

STERYTEMP HIGH SERVICE LIFE FOR HOT AIR FILTRATION

- Intrinsically Hydrophobic PTFE membrane
- High effective enhanced filtering area
- Repeatedly steamable in situ or in autoclave
- Integrity testable
- Bio-Safety per USP-Plastics
- Validation Guide available on request



STERYTEMP filter element is specifically designed for the sterilizing filtration of hot air up that feeds the reactors in aerobic fermentation processes.

The filter media is a hydrophobic expanded PTFE membrane pleated with a specific Polyaramid non-woven support resisting to continuous operating high temperature; the design optimises the flow distribution between the filter media and the internal core in order to exploit the full area of the cartridge generating higher throughput and increases service life.

STERYTEMP is manufactured in a controlled environment and each cartridge is integrity tested and is validated for bacterial retention correlated to microbiological challenge test.

The retention is checked on regular sampling. PH grade is supplied with Certification of quality reporting the serial number in the box.

MATERIALS OF CONSTRUCTION

Filter media	PTFE expanded membrane
Upstream supports	NOMEX®
Downstream supports	NOMEX®
Internal Core	polypropylene
External Cage	polypropylene
End caps/Adapters	polypropylene

BIO-SAFETY

Filter media and components pass USP Biological Reactivity and Chemical-Physical tests for CLASS VI plastics.

Specific for "PH" grade: the filter meets USP "Water for injection" requirements for particle release and the effluent is Non-Pyrogenic per USP Bacterial Endotoxins (< 0,25 EU/ml).

QUALITY STANDARDS

Produced under a certified Quality System ISO 9001 certified to guarantee traceability of manufacturing records and integrity testing results.

OPERATING CONDITIONS

- max. continuous temperature	221°F (105°C)
- max. cumulative time of steam sterilization	80 hours at 284°F (140°C) with cycles of 30 minutes
- sanitization with chemicals	can be sanitized by standard chemical agents
- max. differential pressure	73 psi at 77°F (5,0 bar at 25 °C)
- recommended change out differential pressure	29 psi at 77°F (2,0 bar at 25 °C)

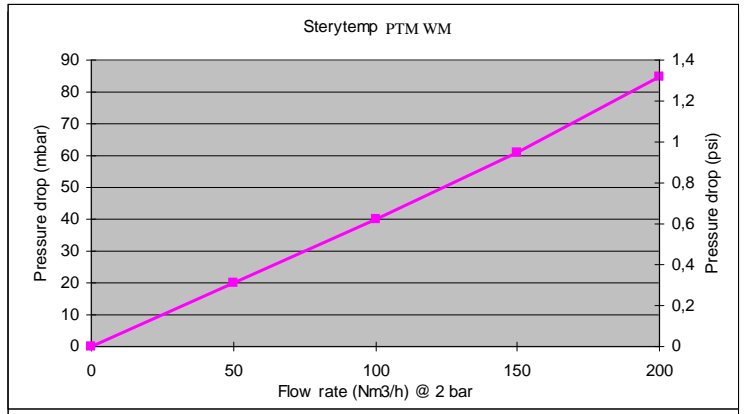
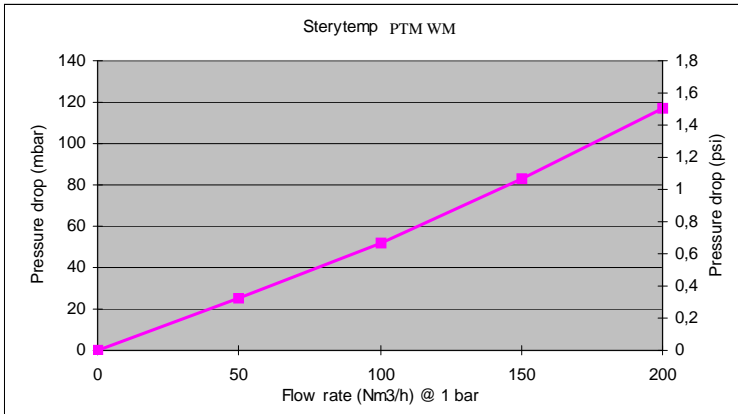
CODE	ABSOLUTE FILTRATION RATING		BACTERIAL RETENTION >10 ⁷ CFU/cm ² (1)	ACCEPTABLE LIMIT FOR DIFFUSION FLOW TEST FOR 10" CARTRIDGE (2)
	IN LIQUID	IN DRY GAS		
WM	0,2 µm	< 0,01 µm	Brevundimonas diminuta in liquid	≤17 ml/min @ 11.6 psi (0,8 bar)

Note:

1- BACTERIAL RETENTION TEST as per ASTM F838-05.

2- The integrity is verified by DIFFUSION TEST using an aqueous solution of isopropyl alcohol (IPA 60/40 V/V) as wetting agent.

AIR FLOW RATE FOR 10" CARTRIDGE



STERYTEMP ORDERING INFORMATION

PTM - 207 1 - WM - BG - SB -

END FITTING	CODE
SOE: open end adapter with (2) O-Ring 2.226 and 2 bayonet locks. Blind end with fin.	207
SOE: open end adapter with (2) O-Ring 2.222. Blind end with fin.	208
SOE: open end adapter with (2) O-Ring 2.222 and 3 bayonet locks. Blind end with fin.	212

ABSOLUTE FILTRATION RATING micron	CODE
0,2	WM (White Nomex)

CODE	PACKING TYPE
SB	Single box
MB	Multiple box

GASKETS		CODE
Standard	Silicone	No code
On request	EPDM	E

CODE	NOMINAL LENGTH
1	10"
2	20"
3	30"
4	40"

CODE	PRODUCT GRADE
BG	Biological Grade
BQ	Biological Grade; Certification of Quality in the box
PH	Biological Non-pyrogenic Grade ; Certification of Quality with serial number, in the box.

Data contained in this bulletin are informative and subject to change without notice. User is responsible for determining whether the product is fit for particular purpose and suitable for User's method of application.



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