

***Dow Corning*[®] Pharma Fabricated Tubing Assemblies**

FEATURES & BENEFITS

- Made from *Silastic*[®] BioMedical Grade Elastomer that exceeds United States Pharmacopeia (USP) Class VI Plastics Test requirements
- Choice of different tubing types to meet specific end-use applications
- Customizable to meet specific configuration requirements
- Contains no peroxide by-products, chlorophenyls, or PCBs
- No added organic plasticizers, phthalates, or latex components
- Manufactured to principles of US FDA 21 CFR 210/211 GMPs for pharmaceutical products
- Helps reduce risk of contaminating ultra-pure fluids
- Reduces in-house assembly and setup time and costs
- Reduces cleaning costs

COMPOSITION*

- Platinum-cure silicone tubing and molded connections

Custom molded silicone assemblies designed for ultra-pure transfer applications in biopharmaceutical and pharmaceutical manufacturing processes.

APPLICATIONS

- *Dow Corning*[®] Pharma Fabricated Tubing Assemblies are designed for fluid transfer applications requiring integrated premium quality silicone tubing, molded silicone connections and customer specified components (when applicable).

TYPICAL PROPERTIES

Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

- Tubing type: Pharma-50 Tubing, Pharma-65 Tubing, Pharma-80 Tubing, and Pharma Advanced Pump Tubing
- Tubing dimensions: Inside diameter, outside diameter, wall thickness
- Connection type: Sanitary flange end, wye (Y), tee (T), reducer, union, cross, stopper
- Assembly design: Length, number of connections, connection type
- Non-silicone components such as thermoplastic connectors, filters, pinch clamps, and other customer-specified components

DESCRIPTION

Dow Corning[®] Pharma Fabricated Tubing Assemblies are produced from Dow Corning's proprietary silicone elastomers, qualified to our BioMedical Grade Elastomer standards. They are intended for biopharmaceutical, pharmaceutical, and veterinary drug manufacturing processes for the transfer of high purity liquids and gases.

Dow Corning[®] Pharma Fabricated Tubing Assemblies may be customized according to each customer's specific processing requirements.

HOW TO USE

Dow Corning[®] Pharma Fabricated Tubing Assemblies come packaged in sealed polyethylene bags. It is the user's responsibility to clean and/or sterilize the assemblies if required for their application.

CUSTOMIZATION

Dow Corning[®] Pharma Fabricated Tubing Assemblies are available in a range of make-to-order configurations.

Examples of customization include:

- Wyes
- Tees

*Applicable only to silicone components. For non-silicone components specified by customers, please refer to the appropriate supplier.

- Crosses
- Reducers
- Sanitary flange ends
- Tubing dimension (ID, OD)
- Variable tubing lengths
- Tubing formulation
- Non-silicone components such as filters and connectors
- Gamma irradiation

Contact your Dow Corning representative to discuss specific requirements.

STERILIZATION CONSIDERATIONS

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

Gamma Radiation Sterilization

Gamma irradiation studies on *Dow Corning*[®] Pharma Tubing products have shown that doses of gamma irradiation up to 5 Mrad (50 kGy) minimally affect the physical properties (durometer, elongation, modulus, tensile, tear strength) and extractables profile of the tubing.

Autoclave (steam) sterilization

Silicone products 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 of silicone tubing has been accomplished in a standard gravity 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).

HANDLING

PRECAUTIONS

PRODUCT SAFETY INFORMATION REQUIRED FOR SAFE USE IS NOT INCLUDED IN THIS DOCUMENT. BEFORE HANDLING, READ PRODUCT

AND MATERIAL SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE MATERIAL SAFETY DATA SHEET IS AVAILABLE ON THE DOW CORNING WEBSITE AT DOWCORNING.COM, OR FROM YOUR DOW CORNING SALES APPLICATION ENGINEER, OR DISTRIBUTOR, OR BY CALLING DOW CORNING CUSTOMER SERVICE.

USABLE LIFE AND STORAGE

When stored in the original unopened containers, the silicone products have a useable life of 36 months from the date of production.

PACKAGING INFORMATION

Standard packaging includes double bagging of each assembly in sealed polyethylene bags. Customized packaging options are available; consult your Dow Corning representative.

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.

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, dowcorning.com or consult your local Dow Corning representative.

MANUFACTURING ENVIRONMENT

The silicone tubing and silicone Elastomers used in *Dow Corning*[®] Pharma fabricated tubing Assemblies are produced at Dow Corning's Healthcare Industries Materials Site, an FDA-registered And ISO 9001-registered facility Dedicated to the production of Silicone materials for healthcare Applications.

REGULATORY STATUS

Dow Corning[®] Pharma Fabricated Tubing Assemblies are manufactured from silicone elastomers which have been tested according to USP <88> "Biological Reactivity Tests, in vivo" and Exceed the USP class VI criteria. These materials also meet the requirements of the European Pharmacopoeia (Ph Eur) 3.1.9, "Silicone elastomers for closures and tubing."

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 customer's tests to ensure that our 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 our products will meet the 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.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.

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