

# Pharma-Clear® 65 Series
## Platinum Cured Tubing

**SaniSure Pharma Clear 65 was developed for bulk transfer and general pumping applications. With a slightly higher hardness rating, it has very good resilience and kink resistance and typically has higher pressure rating than softer alternatives.**

- ISO Class 7 cleanroom manufacturing
- Standard and customer sizes available
- Manufactured for pharmaceutical and biopharmaceutical applications

## Key Features

- Platinum cured Silicone
- Higher pressure ratings
- Excellent clarity
- Hardness: durometer 61 Shore A
- Tasteless, odorless, noncytotoxic and nonhemolytic
- Contains no phthalate plasticizers or peroxides that can leach out into transported fluid
- Low-binding surface minimizes absorption of proteins and food products
- Sterilization Methods: autoclave, gamma irradiation, EtO, and chemical sterilants
- Packaging: Double bagged
- Working Low Temperature Range: -100°F (-73.3°C)
- Working High Temperature Range: 400°F (204.4°C)

## Compliance

- U.S. Pharmacopeia 43, National Formulary 38 (USP), General Chapter <88> Class VI, Biological Reactivity Tests, In Vivo (2020)
- U.S. Pharmacopeia 43, National Formulary 38 (USP), General Chapter <87> Class VI, Biological Reactivity Tests, In Vitro (2020)
- ISO 10993 (various parts)
- Ph.Eur 3.1.9
- Request our comprehensive extractables and biocompa-tibility study for this product: sanisure.com/resources

## Applications

- Transfer Lines
- Cell media processing
- Bioreactor process lines
- Production filtration and fermentation
- Diagnostics and laboratory testing

| Physical | Typical Values |
|---|---|
| **Specific Gravity** | 1.18 |
| **Shore A Hardness** | 61 |
| **Tensile (PSI)** | 1523 |
| **Tensile (Mpa)** | 10.5 |
| **Elongation (%)** | 530 |
| **Tear, Die B, ppi** | 183 |
| **Tear, Die B, KN/mm** | 32 |

# Pharma-Clear® 65 Series

## Regulatory Testing

| | |
|---|---|
| **Biocompatibility USP <87> and USP <88>[2]** | Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below:<br>• USP <87><br>• USP <88> |
| **Biocompatibility Cont. (ISO 10993 and USP Class VI)[1]** | A Representative sample of the compound used to manufacture this product has been tested according to ISO 10993 and USP Class VI testing requirements. The sample met the requirements of the following tests:<br>• Systemic Injection Test (USP Class VI and ISO 10993)<br>• Intracutaneous Toxicity Test (USP Class VI and ISO 10993)<br>• Intramuscular Implantation Test (USP Class VI and ISO 10993)<br>• Agar Diffusion (ISO 10993-5)<br>• L929 MEM Elution (ISO 10993-5)<br>• Implant Effects (ISO 10993-6)<br>• Sensitization (Kligman Maximization) (ISO 10993-10)<br>• Systemic Toxicity (ISO 10993-11) |
| **Extractables - USP[2]** | Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below:<br>• USP <665><br>• USP <661.2> |
| **Extractables - FDA Food Contact[1]** | Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below:<br>• FDA 21 CFR 177.2600 |
| **Endotoxin Testing[2]** | Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below:<br>• USP <85> |
| **Particulate Testing[2]** | Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below:<br>• USP <788> |

[1]The biocompatibility information listed in this section is based on information provided by our compound source. Testing is based on single lots, although lot-to-lot variance would not be expected to show different results.
[2]The assessment is available upon request at: https://sanisure.com/resources/
Validation Package With Extractable Report (BPOG) available up request.

## Regulatory Compliances

Based on the information made available to us by our raw material supplier, the above material is compliant to the below list of regulatory requirements.

- RoHS Compliant
- REACH Compliant
- Conflict Minerals
- California Propositon 65
- ICH Q3D Guideline for elemental impurities
- EU Persistent Organic Pollutants (POPs)

## Presence of Substance

Based on the information made available to SaniSure by its material supplier, none of the following compounds are intentionally added in as a 'raw material' or as a 'process aid' to the above product:

- Bisphenol A (BPA)
- Melamine
- Latex
- N-Nitrosamines
- Phthalates
- Slip Agents
- Polyvinyl chloride (PVC)

# Pharma-Clear® 65 Series

## Animal Derivatives, Plant Derivatives, BSE/TSE Statement*

This product line is formulated from entirely synthetic ingredients; therefore, these polymers contain no animal byproducts, no substances of animal or plant origin, nor are the polymers derived from specified risk materials for BSE/TSE.

*Please note that the information provided is based on best available knowledge; we do not test for the presence of trace amounts of substances that may be introduced our products as contaminants. We do not routinely analyze our products for the presence of the above reportable substances; however, based on information provided by our supplier and to the best of our knowledge, the above material is free from animal derivatives.

**Genetically Modified Organisms (GMO)**
This product is not manufactured with any genetically modified organisms (GMO's).

## Allergens

Based on the information provided to SaniSure by its supplier and our documentation reviews, we have found that the product listed above does not intentionally contain any of the below allergens

- Gluten
- Lactose
- Nuts
- Egg/Protein
- Soy
- Nickel
- Zinc
- Fish/Shellfish

## Manufacturing Standard

The above material is manufactured in an ISO 9001:2015 accredited facility. Furthermore, this product is manufactured in an ISO 14644-1 Class 7 cleanroom.

## Dimensional Tolerance

Inside and outside diameter tolerances are maintained to RMA E1 tolerances.

## Sterilization

**Gamma Irradiation:**
The recommended maximum dosage for gamma irradiation of the above product is 50 kGy. When required of SaniSure, the standard range for gamma irradiation of products is between 27.5 and 40 kGy.

**Autoclave:**
The above product is generally compatible with autoclave sterilization. Please note that users must validate their steriliza-tion conditions and procedure to ensure this product is suitable for a particular application. Below are some examples of common autoclave conditions:

- 30 minutes at 121°C (250°F)
- 10 minutes at 132°C (270°F)

## Shelf Life and Storage Conditions

If stored according to the following recommendations, SaniSure recommends that customers dispose of this product after five (5) years from the date of manufacturing. Store this product in an ambient temperature and humidity environment. The product should be free from exposure to direct outside weather influences and stored in a dark space out of direct contact with light. The area should be free from volatile solvents, corrosive gases, or other potentially harmful vapors. Stack the product flat in an opaque container during storage. The container should be kept off the floor (e.g., on shelving or skids) and remain closed and sealed while in storage. The product should be free of kinking and not be subjected to crushing forces from the weight of the product above it.

SaniSure makes no representations or warranties as to the accuracy of the information contained or referenced herein. Most results mentioned above are based on single lots of material. Although a lot-to-lot variance would not be expected to show different results, this data should not be construed as a warranty of fitness for use. Prior to use for any application, the user has the sole responsibility for determining the suitability of these products in any application.

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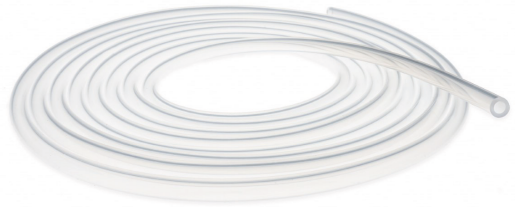
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# Pharma-Clear® 65 Series

## Sizing Chart Standard Offerings

| Part Number | ID (inch) | ID (mm) | OD (inch) | OD (mm) | Wall Thickness (inch) | Wall Thickness (mm) | Working Pressure (psi) | Burst Pressure (psi) | Vacuum Rating (hg) |
|---|---|---|---|---|---|---|---|---|---|
| PLTS-65-031X156-** | 0.031 | 0.8 | 0.156 | 4.0 | 0.063 | 1.6 | 45.9 | 137.8 | 29.5 |
| PLTS-65-063X125-** | 0.063 | 1.6 | 0.125 | 3.2 | 0.031 | 0.8 | 22.7 | 68 | 29.5 |
| PLTS-65-063X187-** | 0.063 | 1.6 | 0.187 | 4.8 | 0.062 | 1.6 | 34.1 | 102.2 | 29.5 |
| PLTS-65-125X250-** | 0.125 | 3.2 | 0.250 | 6.4 | 0.063 | 1.6 | 22.9 | 68.7 | 29.5 |
| PLTS-65-125X312-** | 0.125 | 3.2 | 0.312 | 8.0 | 0.094 | 2.4 | 29.5 | 88.5 | 29.5 |
| PLTS-65-187X312-** | 0.187 | 4.8 | 0.312 | 8.0 | 0.063 | 1.6 | | | 29.5 |
| PLTS-65-187X375-** | 0.187 | 4.8 | 0.375 | 9.6 | 0.094 | 2.4 | 23 | 68.9 | 29.5 |
| PLTS-65-187X437-** | 0.187 | 4.8 | 0.437 | 11.2 | 0.125 | 3.2 | 27.5 | 82.6 | 29.5 |
| PLTS-65-250X375-** | 0.250 | 6.4 | 0.375 | 9.6 | 0.063 | 1.6 | 13.7 | 41.2 | 15 |
| PLTS-65-250X437-** | 0.250 | 6.4 | 0.437 | 11.2 | 0.094 | 2.4 | 20 | 60 | |
| PLTS-65-250X500-** | 0.250 | 6.4 | 0.500 | 12.7 | 0.125 | 3.2 | 22.9 | 68.7 | 29.5 |
| PLTS-65-312X437-** | 0.312 | 8.0 | 0.437 | 11.2 | 0.063 | 1.6 | 11.4 | 34.1 | 5 |
| PLTS-65-312X500-** | 0.312 | 8.0 | 0.500 | 12.7 | 0.094 | 2.4 | 15.8 | 47.4 | 10 |
| PLTS-65-375X437-** | 0.375 | 9.6 | 0.437 | 11.2 | 0.031 | 0.8 | 5.2 | 15.7 | 0 |
| PLTS-65-375X562-** | 0.375 | 9.6 | 0.562 | 14.4 | 0.094 | 2.4 | 13.7 | 41.1 | 10 |
| PLTS-65-375X625-** | 0.375 | 9.6 | 0.625 | 15.9 | 0.125 | 3.2 | 17.2 | 51.5 | 29.5 |
| PLTS-65-500X750-** | 0.500 | 12.7 | 0.750 | 19.0 | 0.125 | 3.2 | 13.7 | 41.2 | 10 |
| PLTS-65-500X875-** | 0.500 | 12.7 | 0.875 | 22.2 | 0.187 | 4.8 | 13.7 | 41.2 | 29.5 |
| PLTS-65-625X1000-** | 0.625 | 15.9 | 1.000 | 25.5 | 0.188 | 4.8 | 15.9 | 47.6 | |
| PLTS-65-750X1125-** | 0.750 | 19.0 | 1.125 | 28.6 | 0.188 | 4.8 | 13.7 | 41.2 | 5 |
| PLTS-65-750X1250-** | 0.750 | 19.0 | 1.250 | 31.8 | 0.125 | 3.2 | 17.2 | 51.5 | |
| PLTS-65-1000X1375-** | 1.000 | 25.4 | 1.375 | 34.9 | 0.187 | 4.8 | 10.8 | 32.5 | 5 |
| PLTS-65-3MMx7MM-** | | 3.1 | | 7.1 | | 2.1 | | | |
| PLTS-65-6MMx12MM-** | | 6.1 | | 12.1 | | 3.1 | | | |
| PLTS-65-8MMx16MM-** | | 8.1 | | 16.1 | | 4.1 | | | |
| PLTS-65-10MMx17MM-** | | 10.1 | | 17.1 | | 3.5 | | | |

NOTE: Standard coil length is 50 feet. Other length and spools available, consult factory.

Custom sizes available

Vacuum Rating
Note: Testing conducted on tubing maintained in a straight configuration (no bends) at a standard laboratory temperature of 23°C, in accordance with ISO 7233 Method A

Bend Radius:
Note: Testing conducted at standard laboratory temperature of 23°C, in accordance with ISO 10619-1 Method A1.

Burst
Note: Tested at 23°C Temp

Tubing has no printing

Please contact our quality department for the most up-to-date regulatory information. Specifications in this document are subject to change without notice.

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