Healthcare Solutions

DUPONT™

Exacting purity

Advancing single-use solutions for
end-to-end purity, reliability and security.

DuPont provides materials and services for the entire pharmaceutical and biopharmaceutical supply chain. Produced from a vertically integrated supply chain, our silicone tubing, molded assemblies and biopharmaceutical fluids are thoroughly tested, fully traceable and comprehensively documented, therefore reducing the risk of contamination.

Purity of silicones

Silicones bring a long history of safety and purity, due to their biocompatibility in healthcare applications documented with extensive testing in addition to their low levels of extractables and particulates.

Purity: The silicone elastomers used to make silicone tubing are composed of a silicone base (polydimethyl siloxane polymers and reinforcing filler), a silicone cross-linker, an inhibitor and a catalyst (at very low level). Consequently, silicone elastomers possess low and predictable extractables profile which prevent contamination of the drug during its manufacturing process. In contrast, plasticizers and other additives are often added to thermoplastic tubing formulations.

Bio compatibility: Silicones are inherently biocompatible and inert, therefore they have no adverse effect on human health, they are not sensitizing, not pyrogenic, not genotoxic, not cytotoxic, not hemolytic and exceed USP <88> Class VI tests.

Silicone elastomers cure irreversibly (thermoset polymers) and are stable at high temperature, which makes them suitable for a wide range of applications and conditions from upstream to downstream process.

Exacting Purity

DuPont assists the biopharma industry risk-based analysis with a tight quality supply chain and manufacturing oversight and provides relevant testing packages on our tubing and overmolded assemblies.

Tubing and overmolded assemblies represent the largest surface area in direct contact with drug substances and products during the drug manufacturing process. Consequently, tubing needs to meet strict regulatory and quality requirements. The quality of tubing is contingent upon the entire manufacturing process including polymer synthesis, elastomer compounding and tubing extrusion.

Manufacturing Expertise and Capabilities

Vertical integration: DuPont offers the most complete vertical integration for tubing with privileged supply relationship and assures quality control on its finished products and upstream intermediates. This ensures traceability at every step of the manufacturing process and an exceptional change control process.

Healthcare Industries Materials Site (HIMS) is an FDA-registered site dedicated to healthcare solutions, utilizing principles of Good Manufacturing Practices for both Active Pharmaceutical Ingredients and elastomers used in the extrusion of tubing.

The site operates in accordance with a robust quality management system, such as the ISO-9001 Quality Management System global standard.

The site enforces strict contamination control. It uses production equipment solely dedicated to healthcare products in a strictly controlled and monitored clean manufacturing environment. The tubing extrusion floor will be classified as ISO 7 manufacturing environment.

Cutting Edge Tests for Process Contact Materials (PCM)

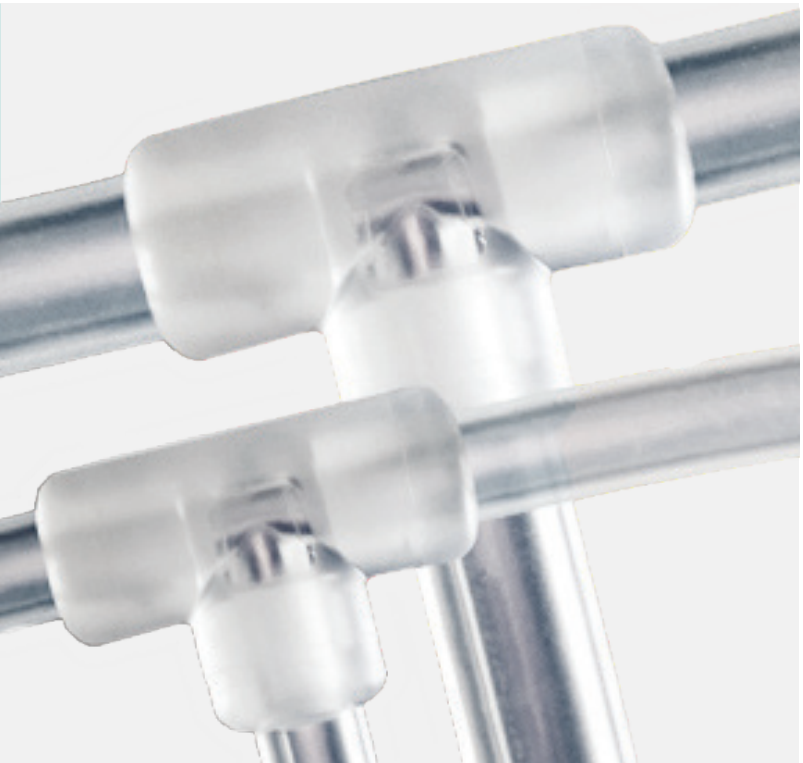
With the rising adoption of single-use components and systems, end-users increasingly rely on their suppliers to generate data on their supplied components.

DuPont is committed to help its customers mitigate risk during the validation of single-use components by generating more data to substantiate the performance, quality and purity of its product solutions.

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

Endotoxins: all Dow Corning™ 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™ Pharma Tubing products are well below the USP ‹788› criteria for Microscopic Particle Count Test



Bioburden: further to test following ISO 11737-1 (Sterilization 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 standardized 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, DuPont has conducted a comprehensive BPOG study.

Learn more about the three tests in our white paper:

Particulates, Endotoxins and Bioburden Characterization of Silicone Tubing for Biopharmaceutical Applications by Lise Tan-Sien-Hee, and Csilla Kollar, Technical Service & Development for DuPont.

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To learn more about DuPont's healthcare solutions visit:
www.dupont.com/healthcare.html

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