

ClariSure GK Polyethersulfone Membrane Mini Cartridge Filter with Microglassfiber prefilter

mdi polyethersulfone (PES) membrane mini cartridge filters *ClariSure GK* are disposable filtration devices for clarification of heavily particle laden solutions or colloidal suspensions. There are especially suited for serum and plasma applications. These cartridges contain an upstream microglassfiber layer and a polyethersulfone membrane layer on the downstream.

The upstream microglassfiber layer retains large size particulate contamination and colloidal particles to protect premature clogging of downstream side PES membrane layer. Thus it gives higher throughputs resulting in better economics.

mdi *ClariSure GK* filters are validated for key performance parameters such as chemical compatibility, extractables, heat stability and flow rates. These are available in a variety of sizes to suit specific microfiltration needs in critical and specialized process applications.

Special Features

- High throughputs
- Multiple autoclavable
- Heat sealed, no glues adhesives
- Low protein binding



Applications

- Prefiltration of parenterals
- Prefiltration of ophthalmic solutions
- Prefiltration of proteinaceous liquid where minimum protein loss is desired, such as sera, culture soups and recombinant proteins, antibodies etc.
- Prefiltration of media, buffers etc for particulate contamination reduction

Complies with USFDA 21 CFR 210.3(b)(6)

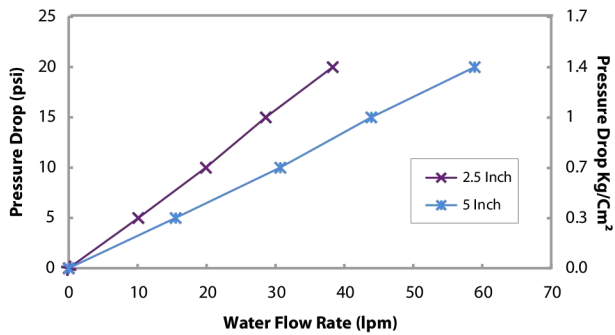
Meets and Exceeds USFDA 21 CFR 177.1520

Specifications

| Construction | | |
|-------------------------------------|--|---------------------|
| Pore Size | 0.1 µm, 0.2 µm and 0.5 µm | |
| Filter Media | Hydrophilic PES | |
| Support Layers | Polyester | |
| Body and Core | Polypropylene | |
| Size | | |
| Size | 2.5" | 5" |
| Effective Filtration Area (Nominal) | 1000cm ² | 1500cm ² |
| Operational | | |
| Max. Operating Temperature | 80 °C @ < 30 psi (2 Kg/cm ²) | |
| Max. Differential Pressure | 50 psi (3.5 Kg/cm ²) @ 25 °C | |
| Sterilization | Autoclavable/Steam Sterilized at 121°C for 30minute, 25 Cycles. | |
| Assurance | | |
| Toxicity | Passes Bioreactivity test, In Vivo, as per USP <88> for Class VI plastics | |
| Non Fiber Releasing | Passes test as per USP and comply with USFDA 21 CFR Part 210.3(b)(6) for fiber release | |
| Extractables with WFI | Passes test as per USP | |
| Oxidizable Substances | Within limits as specified in USP | |
| Particle Shedding | Passes USP test for particulates in injectables | |
| Indirect Food Additive | All Polypropylene components meet the FDA Indirect Food Additive requirements cited in 21 CFR 177.1520 | |
| Good Manufacturing Practice | These products are manufactured in a facility which adheres to Good Manufacturing Practices. | |
| Quality Management System | ISO-9001:2008 Certified | |
| USFDA | DMF No. 015554 | |

Water Flow Rates

0.5 µm ClariSure GK Cartridge Filters



Ordering Information

| Type | | Size | | Pore Size | | Adaptor | | Elastomer | | Sterility | | Pack Size | |
|--|-------------|------|-----------|-----------|-----------|---------|-----------|-----------|-----------|-------------|----------|-----------|-----------|
| | Code | | Code | | Code | | Code | | Code | | Code | | Code |
| Clarisure GK (Polyethersulfone Membrane Cartridge with Microglassfiber Upstream Layer) | CGKX | 2.5" | 50 | 0.1 µm | 36 | 4463 | E0 | Silicone | SS | Non Sterile | 1 | 1 | 01 |
| | | 5" | 53 | 0.2 µm | 01 | 4463B | H0 | | | | | | |
| | | | | 0.5 µm | 04 | 4440 | U0 | | | | | | |
| Example | | | | | | | | | | | | | |
| | CGKX | | 50 | | 04 | | E0 | | SS | | 1 | | 01 |

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