GORE® Microfiltration Media
for Drug Transfer Devices

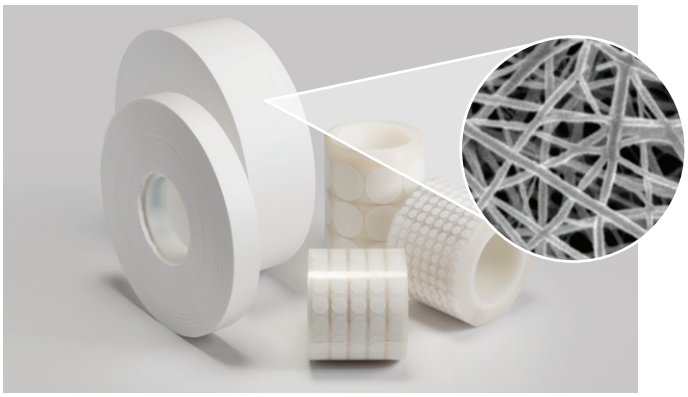
PROTECTING HEALTHCARE WORKERS FROM EXPOSURE DURING COMPOUNDING AND ADMINISTRATION OF HAZARDOUS DRUGS

For more than 20 years GORE® Microfiltration Media help to protect healthcare workers from exposure during the compounding and administration of hazardous drugs. Unlike other materials, GORE Microfiltration Media are highly inert and engineered to contain aggressive reagents and solvents. Therefore, our PTFE laminate is the first choice when it comes to designing reliable closed system transfer devices (CSTD).

Key Features and Benefits

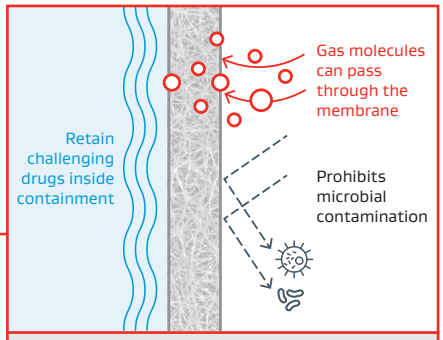
- Retains challenging liquids with surface energy >28 mN/m
- Aerosol Bacterial and Viral Efficiency of 99.99999% (log 7 Reduction)
- High air transfer of 183.8 ml/min ensures fast pressure equalization to allow proper equipment function and ease of use
- High material uniformity enables high yield integration using ultrasonic or heat welding
- Inherently inert and meet cleanliness and biocompatibility requirements according to ISO 10993.

Unique Filter Membrane



Our high performance ePTFE membrane structure is designed for a wide variety of challenging drugs and enables fast pressure equalization while preventing microbial contamination.

Primary vent functions



- Reliably retains hazardous drugs
- Equalizes pressure differences easily
- Protects patient from potential microbial contamination

Together, improving life

GORE® Microfiltration Media Performance*

Product Performance*		
Typical Airflow**	183.3 ml/min (11.0 l/h)	2015 ml/min (120.9 l/h)
Typical Water Entry Pressure	738.5 kPa (107.1 psi)	112.1 kPa (16.3 psi)
Typical Thickness	0.24 mm (9.4 mils)	0.20 mm (7.9 mils)
Reference pore size***	0.1 µm	3.0 µm
Bacterial Filtration Efficiency (BFE)	< 99.99999 (Log 7 Reduction)	<99.999 (Log5 Reduction)
Viral Filtration Efficiency (VFE)	< 99.99999 (Log 7 Reduction)	<99.999 (Log5 Reduction)

* based on 2-years lot release manufacturing data representing 99% of the manufactured product
** measured per 2.99 cm² at 1.2 kPa differential pressure
*** other pore sizes available on request

Material Characteristic	
Membrane material	Polytetrafluoroethylene (PTFE)
Membrane structure	Expanded PTFE with a three-dimensional structure
Membrane characteristic	Hydrophobic
Support material	PET non-woven
Form	GORE® Microfiltration Media can be provided in different laminate forms on 3-inch core rolls: • Rolled Goods in customized slit widths • Die Cut parts in customized designs Contact Us for detailed part number set up
Biocompatibility	ISO 10993-4, -5, -10, -11
Shelf life	1 year after manufacturing prior integration

Integration Guidance	
Processability Integration	GORE Microfiltration Media for Drug Transfer Devices are designed to be suitable with typical manual, semi- and fully automated production steps. Specific considerations are required depending on used technology. Please contact Gore for support.
Integration	GORE Microfiltration Media for Drug Transfer Devices are designed to be suitable for typical integration methods. Welding parameters are device design and integration technology depending. Please contact Gore for support. • Ultrasonic welding integration using a clean flat round welding area with a cavity inside. Avoid structured welding surface. • Heat welding integration using a clean flat welding horn with a cavity inside

GORE® Microfiltration Media Performance

Bacterial Filtration Efficiency (BFE)	• GORE Microfiltration Media for Drug Transfer was designed to provide a minimum individual Aerosol Bacterial Filtration Efficiency (BFE) of 99.99999% or a Log Reduction Value of 7 • Gore's Quality Assurance Test 0807 measures Aerosol Filtration Efficiency • The aerosol microorganism retention results for BFE have been statistically correlated to Gore's Quality Assurance Test 0807 Related BFE Customer Information • Retention of aerosolized bacteria was measured using Brevundimonas diminuta as the model organism. A standard organism used for validating membrane filters, Brevundimonas diminuta (National Collection of Industrial, Food and Marine Bacteria (NCIMB) 11091, ATCC® 19146™) is a gram-negative bacteria between 0.4 and 1.0 micrometer in diameter. • BFE tests are conducted with a challenge load of $>1x10^8$ colony forming units (cfu) and ≥90% relative humidity to promote cellular viability
Viral Filtration Efficiency (VFE)	• GORE Microfiltration Media for Drug Transfer was designed to provide a minimum individual Aerosol Viral Filtration Efficiency (VFE) of 99.99999 % or a Log Reduction Value of 7 • Gore's Quality Assurance Test 0807 measures Aerosol Filtration Efficiency • The aerosol microorganism retention results for VFE have been statistically correlated to Gore's Quality Assurance Test 0807 Related VFE Customer Information • Bacteriophage aerosol retention tests were conducted with MS-2 coliphage (National Collection of Industrial, Food and Marine Bacteria (NCIMB) 10108). This coliphage is an unenveloped, single-stranded RNA model virus, 23 nanometers (nm) in diameter with a molecular weight of 3.6×10^6 Daltons. • VFE tests are conducted with a challenge load of $>1x10^8$ plaque forming units (pfu) and ≥90% relative humidity to promote cellular viability.
Biocompatibility	GORE Microfiltration Media for Drug Transfer was designed to meet the following Biocompatibility requirements: • ISO 10993 "Externally Communicating Devices; Blood Path Indirect; Prolonged Contact Duration (24 hours - 30 days)" Biocompatibility testing was performed by a certified laboratory and passed the requirements of: • ISO 10993-4 Tests for complement activation assay, hemolysis and coagulation (PTT) • ISO 10993-5 Tests for in vitro cytotoxicity • ISO 10993-10 Tests for skin sensitization • ISO 10993-11 Tests for systemic toxicity • ISO 10993-23 Tests for skin irritation

Quality Statement

- GORE® Microfiltration Media are manufactured following the applicable material quality requirements, including relevant Good Manufacturing Processes as defined in the Gore PharmBIO quality system which is certified to ISO 13485.
- Each produced lot is controlled according to agreed specification and lot data can be provided on a Certificate of Analysis.
- For quality control information: Contact Us

Controlled Environment

- Assembly operations, final inspection. And packaging for GORE Microfiltration Media are conducted in a cleanroom environment that employs a non-viable particulate monitoring program consistent with particle levels as defined for ISO 8 designation.

Ordering Information

- Please contact Gore for ordering samples of GORE Microfiltration Media and for more information.

Intended Use

GORE Microfiltration Media for Drug Transfer devices is a key component material for hydrophobic, antibacterial, antiviral venting solutions where fast pressure equalization is required while containing hazardous drugs. Point of use is possible in hospital and homecare applications.

Regulatory Compliance

- GORE Microfiltration Media are manufactured following the applicable material quality and regulatory requirements.
- Please contact Gore for current applicable compliance statements and quality control information.

Gore PharmBIO Products

Our technologies, capabilities, and competencies in fluoropolymer science are focused on satisfying the evolving product, regulatory, and quality needs of pharmaceutical and bioprocessing customers, and medical device manufacturers. The products in the Gore PharmBIO Products' portfolio, are tested and manufactured under stringent quality systems. These high-performance products provide creative solutions to our customers' design, manufacturing, and performance-in-use needs.

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