PERFORMANCE GUIDE

POREX® STERILIZING FILTERS

POREX Filtration Group®

BioSolutions

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Introduction

World Class Filtration

Since 1961, Porex has been a global leader in porous plastic solutions. Our technological proficiency, commitment to stringent regulatory and quality standards, and dedication to customer service have enabled us to serve many diverse and demanding markets. From advanced filtration media to cutting-edge fluid management, our engineering expertise and extensive global manufacturing network empower our partners to explore new realms of innovation and efficiency. At our core, we strive in everything we do to make the world safer, healthier, and more productive.

Customer Focused

We believe in developing and maintaining long-term, strategic relationships with clients in order to deliver innovative real time solutions to specific customer and market requirements. Our new product innovations are derived from a collaborative philosophy where new products are developed through customer-supplier communication and cooperation. Additionally, within our organization, a crossfunctional approach to product development is utilized to ensure that the product realization cycle is fast, complete, and efficient. Due to this unique cross-functional approach and our customer-focused company culture to support this philosophy; we are able to consistently meet and exceed our customers' expectations.

Quality Control and Technical Support

All pleated filter cartridges are manufactured in one of our US facilities with US sourced materials. Our Quality Management System is certified to be ISO 9001 :2008 compliant, and our extensive internal systems ensure the highest quality products and processes. Our state-of-the-art equipment and highly skilled technicians are able to maintain the highest levels of product reliability and repeatability, from receipt of raw materials to shipment of finished filters.

A few of the controls that are in-place include:

- Raw material performance verification
- Bubble point and air diffusion testing
- Bacteria challenge verifications of performance
- Extractable verification and determination
- Ultra-pure water rinsing with resistivity verification of effectiveness
- Finished validated products are integrity tested by air diffusion

Our technical and scientific staff work closely with our clients during the validation process. The focus of this support is to offer technical advice on developing effective protocols and experimental testing parameters to assure predictable and repeatable results.

POREX STERILIZING FILTER SPECIFICATIONS

Materials of Construction

Filter Media:	Polyethersulfone
Pleat Support Material:	Polypropylene
End Caps:	Polypropylene
Reinforcing Ring:	316 Stainless Steel
Cage/Core:	Polypropylene
Sealing:	Thermal Bond
Seals:	Buna N, Fluorocarbon, EPDM, Silicone

Dimensions

Outside Diameter:	2.7” (6.87cm)
Lengths:	10" (25.4cm), 20" (50.8cm), 30" (76.2cm), 40" (102cm)
Nominal Filtration Area (10”):	6ft^2 (0.56m^2)

Performance Specifications:

Absolute Rated Retention: 0.20µm

Maximum Forward Differential Pressure

Forward:	75 psid (5.1 bar) @ 24°C
	40 psid (2.8 bar) @ 82°C
Reverse:	50 psid (3.4 bar) @ 24°C

Maximum Operating Temperature

82°C Continuous Duty

Packaging Economy

Bulk packaging in case quantities to reduce material disposal:

10 inch	24 per carton
20 inch	12 per carton
30 inch	12 per carton
40 inch	9 per carton

INTEGRITY TESTING PROCEDURES

Cartridge Installation and Sterilization Procedure

- Cut the bottom end of the sealed plastic bag, exposing the O-ring at the end of the cartridge, leaving the bag on the element for protection while handling and installing. Be careful not to damage or cut the O-ring or filter cartridge.
- Lubricate the O-rings with the process fluid, water, or other appropriate liquid (Submerging is best).
- Holding the cartridge as close to the cartridge fitting as practical, insert into base cup with slight twisting motion. Rotate the element a few degrees, if 226, to engage the retaining tabs. Please note that excessive twisting of the cartridge may cause damage.
- Remove protective bag once filter is fitted into the housing and then assemble housing based on manufacturer's protocol.
- Sterilized based on housing manufacturer's protocol.
- Differences in filter housings and configurations may affect sterilization process. Steam in place and autoclave sterilization process need to be validated by the end user. We recommend in situ steam or autoclave sterilization at 125°C for 1 hour for a total of 20 cycles, with differential pressure across the filter maintained at less than 3psi for each sterilization cycle.

Filter Wetting Procedure

- Open the vent valve to allow air inside the vessel to escape freely.
- After closing the outlet valve, fill the vessel with clean, filtered water at 15°-25 °C until it flows from the vent valve; at which time the vent may be closed.
- Open outlet valve and rinse at a flow of 7.6-11.4 LPM per 10-inch cartridge for 10-15 minutes.

Integrity Testing

We recommend an integrity test before each process run to ensure the integrity and function of the filters cartridges.

Cartridges and vessel must be at ambient temperature to perform the integrity test.

Bubble Point Testing

- Wet cartridges using filter wetting procedure.
- Open the outlet valve and using 3-4 psi/0.25 bar clean, oil and moisture-free, compressed air, apply pressure to the filter cartridge housing in the direction of filtration flow for 1 minute. This will allow residual water to drain.
- Connect the housing outlet to a tube extending into an open-top container partially filled with water, ensuring the tube end is held below the surface of the water.
- Slowly increase the inlet pressure while watching for air bubbles in the open top container.
- The bubble point is the pressure at which a surge of bubbles escapes from the tube in the open top container.
- The minimum bubble point values are listed below:

Table 1

Filter Cartridge	Min. Bubble Point (psi/bar)
SRC (0.2/0.2µm)	49/3.4
SCW (0.45/0.2µm)	49/3.4

- In the event you are unable to reach the minimum bubble point as indicated in Table 1, repeat filter wetting procedure and bubble point test, as most bubble point failures are due to incomplete wetting of the filters.

Diffusive Flow Test

- Wet cartridges using filter wetting procedure.
- Open the sample or outlet valve and using 3-4 psi/0.25 bar clean, oil and moisture-free, compressed air, apply pressure to the filter cartridge housing in the direction of filtration flow for 1 minute. This will allow residual water to drain.
- Connect suitable air flow measuring device to the vessel outlet.
- Slowly increase pressure to the filter cartridge housing up to the appropriate test pressure at 40psi.
- Upon reaching test pressure, wait 2 minutes for system to stabilize, ensuring pressure is maintained at 40psi.
- After 2 minutes, verify air diffusion flow rate (mL/min) for the system meets the acceptable limits per 10 inch equivalent as listed in Table 2.
- If the air diffusion flow exceeds the prescribed value, repeat wetting and test procedure as most failures are due to incomplete wetting of the filters.
- If the air diffusion flow fails the second time, the filter cartridge may be defective.

Table 2

Filter Cartridge	Max Air Diffusion Rate
SRC (0.2/0.2µm)	16 mL/min @ 10" cartridge
SCW (0.45/0.2µm)	26 mL/min @ 10" cartridge

BACTERIA RETENTION

Purpose:

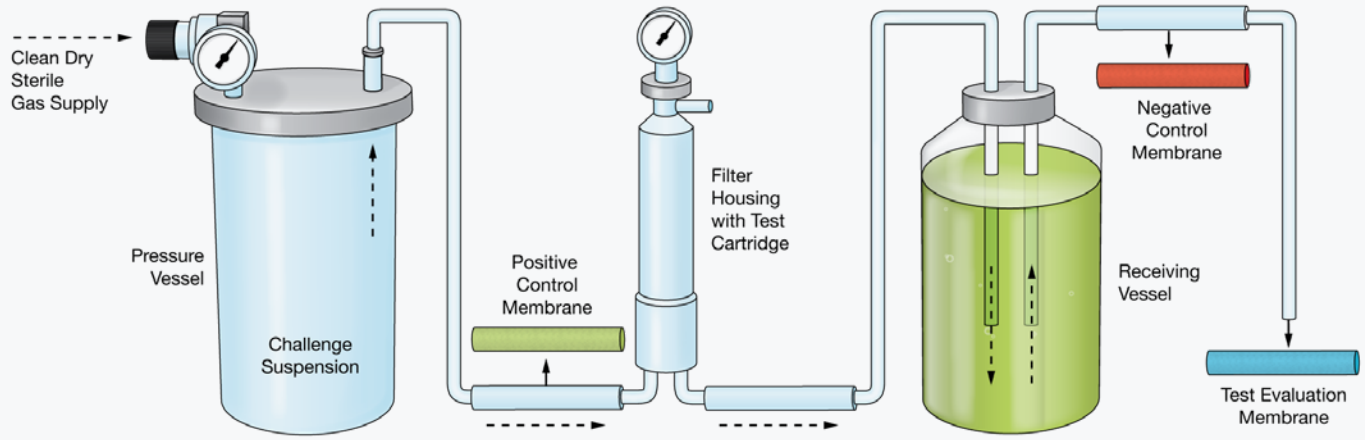
The purpose for this series of data is to provide objective evidence that the Porex Sterilizing Grade cartridges provide 100% removal of *Brevundimonas diminuta*, ATCC#19146, at a minimum challenge level of 10^7 colony forming units (CFU) per square centimeter of effective filtration area.

Methodology:

The test method utilized to conduct these studies is Nelson Laboratories, Inc. Document Number STP0l 03, revisions 1 and 2. The procedure complies in intent and content with the ASTM F838-05 Standard Test Method 'Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration" and the Health Industry Manufacturers Association (HIMA) Test Method "Microbiological Evaluation of Filters For Sterilizing Liquids".

To summarize the protocol, *Brevundimonas diminuta* is incubated in soybean casein digest broth (SCDB) initially and then a portion is transferred into saline lactose broth (SLBR) to grow the colony to a minimum challenge titer of 1 X 10^7 CFU/cm^2. The total challenge titer is based on the effective filtration area of the test filter. The positive control apparatus is setup and the culture is filtered. An aliquot of the filtrate is serially diluted. An aliquot of the appropriate dilutions is plated using the medium and incubation parameters specific to the challenge organism. The test apparatus is setup and the test filter is installed. The filter is wetted and then integrity tested, by measuring the air diffusion at specific pressures until the bubble point of the filter is reached. The filter is then sterilized either by in-line steam at 121°C-125°C or autoclaved at 121°C ± 2°C for 40 minutes. Upon completion of the sterilization cycle, the filter is then rewetted and the filtrate is collected to confirm effective sterilization; this constitutes the negative control. The filter is integrity tested again using the same methods as explained previously. The challenge suspension is then added to the system and diluted to achieve the desired challenge concentration. The system is vented, adjusted to the appropriate pressure, and then the system outlet is opened and the filtrate is collected in a sterile vessel. Upon completion, the integrity test is performed as previously explained. An aliquot of the filtrate is serially diluted. An aliquot of the appropriate dilutions is plated using the medium and incubation parameters specific to the challenge organism. The plates are then analyzed to verify each of the sequences and the log reduction value is (LRV) is calculated using the formula:

$$\mathbf{LRV = Log_{10} \frac{Number\ of\ Organisms\ in\ Challenge}{Number\ of\ Organisms\ in\ Filtrate}}$$



Schematic Diagram of the Bacteria Retention Test Apparatus

Data:

Lot #	Air Diffusion Test Pressure (psi / bar)	Air Diffusion Rate (mL/min)	CFU's in Effluent	Log Reduction Value (LRV)
393863 – 21.4	39.2/2.70	8.55	<1	>11.12
262630-63	39.2/2.70	8.75	<1	>10.84
248632-DIA 12	39.2/2.70	7.26	<1	>11.14
237382-17*	17 /1.17	12.7	<1	>11.12
237382-30*	17 /1.17	20.1	<1	>11.06
198224-1 *	17/1.17	10.0	<1	>10.92
198224-4*	17/1.17	9.0	<1	>10.92
264344-1	40/2.78	6.48	<1	>11.26
264344-2	40/2.78	8.88	<1	>11.26
267908-1	40/2.78	10.2	<1	>11.40
267908-2	40/2.78	8.7	<1	>11.40
266105-1	40/2.78	5.65	<1	> 11.26
266105-2	40/2.78	6.61	<1	>11.26
264342-1	40/2.78	5.91	<1	>11.26
264342-2	40/2.78	7.11	<1	> 11.26
264343-1	40/2.78	8.43	<1	>11.06
264343-2	40/2.78	9.56	<1	>11.06
267907-1	40/2.78	8.57	<1	> 11.40
267907-2	40/2.78	10.2	<1	> 11.40
286522-1	40/2.78	11.4	<1	> 11.02
286522-2	40/2.78	11.9	<1	> 11.02
286523-1	40/2.78	14.1	<1	>14.10
286523-2	40/2.78	15.7	<1	>15.70

*Tested with 100% water as wetting agent

Results:

Based on the table of data listed above, full removal cannot be predicted with diffusion rates above 20.1 mL/min; a safety factor of 0.8 was applied, therefore the maximum air diffusion rate that corresponds to full removal of *B. diminuta* is 16mL/min.

LIMULUS AMEBOCYTE LYSATE (LAL)

Purpose:

The Limulus Amebocyte Lysate (LAL) test is an in vitro assay for detection and quantification of bacterial endotoxin. The purpose of this report is to present the endotoxin information for appropriate specification into end user's applications.

Methodology:

The method used for the detection and quantification of bacterial endotoxins was Nelson Laboratories, Inc:s STP0046, *LAL Test; Kinetic Turbidimetric and Chromagenic Techniques Revision 5*. The summary of the method is as follows:

The instrument, assays, and templates are setup according to the appropriate Kinetic test. The sample was prepared with the extract completed using LAL reagent water (LRW) for 40-60 minutes at 37°C-40°C on an orbital shaker. A 96-well microplate is loaded, according to the template setup. Vortex all samples immediately prior to loading. 0.1 mL of endotoxin standard dilutions, 0.1 mL of LRW as the negative control, and 0.1 mL of sample are added to the designated wells. A positive control is also performed on each test article. The LAL reagent is reconstituted with an appropriate amount of LRW, and 0.1 mL is added to all of the control and sample wells. The wells are then analyzed in the micro-plate reader. The test is then incubated at 37°C ± 1 °C. Upon reaching the defined optical density, the test is initiated and analyzed with the EndoScan-V™ software or equivalent and the test reports are printed.

Data:

Lot #	**Extraction Volume** (mL/device)	**Detected Endotoxin** (EU/mL)	**Spike Recovery** (inhibition/ enhancement)
198224	2000	<0.0056	93%

Lot #	**Extraction Volume** (mL/device)	**Detected Endotoxin** (EU/device)	**Spike Recovery** (inhibition/ enhancement)
198224	2000	<11	93%

Results:

Based on the table of data listed above, Porex sterilizing filters pass USP<85> Bacteria Endotoxins.

MEM ELUTION

Purpose:
The purpose of this analysis is to evaluate the cytotoxicity of Porex filters. Samples were extracted and placed in contact with cells which are then examined for the presence or absence of cytotoxic effects.

Methodology:

The test was performed according to Nelson Laboratories, Inc:s STP0032, MEM Elution, revision 3. The summarized procedure is as follows:

The cell monolayers were rinsed and trypsinized, and re-suspended. The cell confluency was verified with a hemocytometer. The number of cells was averaged over 5 grid areas and multiplied by 10,000 to obtain the concentration of cells per mL of suspension. The cells were then diluted to a concentration of approximately 10^5 cells/mL. The culture was then seeded into cell culture plates and incubated at 37°C ±1°C with 5%±1% CO_2 for 24 hours or until the confluency approaches 80%-90%.

The samples were extracted based on weight at 0.1g/mL using 1X Minimal Essential Media with 5% Bovine Serum (filtered). Positive and negative controls are extracted concurrently. The extraction is done for 24-25 hours at 37°C ±1°C containing 5% ±1% CO_2. Sodium chloride extracts are then prepared. All extracts are filtered prior to exposure to cell monolayer. The extracts are then added to the cell culture plates and incubated at 37°C ±1°C with 5% ±1% CO_2 for 48 hours ± 3 hours and 72 hours ± 3 hours.

Data:

ID	Amount tested/ Sample Extract	Score 1		Score 2		Score 3		Score 4	
		48 hr	72 hr	48 hr	72 hr	48 hr	72 hr	48 hr	72 hr
Negative Control	4g/20mL	0	0	0	0	0	0	0	0
Media Control	20mL	0	0	0	0	0	0	0	0
Positive Control	4g/20mL	4	4	4	4	4	4	4	4
Lot# 198224	33g/1670mL	0	0	0	0	0	0	0	0

Scale:

Grade	Reactivity	Description of Reactivity Zone
0	None	Discreet intra-cytoplasmic granules, no cell lysis.
1	Slight	Not more than 20% of the cells are rounded, loosely attached, and without intra-cytoplasmic granules; occasional lysed cells are present.
2	Mild	Not more than 50% of the cells are rounded and devoid of intra-cytoplasmic granules; no extensive cell lysis and empty areas between cells.
3	Moderate	Not more than 70% of the cells are rounded and/or lysed.
4	Severe	Nearly complete destruction of the cells.

Results: Based on the data above, Porex sterilizing filters are non-cytotoxic per MEM Elution ISO 10993-5.

INTEGRITY AFTER STEAM STERILIZATIONS

Purpose:

The purpose of this study is to provide the data to support the claim that Porex filters maintain structural and performance integrity after 20, 1-hour in situ steam sterilization cycles at 257°F (125°C).

Methodology:

Ten inches filter cartridges were integrity tested and then in situ steam sterilized at 257°F for 1 hour for a total of 20 cycles. The air diffusion of the filters was evaluated after every cycle (and 20th) to ensure no quality degradation was occurring due to the repeated steam cycles. Differential pressure across filters was maintained at less than 3 psi for each sterilization cycle.

Data:

Lot #	Sterilization Cycle (in situ steam at 257ºF/125ºC for 1-hour)	Test Pressure (psi)	Air Diffusion Rate (mL/min)
248632-DIA 13	Initial	39.2	3.8
	1	39.2	4.2
	2	39.2	4.0
	3	39.2	3.8
	4	39.2	4.6
	5	39.2	4.6
	6	39.2	2.0
	7	39.2	3.1
	8	39.2	2.8
	9	39.2	5.9
	10	39.2	4.0
	11	39.2	3.2
	12	39.2	1.6
	13	39.2	3.4
	14	39.2	3.9
	15	39.2	3.1
	16	39.2	3.8
	17	39.2	3.2
	18	39.2	4.1
	19	39.2	2.5
	20	39.2	2.4

Results:

These test results validate that filter integrity is maintained after 20, 1 hour in situ steam sterilization cycles at 125°C, with differential pressure across the filter maintained at less than 3psi for each sterilization cycle.

USP BIOLOGICAL REACTIVITY TESTS, IN VIVO

Purpose:

The purpose of this test is to verify that the filters meet the requirements of USP Plastic Class VI, by performing and meeting the requirements of USP Intracutaneous Irritation Test, USP Acute Systemic Injection Test, and USP Intramuscular Implantation Test – 1 week.

Methodology:

The USP Intracutaneous Irritation Test determines if any chemicals that may leach or be extracted from the test article were capable of causing local irritation in the dermal tissues of the rabbit using the standard USP Intracutaneous Test procedure.

The USP Acute Systemic Injection Test screens test article extracts for potential toxic effects as a result of a single dose systemic injection in mice using standard USP Acute Systemic Injection Test procedure.

The USP Intramuscular Implant Test evaluates the potential toxic effects of a biomaterial in direct contact with living muscle tissue of the rabbit for 7 days using the Standard USP Implantation Test.

USP Intracutaneous Irritation Test: Each rabbit received five sequential 0.2mL Intracutaneous injections along either side of the dorsal mid-line with the test article extract on one side and the concurrent vehicle control on the other. The vehicles used were 0.9% normal saline (NS), cottonseed oil (CSO), polyethylene glycol 400 (PEG) and 5% ethanol in normal saline (AS). The irritation reaction of the extracts was compared to vehicle controls and recorded over a 72-hour period according to the standard USP Irritation Scoring System. According to USP test criteria, if the difference between the average scores for the extract of the test article and the vehicle control is less than or equal to 1.0, the test article is considered non-irritating. This study was conducted in accordance with the USP Intracutaneous Test Procedure, United States Pharmacopeia, Section 88.

USP Acute Systemic Injection Test: For the safety evaluation of the test article, mice were injected systemically with extracts of the test article in standard USP solutions (normal saline, sesame oil, 5% ethanol in saline and polyethylene glycol 400). The animals were observed for signs of toxicity immediately after injection and at 24, 48 and 72 hours (+/- 2 hrs.) post-injection. The requirements of the test are met if none of the animals treated with the test article extract have a significantly greater adverse reaction than the animals treated with the vehicle control. This study was conducted in accordance with the USP Acute Systemic Injection Test Procedure, United States Pharmacopeia, Section 88.

USP Intramuscular Implant Test: For the safety evaluation of a test article, sec tions of the test article and negative control were implanted surgically in the paravertebral muscles of rabbits. After a 7-day exposure period, the animals were sacrificed and the paravertebral muscles removed. The implantation sites were examined macroscopically and scored for encapsulation. The requirements of the test are met if the difference between the mean test article score and the negative control mean score do not exceed 1.0 for more than one of the four implant sites for any implanted animal. This study was conducted in accordance with the USP Implantation Test Procedure, United States Pharmacopeia, Section 88, but modified for a surgical (direct) implantation.

Data:

Study	Results
USP Intracutaneous Irritation Test	Non-Irritant
USP Acute Systemic Injection Test	No Clinical Signs of Toxicity
USP Intramuscular Implantation Test – 1 week	Non-Irritant

Results:

Based on the results of the USP Intracutaneous Irritation Test, USP Acute Systemic Injection Test, and USP Intramuscular Implantation Test – 1 week, the filters meet the requirements of USP<88> Biological Reactivity test in vivo, for class VI plastics.

USP PHYSICOCHEMICAL TESTS FOR PLASTICS

Purpose:

The purpose for this is to provide data regarding the chemical composition of materials that may be extracted from a typical Porex product in samples of sterile purified water, sterile water for irrigation, sterile water for injection, sterile water for inhalation, and/or water for hemodialysis.

Methodology:

The methods used to complete these testes are outlined in Nelson Laboratories, Inc. Document Numbers STP0017, USP Physicochemical Tests for Plastics, and STP0018, USP Oxidizable substances.

Extraction:

The sample is extracted using USP Purified Water with a blank of USP Purified Water of identical volume. The sample is then placed in an oven at 70°C±2°C for 24±2 hours. Upon completion, the samples are cooled to approximately, but not below, 20°C and the sample extract is immediately decanted into a separate container and sealed.

Buffering Capacity:

After measuring the pH of 20mL of sample extract and a similar volume of the blank, titrate, in 0.1 mL increments, 0.01 N HCL or 0.01 N NaOH, to a pH of 7.0 and record the volume of reagent used. If the difference between the volumes of reagent required to achieve a pH of 7.0 is ≤ 10mL, the sample passes the test.

Nonvolatile Residue (NVR):

The test crucibles are acid cleaned with 6N HCL and then, at a minimum, triple-rinsed with purified water. The crucibles are then dried in an oven at 105°C ± 2°C for at least 30 minutes and then they are placed into a furnace at approximately 800°C for at least an hour, and then they are placed back into the oven at 105°C ± 2°C for an additional 1 hour. The crucibles are then placed in a desiccator for at least 2 hours. Upon completion, the crucibles are weighed to the nearest 0.1 mg. 50mL of sample extract and blank are transferred into separate crucibles and heated without boiling to evaporate the volatile material. The crucibles are placed into an oven at 105°C ± 2°C for 1 hour 10 minutes ± 10 minutes and then allowed to cool for 2 hours. Each crucible is re-weighed to the nearest 0.1 mg to determine the amount of nonvolatile residue by calculating the difference between the blank and sample. The sample passes the test if the residue does not exceed 15mg.

Residue On Ignition:

The residue from the NVR, both sample and blank, is moistened with a small amount of concentrated sulfuric acid and heated on a hot plate until no more white fumes are observed. Each sample is ignited in a furnace at 600°C ±50°C for approximately 30 minutes. The crucibles are then removed and allowed to cool in a desiccator. Each crucible is re-weighed and subtracted from the initial weight, with the difference being the weight of the residue on ignition. The sample passes the test if the residue on ignition is ≤5mg.

Heavy Metals:

A standard lead solution is prepared by diluting 1 mL of 1000mg/L lead stock solution with 100mL of USP purified water. 20mL of sample extract and blank are transferred to separate test tubes. 2mL of lead solution is added to the blank test tube; this is the test control. The pH of the sample test tube is adjusted to between 3 and 4 using either 1 N acetic acid or 6N ammonium hydroxide. Dilute each test tube, both blank and sample, with purified water to a total volume of 35mL and mix. A thioacetamide-glycerin base TS is then prepared. 2mL of pH 3.5 acetate buffer followed by 1.2mL of thioacetamide-glycerin base TS is added to each test tube and then diluted with purified water to a total volume of 50mL and mixed. The test tubes are allowed to stand for 10 minutes and then observed by looking down the test tube, through the liquid using a white surface as a background. The sample passes the test if after 10 minutes any brown color produced in the sample extract is not darker than the color produced in the control.

USP Oxidizable Substances:

Using 100mL of extract, 10mL of 2N sulfuric acid is added and the solution is heated to boiling. The appropriate amount of 0.1 N potassium permanganate is added as defined in Nelson Laboratories, Inc. STP0018 and allowed to boil an additional 5 minutes. If a precipitate forms, the solution is cooled to room temperature and filtered. The sample passes if the pink color does not completely disappear.

Data:

Total Extractable Residue:	
Lot #	**Total Extractable Residue (mg)**
207910-1	26
198224	120

Buffering Capacity:			
Lot #	**Result (mL)**	**Maximum Limit (mL)**	**Pass/Fail**
207910-1	<0.1	≤10.0	Pass

Nonvolatile Residue:			
Lot #	**Result**	**Maximum Limit**	**Pass/Fail**
207910-1	<1	≤15	Pass
198224	3.7	≤15	Pass

Residue on Ignition:			
Lot #	**Result**	**Maximum Limit**	**Pass/Fail**
207910-1	Waive Pass*	≤5mg	Pass
198224	Waive Pass*	≤5mg	Pass
*Due to nonvolatile residue be ≤5mg, Residue on ignition will also be ≤5mg			

Heavy Metals:			
Lot #	**Result**	**Maximum Limit**	**Pass/Fail**
207910-1	<1ppm	≤1ppm	Pass

USP Oxidizable Substances:			
Lot #	**Result**	**Maximum Limit**	**Pass/Fail**
207910-1	Pink	Pink Remains	Pass
198224			Pass

Results:

Based on the tables of data listed above, Porex sterilizing filters meet the criteria for extractables per USP Physicochemical Tests for plastics, and USP Oxidizable Substances.

CONTACT US

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For technical information including performance guide, instructions for use, and certificate of quality, please visit our website.

POREX Filtration Group®

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