

DOW CORNING® PHARMA FABRICATED TUBING ASSEMBLIES

We can help you reduce risk

For more than 65 years, Dow Corning has drawn upon the versatility and biocompatibility of silicones to help our customers develop and manufacture innovative pharmaceutical and biopharmaceutical products. Yet today's pharma and biopharma companies face a range of challenges that demand new ways of thinking—ones that help reduce the risk of contamination and improve processing efficiency. That is why we are positioned to **GO BEYOND** the ordinary with products and processes that can help, such as our *Dow Corning®* Pharma Fabricated Tubing Assemblies.

Our ultimate goal is to help you minimize risk by providing solutions to meet the stringent performance and regulatory requirements of your industry.

The facts about *Dow Corning* Pharma molded assemblies:

- ▶ Dow Corning is **engaged at every step of the process**—not just at the point of extrusion or fabrication—from synthesizing silicone to formulating the elastomer to delivering the molded assemblies that you require
- ▶ Dow Corning's supply chain is **vertically integrated**; our Pharma Fabricated Tubing Assemblies are thoroughly tested, fully traceable and comprehensively documented, substantially reducing the risk of contamination
- ▶ *Dow Corning* platinum-cured Pharma Fabricated Tubing Assemblies are made from our own *Silastic®* Medical Grade Elastomer at our **dedicated, FDA-registered** Healthcare Industries Materials Site

Molded assemblies produced to meet your specific needs

- ▶ Fully customizable: wyes, tees, cross-connections, reducers, TC ends, custom sizes, marking, packaging, lengths, shape, multi-lumen, tolerances, formulations, gamma irradiation, special testing and more
- ▶ Available in your choice of silicone tubing formulation according to your process requirements
- ▶ Produced in strictly controlled and monitored clean manufacturing environment

Extensive data and technical support

When you work with Dow Corning, you can expect dedicated support, including:

- ▶ Extensive extractables, physical properties and engineering data
- ▶ Validation and qualification support
- ▶ Regulatory expertise
- ▶ Worldwide network for technical support
- ▶ Environmental, health, and safety data and services

Dedicated FDA and ISO-registered production facility

Our FDA-registered and inspected Healthcare Industries Materials Site is dedicated to the production of silicone materials for the biopharmaceutical, pharmaceutical and medical device markets and has more than 40 years of extrusion experience. Our molded assemblies are qualified to a range of monographs that include:

- ▶ Produced from Dow Corning's USP Class VI-compliant *Silastic*[®] BioMedical Grade Elastomers
- ▶ European Pharmacopoeia 3.1.9 (Silicone Elastomer for Closures and Tubing)
- ▶ USP<661> (Physicochemical Tests – Plastics)
- ▶ USP<381> (Elastomer Closures for Injection – Physicochemical Test Procedures)
- ▶ FDA Food Grade (21 CFR 177.2600)
- ▶ Selected Sanitary 3-A standards
- ▶ Japanese Pharmacopoeia (Section 11: Plastic Containers for Pharmaceutical Products)
- ▶ ANSI/NF Standard 51

During manufacture, we follow strict contamination control policies in accordance with appropriate principles of cGMPs to ensure consistent product purity and quality. Frequent monitoring of air, critical surfaces and equipment verifies compliance to these policies.

Learn More

Dow Corning has sales offices and manufacturing sites, as well as science and technology laboratories, around the globe. Telephone numbers of locations near you are available online at www.dowcorning.com or by calling one of our primary locations listed below.

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