

# **STERYSAN TSA-PH**

- Easy integrity testable in situ
- Repeatedly steamable in situ or in autoclave
- Sanitizable
- Thermowelded construction
- EC-listed materials for Food contact
- FDA-listed materials per CFR21
- **Bio-Safety per USP-Plastics**
- Validation Guide available on request

STERYSAN TSA-PH cartridge is final sterilizing filter for general application in pharmaceutical industries; prefluxed with pyrogenic water and with certification of quality reporting the serial number, it is utilized in critical applications.

Steryflus cartridges have liquid absolute filtration ratings from 0,2 micron to 0,45 micron; 0,2 micron is available with single and double membrane layers.

Manufacturing is completed in a controlled environment; each cartridge is integrity tested and the limits of acceptability are monitored on regular basis by bacteria challenge test.

Filter media	PES membrane
Upstream supports	polypropylene
Downstream sup- ports	polypropylene
Internal Core	polypropylene
External cage	polypropylene
End caps	polypropylene

### **MATERIALS OF CONSTRUCTION**

### **FOOD-SAFETY**

STERYFSAN TSA-PH filter elements meet regulation (EC) 1935/2004 for indirect food contact. **BIO-SAFETY** 

**BIO-SAFETY** Filter media and components pass USP Biological Reactivity and Chemical-Physical tests for CLASS VI plastics. 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 to guarantee traceability of manufacturing records and integrity testing results.

results.

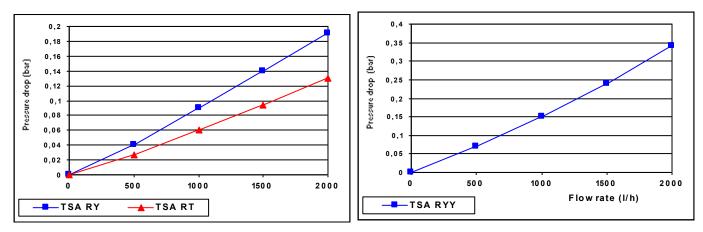
## **OPERATING CONDITIONS**

- max. continuous temperature	65 °C				
<ul> <li>max. continuous temperature for vent filter in recirculation loop</li> </ul>	20 hours at 135 °C or 40 hours at 121 °C (cycles of 30')				
- sanitization with hot water	80 °C max				
- sanitization with chemicals	can be sanitized by standard chemical agents				
- max. differential pressure	5,0 bar at 25 °C - 1,7 bar at 80 °C				
- recommended change out differential pressure	2,0 bar at 25 °C				

CODE	ABSOLUTE FILTRATION RATING IN LIQUIDS	BACTERIAL RETENTION >10 <sup>7</sup> CFU/cm <sup>2</sup> *	ACCEPTABLE LIMIT FOR INTEGRITY TEST WITH WATER FOR 10" CARTRIDGE (ml/min)			
RYY	0,2 µm double membrane	Brevundimonas diminuta	≤ 30 @ 2,8 bar			
RY	0,2 μm	Brevundimonas diminuta	≤ 30 @ 2,8 bar			
RT	0,45 µm	Serratia marcescens	≤ 30 @ 1,7 bar			
* as per ASTM F838						



### WATER FLOW RATE FOR 10" CARTRIDGE



### **STERYSAN TSA-PH ORDERING INFORMATION**

TSA -	<u>207</u>	<u>1</u> -	<u>RY</u> ·	-		-	<u>PH</u>			
END FITTING DOE: double open	CODE	FIL	SOLUTE TRATION ATING ICRON	CODE						
end with flat gaskets	200	0,	2 double embrane	RYY		CODE		PR	PRODUCT GRADE	
SOE: open end with (2) O-Ring 2.222.		0,2		RY						
Blind end with flat top.	203		0,45	RT				Biological Grade tested and prefluxed with		
SOE: open end with (2) O-Ring 2.226 and 2 bayonet locks. Blind end with fin.	207						PH	the b	ty Certificat ox.	
SOE: open end with (2) O-Ring 2.222. Blind end with fin.	208					F	РНН	and pyroo Quali	ty Certificat box with	with water. ion in
		CODE	NOMIN LENGT					num	Jei.	
		05	5″		co	CODE		GASKETS		]
		1	10″		No	code	Standard		Silicone	
		2	20″			E O		equest	EPDM	1
					'	V On re		equest	VITON	
						ĸ	On re	equest	SOFT TEFLON	

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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