

mbar 60

50

30

20

10

Differentlial pressure

PROCLEAR GF filter elements

Technical changes reserved | Rev.: 004.24.02





12

(10" Cartridge)

PROCLEAR GF filter elements are designed for reliable and economical removal of particles and microorganisms from pharmaceutical fluids.

The glass microfiber filter media does not shed fibers and provides excellent dirt retention rates and high flow rates for long life and cost effective filter system design.

PROCLEAR GF filter elements have low extractables, making them ideal for general clarification and pre-filtration applications in pharmaceutical processing.

Quality standards

• Pharmaceutical grade products are manufactured according to cGMP and rinsed 100% with purified pharmaceutical grade water.

Pharmaceutical validation

A full validation quide is available upon request.

Non-volatile extractables (NVE)

The total number of NVE's extracted in the first 5 liters of purified water for a 10" filter element is <10 mg.

Oxidizable substances

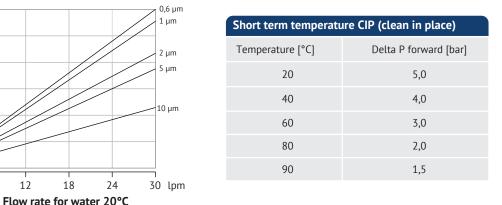
PROCLEAR GF filter cartridges meet current USP and EP quality standards for sterile purified water for oxidizable substances following a <1 liter water flush.

Food contact

The materials meet the relevant requirements of FDA 21 CFR Part 177, USP Plastics Class VI -121°C and ISO10993 equivalents.

Endotoxins

Aqueous extracts from a 10" (250 mm) PROCLEAR GF contain <0.25 EU / ml when tested according to the Limulus Amoebocyte Lysate-Test.



| Technical data | -> to the product | |
|-------------------------------|--|--|
| Material: | Glass Microfibre | |
| Support layer up-/downstream: | Polypropylene | |
| Gasket: | EPDM, Silicone, Viton | |
| Micron rating: | 0,6/ 1/ 2/ 5/ 10 μm | |
| Filter surface (10"): | 0,56 m ² | |
| Element length: | 10" - 40" | |
| Max. Working temperature: | 70°C | |
| Differential pressure: | max. 5,0 bar at 20°C (forward) max. 3,0 bar at 60°C (forward) | |

| Autoclave | | SIP (steam in place) | |
|-----------|--------|----------------------|--------|
| Cycles | Temp. | Cycles | Temp. |
| 10 | 130 °C | 10 | 121 °C |

Sterilization

Proclear GF filter elements can be sterilized with hot water at up to 90 °C

TOC / conductivity

The filtrate quality of a 10" (250 mm) PROCLEAR GF meets the requirements of the current USP <643> (TOC) and USP <645> (conductivity) within the first 200 ml of rinsed water

