Silicone Tubing and Molded Assemblies from Dow Corning
Products and Processes Designed to Reduce Risk

For more than 70 years, Dow Corning has drawn upon the versatility and biocompatibility of silicones to help our customers develop and manufacture innovative pharmaceutical products. Yet today’s pharma and biopharma companies face a number of challenges that demand new ways of thinking—ones that help reduce the risk of contamination and improve processing efficiency, while assisting customer development of innovative new products. That’s why Dow Corning is positioned to go beyond the ordinary with products and processes that can help.

Our ultimate goal is to help you minimize risk by providing solutions to meet the stringent performance and regulatory requirements of your industry. To that end, you can rely on us for:

- High-purity, BioMedical Grade, platinum-catalyzed silicone
- Strict contamination control in manufacturing facilities dedicated to healthcare applications
- Exceptional 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

Products That Meet Your Specific Needs

*Dow Corning*® brand Pharma Tubing is designed and produced to meet our customers’ specific needs:

- *Dow Corning*® Pharma-50 Tubing: for standard tubing transfer and filling operations
- *Dow Corning*® Pharma-65 and *Dow Corning*® Pharma-80: cost-effective alternatives to reinforced tubing in many operations
- *Dow Corning*® Pharma Advanced Pump Tubing: for up to six times the pump life of standard platinum-cure silicone tubing in peristaltic pump applications

All *Dow Corning* Pharma Tubing products are fully customizable:

- Dimensions
- Multi-lumen
- Configuration
- Gamma irradiation
- Tolerances
- Special testing
- Marking
- Packaging

*Dow Corning*® brand Overmolded Assemblies offer customers the flexibility they desire:

- Molded assemblies produced according to customer-specific designs
- Available in a choice of tubing formulations according to your process requirements
- Produced using *Dow Corning*’s BioMedical Grade silicone elastomers
- Produced in strictly controlled and monitored clean manufacturing environment

*Dow Corning* Overmolded Assemblies are 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.
Extensive Data and Technical Support

When you work with Dow Corning, you can expect dedicated service, including:
- Worldwide network for technical support
- Validation and qualification support
- Extensive data on extractables, physical properties and performance testing
- Regulatory expertise and support
- Specialized testing services such as batch-to-batch EP and endotoxin testing
- Environmental, health and safety services

Additional Features and Benefits

- Low-extractables profile to prevent contamination of your product; no added phthalates, plasticizers or latex
- Hydrophobic surface to cut fluid loss
- Smooth inner bore
- Regulatory expertise and support
- Stability over a wide range of conditions; suitable for diverse applications
- Readily sterilized via autoclave or gamma irradiation

**Pharma Tubing Properties**

<table>
<thead>
<tr>
<th>Tubing Size (ID x OD)</th>
<th>Burst**</th>
<th>Vacuum**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>psi</td>
<td>MPa</td>
</tr>
<tr>
<td>0.13 x 0.25</td>
<td>3.18 x 6.35</td>
<td>80</td>
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<tr>
<td>0.19 x 0.38</td>
<td>4.78 x 9.53</td>
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<tr>
<td>0.25 x 0.50</td>
<td>6.35 x 12.70</td>
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<tr>
<td>0.38 x 0.63</td>
<td>9.53 x 15.88</td>
<td>59</td>
</tr>
<tr>
<td>0.50 x 0.75</td>
<td>12.70 x 19.05</td>
<td>48</td>
</tr>
<tr>
<td>0.63 x 0.88</td>
<td>15.88 x 22.23</td>
<td>37</td>
</tr>
<tr>
<td>0.75 x 1.00</td>
<td>19.05 x 25.40</td>
<td>33</td>
</tr>
</tbody>
</table>

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**Dow Corning® Pharma Reinforced Tubing Properties**

<table>
<thead>
<tr>
<th>Tubing Size (ID x OD)</th>
<th>Burst**</th>
<th>Vacuum**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>psi</td>
<td>MPa</td>
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<td>0.13 x 0.37</td>
<td>3.18 x 9.27</td>
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<tr>
<td>0.19 x 0.45</td>
<td>4.75 x 11.35</td>
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<td>6.35 x 13.21</td>
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<td>0.31 x 0.59</td>
<td>7.92 x 15.04</td>
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<tr>
<td>0.38 x 0.66</td>
<td>9.53 x 16.64</td>
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<tr>
<td>0.50 x 0.80</td>
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<tr>
<td>0.63 x 0.97</td>
<td>15.88 x 24.51</td>
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<tr>
<td>0.75 x 1.10</td>
<td>19.05 x 27.94</td>
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<tr>
<td>0.88 x 1.24</td>
<td>22.23 x 31.37</td>
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</tr>
<tr>
<td>1.00 x 1.36</td>
<td>25.40 x 34.54</td>
<td>208</td>
</tr>
</tbody>
</table>

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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.

c. Tubing did not collapse, but did deform.
Dedicated Production Facility

Dow Corning is the global leader in silicone technology. Dedicated to the production of silicone materials for medical device and pharmaceutical applications, our FDA-registered Healthcare Industries Materials Site has more than 65 years of extrusion experience. Our tubing and molded assemblies are qualified to a range of globally recognized monographs, including:

- USP<87> and <88> Class VI (Biological Reactivity) tests (tubing and assemblies produced from Dow Corning® BioMedical Grade Elastomer)
- European Pharmacopoeia 3.1.9 (Silicone Elastomer for Closures and Tubing)
- USP<661> (Physicochemical Tests – Plastics)
- FDA Food Grade (21 CFR 177.2600)
- Selected Sanitary 3-A standards
- Japanese Pharmacopoeia (Section 11: Plastic Containers for Pharmaceutical Products)
- USP<85>, <788>, <151>

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.

Contamination control, batch traceability and change control all converge to improve risk management.

Contact Dow Corning

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