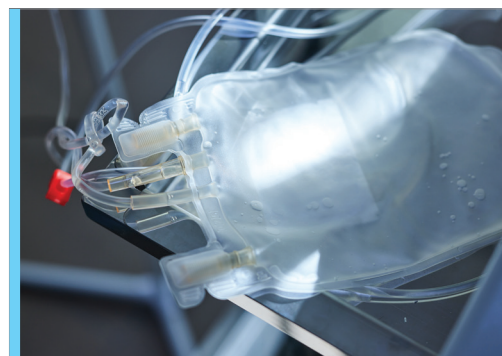


Cell Therapy Tubing

Cleanroom-manufactured tubing specifically designed for cell therapy applications

TekniPlex Healthcare's cell therapy tubing has excellent biocompatibility properties and is compatible with RF sealing and welding.



OVERVIEW

As one of the industry leaders in PVC compounding and with decades of materials science expertise, TekniPlex Healthcare developed a unique non-phthalate compound with a low extractable profile. This compound is used to manufacture tubing that is well-suited for high-throughput biopharmaceutical processing and cell therapy applications. As a vertically integrated compounder and tubing extruder, TekniPlex Healthcare is uniquely positioned to ensure strict quality controls across both processes, resulting in a higher-quality finished product. The finished tubing has excellent biocompatibility properties and is compatible with RF sealing and welding. See test results on page two.

Product Features and Highlights

- Compounded and developed in-house to reduce supply chain and minimize process risk
- Extruded at six sites globally to reduce transit time and carbon emissions
- Optimized non-phthalate plasticizer formulation for superior extractable profile
- RF sealing and welding compatible
- Optically clear
- Excellent kink resistance
- 100% in-line inspection of tubing ID for any occlusions or anomalies
- Extrusion performed in a Class 100,000 clean room
- UV sterilized water filtration (bioburden and pyrogenic micro-pore filtration)



Cell Therapy Tubing

| Physical Properties | | | |
|-----------------------------------|-------------|--------------------------------------|-----------------------------------|
| Description | Test Method | Result (unsterilized) | Results (post gamma) ¹ |
| Tensile Stress at Break | ASTM D638 | 2311 ± 100 psi 15.93 ± 0.69 MPa | 2322 ± 67 16.01 ± 0.46 |
| Strain at Break | ASTM D638 | 404 ± 33% | 419 ± 23 |
| Tensile Stress at 100% Elongation | ASTM D638 | 1117 ± 42 psi 7.70 ± 0.23 MPa | 1136 ± 27 2.89 ± 0.16 |
| Tear Strength | ASTM D624 | 370 ± 41 lbf/in 64.80 ± 7.18 kN/m | 390 ± 36 68.30 ± 6.30 |
| Hardness | ASTM D2240 | 70 Shore A | |
| Specific Gravity | ASTM D792 | 1.21 | |

1. "post gamma" samples were exposed to ~30 kGy gamma sterilization.

| Biocompatibility | | |
|--|---|------------------------------|
| Description | Test Method | Outcome |
| Cytotoxicity | ISO 10993-5 | Pass |
| Class VI, Intracutaneous Test ¹ | USP-NF 2023 Issue 2 par 88, Intracutaneous Test Protocol | Pass |
| Class VI, Systemic Injection Test ¹ | USP-NF 2023 Issue 2 par 88, Acute Systemic Toxicity Test Protocol | Pass |
| Class VI, Implantation Test | USP-NF 2023 Issue 2 par 88, Implantation Test Protocol | Pass |
| Bacterial Endotoxins | USP <85> Bacterial Endotoxin - kinetic turbidimetric | <0.000666 EU/cm ² |
| Physiochemical Properties - Plasticized PVC | USP <661.1>, Plastic Materials of Construction | Pass |

1. Class VI extractions conducted at 70°C for 24 hours.

2. Bacterial Endotoxin test utilized a surface area to volume ratio of 1ml/3cm². Extraction with LAL reagent water conducted at 37-40°C for 60 minutes with periodic agitation.



For additional information, please visit:
tekni-plex.com/healthcare