <85> and passes stringent acceptance criteria of <0.125 EU/ml.

Particulates: The particulate count for the Dow Corning™ brand Pharma Tubing products are well below the USP <788> criteria for Microscopic Particle Count Test.

Bioburden: Further to test following ISO 11737-1 (Sterilisation of medical devices, microbiological methods - Part 1: Determination of a population of micro-organisms on products), no bioburden of any kind (aerobic bacteria, yeast, mold and/or spores) was detected in any of the Dow Corning™ Pharma Tubing products.

Extractables: Extractables testing information is important for the implementation of the single-use components and systems and for risk assessment of the potential impact on drug substances and drug products. The extractables testing packages between suppliers are not consistent and incomplete. For this reason, the BioPhorum Operations Group (BPOG) developed a standardised protocol for generating extractables data that would meet the end users requirements and simplify/reduce the implementation time. To meet the end users' requirements in accessing reliable and consistent data for faster implementation of the tubing component, Dow Silicones Corporation has conducted a comprehensive BPOG study.

Regulatory

Pharma Tubing	Pharma APT	Pharma Reinforced Tubing	RX Medical Grade Tubing	RX Pump Tubing
Compliance with: • EP 3.1.9 Silicone Elastomers for Closures & Tubing • USP <661> Physicochemical tests - Plastics • FDA 21 CFR 177.2600 Rubber articles intended for repeated use • JP XIV Section 11 - Plastic Containers for Pharmaceutical Products • ISO 11737-Part 1 Bioburden • USP <788> Particulate Matter in Injections • USP <88> Class VI (Biological reactivity tests, in vivo) • USP <85> Bacterial Endotoxins • USP <151> Pyrogen test • ISO 10993-3 Tests for genotoxicity, carcinogenicity and reproductive toxicity • ISO 10993-4 Selection of tests for interactions with blood (related to hemolysis) • ISO 10993-5 Tests for in vitro cytotoxicity (equivalent to USP <87> Biological reactivity tests, in vitro) • ISO 10993-6 Tests for local effects after implantation • ISO 10993-10 Tests for irritation and skin sensitisation • ISO 10993-11 Tests for systemic toxicity				• USP <85> Bacterial Endotoxins
			• ISO 10993 guidelines for body contact applications • Exceeds USP Class VI Plastic Tests (90 day Implant test) • Ph.Eur. 3.1.9 (Silicone Elastomer for Closures and Tubing)	

Performance Testing

Burst testing gives the maximum pressure measured a tubing can withstand before breakage (using water). Vacuum resistance testing gives the pressure minimum a tubing can withstand without collapse/deformation.

Pharma Tubing Properties*

Tubing Size (ID x OD)	Dow Corning™ Pharma-50 Tubing				Dow Corning™ Pharma-65 Tubing				Dow Corning™ Pharma-80 Tubing				Dow Corning™ Advanced Pump Tubing			
	Burst ¹		Vacuum ^{**}		Burst ¹		Vacuum ^{**}		Burst ¹		Vacuum ^{**}		Burst ¹		Vacuum ^{**}	
mm	psi	MPa	in Hg	kPa	psi	MPa	in Hg	kPa	psi	MPa	in Hg	kPa	psi	MPa	in Hg	kPa
3.18 x 6.35	80	0.55	29.2	96.9	123	0.85	29.2	98.9	191	1.32	29.0	98.2	79	0.54	29.3	99.2
4.78 x 9.53	101	0.70	29.2	96.9	157	1.08	29.5	99.9	246	1.70	28.8	97.5	69	0.48	29.1	96.6
6.35 x 12.70	85	0.59	28.8	97.5	147	1.01	28.7	97.2	254	1.75	29.1	95.6	75	0.52	29.3	99.2
9.53 x 15.88	59	0.41	29.5	99.9	112	0.77	29.0	98.2	192	1.32	29.3	99.2	50	0.34	29.3	99.2
12.70 x 19.05	48	0.33	15.1 ^a	51.1	90	0.62	28.0 ^b	94.8	147	1.01	28.5	96.5	37	0.26	17.4 ^a	58.9
15.88 x 22.23	37	0.26	8.6 ^a	29.1	67	0.48	26.6 ^b	90.1	123	0.85	29.7	100.5	33	0.23	12.1 ^a	40.9
19.05 x 25.40	33	0.23	9.3 ^a	31.5	63	0.43	13.7 ^a	45.4	107	0.74	23.2 ^a	78.6	24	0.17	7.9 ^a	26.8

Pharma Reinforced Tubing Properties*

Tubing Size (ID x OD)	Dow Corning™ Pharma Reinforced Tubing			
	Burst ¹		Vacuum ^{**}	
mm	psi	MPa	in Hg	kPa
3.18 x 9.27	893	6.16	28.7	97.2
4.75 x 11.35	787	5.43	29.4	99.6
6.35 x 13.21	837	5.77	29.6	100.3
7.92 x 15.04	629	4.34	29.7	100.6
9.53 x 16.64	597	4.12	29.6	100.6
12.70 x 20.32	546	3.77	29.1	96.6
15.88 x 24.51	470	3.24	29.6	100.3
19.05 x 27.94	310	2.14	29.3	99.2

¹ Methods described in Dow Corning form number 52-1047-01, "Burst Strength Testing of Dow Corning® 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 result 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 10min.

Stability to Sterilisation

Tubing base elastomer (50 durometer platinum-catalysed) and many other Dow Corning™ Pt-cured silicone formulations have been exposed to 25 repeated flash or standard gravity autoclave cycles with no significant alteration in tensile, elongation, Shore A durometer or modulus (100% and 200%) properties. The gravity cycle was 30 min, 15 psi (1 bar), 121°C. The flash cycle was 15 min at 30 psi (2 bar) and 132°C.

The autoclave resistance of tensile, elongation, modulus and burst properties was also investigated for all Pt-cured Pharma Tubing. In general, there were no significant effects, even after 10 repeated autoclavings of 30 min on dry cycle.



Biesterfeld Spezialchemie GmbH

Ferdinandstrasse 41

20095 Hamburg

Contact Person: Nina Held

Phone: +49 40 32008-620

Fax: +49 40 32008-696

www.biesterfeld-spezialchemie.com

n.held@biesterfeld.com

Published by:

Biesterfeld Spezialchemie GmbH, Ferdinandstrasse 41, 20095 Hamburg, Deutschland,
Tel.: +49 40 32008-0, www.biesterfeld.com

Disclaimer:

Our advice, information or recommendations regarding application shall be provided to the best of our knowledge. As the actual application is beyond our scope of influence, and as the circumstances of such application are not completely foreseeable, written and verbal indications, suggestions etc. can only be provided on a non-binding basis.