



sartorius stedim
biotech

Sartopure® GF Plus The New Generation of Adsorptive Depth Filters



turning science **into solutions**

Sartopure® GF Plus – An innovative solution for prefiltration in pharma|biotech applications

Importance of Prefiltration

Key target for prefiltration in pharmaceutical and biotechnological production processes is the effective removal of contaminants from the fluid stream. Such contaminants like

- Lipids
- Colloids
- Protein Aggregates (Host Cell Protein)
- Particles

lead either to premature blockage of downstream membrane filters or reduce the effectiveness of downstream purification equipment like chromatography columns and ultrafiltration systems.

Features & Benefits of Sartopure® GF Plus

Sartopure® GF Plus adsorptive depth filters are specifically designed for efficient removal of these contaminants. Prefiltration with Sartopure® GF Plus provides clarified fluid streams for further downstream processing or final sterilizing grade or mycoplasma removal filtration.

Sartopure® GF Plus depth filters feature an innovative, dual layer, 3-dimensional glass fibre fleece matrix for

- Enhanced adsorptive capacity
- Outstanding total throughput performance
- Defined particle retention

The combination of adsorptive and mechanical retention assures that deformable and non deformable particles, even smaller than the retention rate of the filter itself, are effectively retained. Key benefits of this innovative adsorptive depth filter technology are

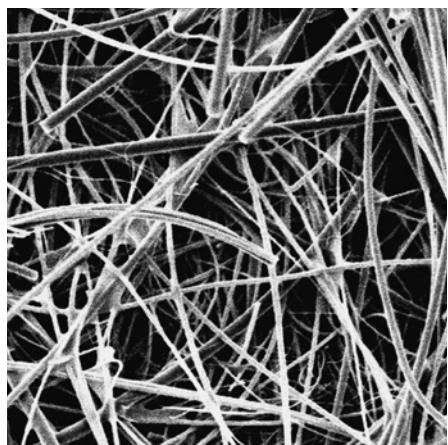
- Effective clarification
- Economic prefiltration design
- Reliable operation

Applications

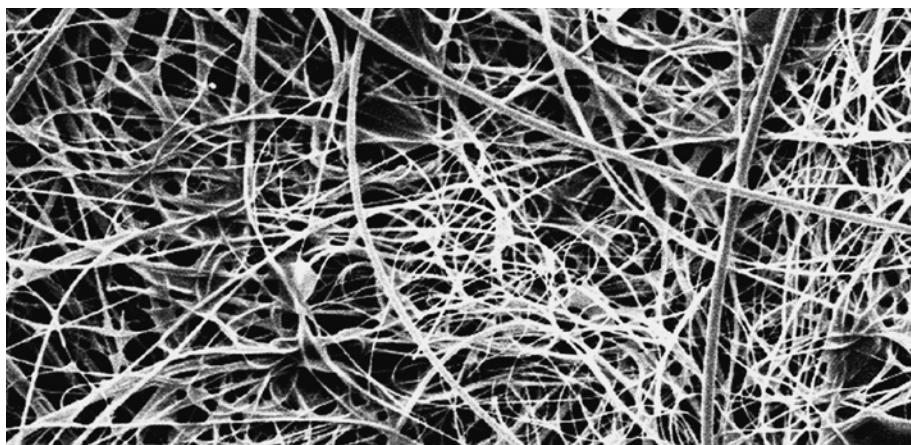
Sartopure® GF Plus adsorptive depth filters are ideally suited for clarification and prefiltration of:

- Fermentation broths
- Cell Culture solutions after cell harvest
- Serum free and serum containing cell culture media
- Serum
- Highly viscous ophthalmic and LVP fluids

Scanning electron microscope picture of Sartopure® GF Plus glassfibre fleeces



Structure of Sartopure® GF Plus
1,2 µm glassfibre (1.000 fold magnified)



Structure of Sartopure® GF Plus
0,65 µm glassfibre (1.000 fold magnified)

Sartopure® GF Plus in Biotech Manufacturing

Fermentation broths and cell culture solutions can contain high levels of colloids, lipids, protein aggregates, host cell protein and other contaminants.

Sartopure® GF Plus assures effective removal of these contaminants in the very early stages of the downstream process, while retaining valuable fractions of interest.

Sartopure® GF Plus adsorptive depth filters provide clarified fluid streams in front of chromatography columns and ultra-filtration systems to assure optimal effectiveness of these purification steps.

In upstream processing, Sartopure® GF Plus depth filters, are the ideal choice for prefiltration of serum or serum free cell culture media. Sterilizing grade or mycoplasma retentive membrane filters are effectively protected from contaminants and particulate matter assuring economic filtration solutions in media preparation.

Sartopure® GF Plus in Pharma Manufacturing

Highly viscous fluids like ophthalmic preparations and large volume parenterals (LVP) containing high concentrations of dextrose are a severe challenge for sterilizing grade membrane filters. The unparalleled retention efficiency in combination with the outstanding total throughput performance of Sartopure® GF Plus assures effective protection of membrane filters while providing economic solutions for prefiltration. The use of Sartopure® GF Plus depth filters will help to significantly reduce filtration costs in classical pharma manufacturing.

Flexibility

Sartopure® GF Plus depth filters are available as standard filter cartridges and disposable MaxiCaps as well.

Sartopure® GF Plus filter cartridges can be used in processes that require maximum pressure differentials. Cartridges are robust, strong, resistant and designed to withstand multiple in-line steaming cycles.

MaxiCaps incorporate standard filter cartridges in a disposable capsule format and are designed for single use. The integration of MaxiCaps permits to design complete disposable processing lines reducing cleaning validation and investment costs into stainless steel equipment.

Key Performance Parameters of Sartopure® GF Plus adsorptive depth filters

| Product Features | Function | Customer Benefits |
|--|---|--|
| Highly charged glass fibre layers | Exceptional clarification efficiency | Excellent protection of final filters and subsequent downstream processing equipment |
| Multi-layer, 3-dimensional glass structure | Extremely high total throughput performance | Cost effective design of the prefiltration scheme |
| Mechanical and adsorptive retention | Defined & finest particle retention (even smaller than actual retention rate) | Reliable operation even under varying process conditions |

Technical specifications

| | |
|---|---|
| Filter medium | Glass fibre |
| Core outer support | Polypropylene |
| End caps | Polypropylene |
| O-rings | Silicone (EPDM, Fluoroelastomer)* |
| Filtration area | 0.6 m ² 6 ft ² per 10" cartridge or MaxiCaps® |
| Retention rates | 0.65 µm 1.2 µm |
| Heights | 10" (250 mm), 20" (500 mm), 30" (750 mm) |
| Maximum differential pressure in the direction of filtration | Cartridges 5 bar 72.5 psi at 20°C 2 bar 29 psi at 80°C MaxiCaps® 4 bar 58 psi at 20°C 3 bar 43.5 psi at 50°C |
| Maximum back pressure | 2 bar 29 psi at 21°C 1 bar 14.5 psi at 121°C |

* optional

Ordering information



Cartridges

The diagram shows five horizontal lines representing digital signals over time. From left to right, the lines are labeled: 555, 25, 03, P, and 1. The signal for pin 555 starts at logic 1, goes to 0 at approximately 1/3 of the period, and returns to 1 at approximately 2/3 of the period. The signal for pin 25 is the inverse of pin 555. The signal for pin 03 is constant at 1. The signal for pin P is constant at 0. The signal for pin 1 is constant at 1.

Sartopure® GF Plus Pharma

| | | |
|----------------|----|--|
| Adapter | 21 | Double open end |
| | 25 | S-adapter on top, 2-flange bayonet adapter with double O-ring on bottom |
| | 27 | Double O-ring |
| | 28 | S-adapter on top, 3-flange bayonet adapter with double O-ring on bottom |

Retention rate Nominal retention rating

03 1.2 μm
05 0.65 μm

| | | |
|---------------|---|-----|
| Height | 1 | 10" |
| | 2 | 20" |
| | 3 | 30" |



MaxiCaps®

A timing diagram illustrating the logic levels of five digital signals over time. The signals are labeled vertically on the left: 555, 13, 03, P, and 1. The horizontal axis represents time. The signal 555 starts at 1, goes to 0 at approximately 1/4 of the period, and returns to 1 at approximately 3/4 of the period. The signal 13 starts at 0, goes to 1 at approximately 1/4 of the period, and returns to 0 at approximately 3/4 of the period. The signal 03 starts at 1, goes to 0 at approximately 1/2 of the period, and returns to 1 at approximately 3/4 of the period. The signal P starts at 0, goes to 1 at approximately 1/2 of the period, and returns to 0 at approximately 3/4 of the period. The signal 1 starts at 0, goes to 1 at approximately 3/4 of the period, and remains at 1 until the end of the shown period.

Sartopure® GF Plus Pharma

MaxiCaps

| Retention rate | Nominal retention rating |
|----------------|--------------------------|
| 03 | 1.2 µm |
| 05 | 0.65 µm |

| | | |
|---------------|---|-----|
| Height | 1 | 10" |
| | 2 | 20" |
| | 3 | 30" |



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