BioPharmaceuticals

Validation Guide

USTR 2058

Validation Guide for Pall Preflow filter cartridges

*Filtration. Separation. Solution.*SM

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Independent Report On Biological Safety Of 'Pall' 'Preflow' Filter Cartridges 16

1 Overview

1.1 Introduction

Pall Preflow pre-filter cartridges utilise pleated glass fibre membranes for the enhanced protection of final sterilising grade filters used in the pharmaceutical industry. Pall Preflow filters are available in two membrane grades: UUA and UB.

This report summarises the results of the validation test work that has been performed to substantiate the claims made for these products. This validation program included:

- Determination of water flow / differential pressure characteristics
- Determination of gravimetric extractables
- Steam sterilisation endurance tests
- Biological safety tests on all filter components
- Review of typical QC manufacturing tests

1.2 Summary of conclusions

Water flow / differential pressure

The water flow rates at 100mbar differential pressure for standard Preflow filter cartridges from production were found to be:

- 30.5 l/min for Preflow grade UUA filters, part number AB1UUA7PH4
- 27.5 l/min for Preflow grade UB filters, part number AB1UB7PH4

Theses data can be used to form the basis of sizing filter systems using Preflow filter cartridges.

Gravimetric extractables

For Preflow filter cartridges pre-treated by in-line steam sterilisation or autoclave, the average amount of aqueous extractables were determined to be as follows:

- 91 mg per AB1UUA7PH4 filter cartridge determined over a 24 hour extraction period
- 152 mg per AB1UB7PH4 filter cartridge over a 4 hour extraction period

These levels of aqueous extractables determined for Preflow filters are typical for production elements.

Endurance to steam sterilisation

Preflow filters retained constructional integrity following exposure to three one hour steam cycles. These data demonstrate that Preflow filters withstand cumulative steam exposure.

Biological reactivity tests

Preflow filter cartridges meet the requirements of the USP for Class VI -121°C Plastics *(in vivo)*.

Certification of 'P' grade filters

Preflow UUA and UB ‘P’-grade filters are supplied with a certificate of test that confirms that the filters have been manufactured in a controlled environment and that samples from each batch have been subjected to QC testing for filter cleanliness.

2. Water flow / differential pressure

2.1 Aims

The aim of these tests was to determine the differential pressures measurements across Preflow filter cartridges at set water flow rates.

2.2 Summary of methods

The tests were performed on standard production filters (part numbers AB1UUA7PH4 and AB1UB7PH4). Test filters were installed in an appropriate assembly and pre-filtered deionised water was pumped through the filters in the normal flow ('out to in') direction. Pressure transducers on the upstream and downstream side of the test assembly were monitored to calculate the differential pressure at set water flow rates.

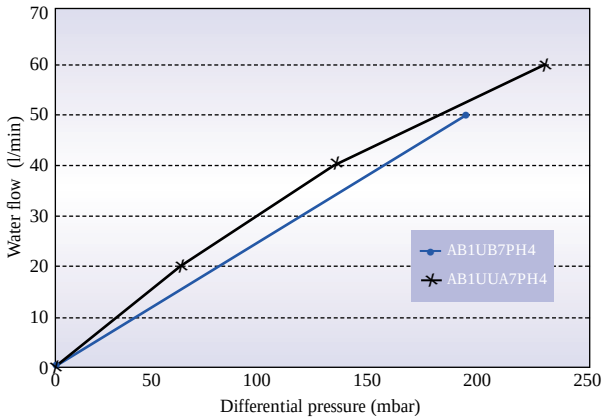
Further measurements were taken with the filter housing only, with no filter installed. The housing - only results were subtracted from the filter assembly results in order to provide flow/pressure characteristics for the filter only. All data were corrected to a standard temperature of 20°C.

Please contact Pall if further details about the test methods are required.

2.3 Results

The water flow / differential pressure measurements obtained using typical Preflow filters (part numbers AB1UUA7PH4 and AB1UB7PH4) are shown in Figure 2-1.

Figure 2-1. Water flow / differential pressure characteristics for 25cm Pall Preflow filters



2.4 Conclusions

The water flow rates at 100mbar differential pressure for standard Preflow filter cartridges from production were found to be:

- 30.5 l/min for Preflow grade UUA filters, part number AB1UUA7PH4
- 27.5 l/min for Preflow grade UB filters, part number AB1UB7PH4

These data can be used to form the basis of sizing filter systems using Preflow filter cartridges.

Note: The differential pressures quoted are for liquids with a viscosity of 1cP. Differential pressures for liquids at other viscosities can be estimated by multiplying the differential pressure by the viscosity in cP. To obtain the total pressure drop of a complete filter assembly the housing pressure drop must also be added. Please contact Pall if further details are required.

3. Extractables testing of Preflow filter cartridges

3.1 Aims

The aim of this series of tests was to quantify and characterise the material that can be extracted from Preflow filters by water.

3.2 Summary of methods

Extractables tests were performed on standard production filter cartridges (part numbers AB1UUA7PH4 and AB1UB7PH4). The tests were performed on filters as received directly from production and also on filter samples that had been pre-treated by autoclave or in-line steaming at 125°C (257°F) for one hour. The purpose of the pre-treatment was to mimic the process conditions that could increase the quantity of any extractable material present.

The dynamic extraction tests were performed in water. The test filters were immersed in a volume of extraction fluid in a clean measuring cylinder. For a number of hours (> 4 hours) the filter was gently moved up and down in the extraction fluid. This movement of the filter created flow through the membrane as a result of the pressure head that was created each time the element was partially lifted out of the liquid.

Following the extraction period a sample of the water was evaporated to dryness and the level of non-volatile extractable material was determined gravimetrically. A correction factor was applied to give a value for the entire extraction volume.

The material extracted from each grade of filter was also analysed by Fourier Transform Infrared Spectroscopy (FTIR).

Please contact Pall if a more detailed description of the test methods is required.

3.3 Results

Table 3-1 shows the levels of aqueous extractables obtained using standard Preflow filters from production (part numbers AB1UUA7PH4 and AB1UB7PH4).

Some of the filters had been pre-treated by steaming or autoclaving in order to simulate ‘worst case’ conditions. Pre-steaming the filters was found to increase the level of extractables for the UUA-grade filters, however autoclaving was found to have little influence on the amount of material extracted from the UB-grade samples. In all cases the extractables were found to be less ≤ 106 mg per AB1UUA7PH4 and ≤ 167 mg per AB1UB7PH4 filter.

Table 3-1. Non-volatile aqueous extractables obtained from 25cm Preflow filters

Pall filter part number	Pall filter part serial number	Pre-treatment	Extraction time	Residue
AB1UUA7PH4	EJ0680039 EJ0680023 EJ0690000 EJ0690039 EJ0700049 EJ0700085	None	24 hours 24 hours 24 hours 24 hours 24 hours 24 hours	62mg 64mg 67mg 51mg 54mg 48mg
AB1UUA7PH4	EJ0680037 EJ0680076 EJ0690076 EJ0690009 EJ0700005 EJ0700026	Steamed 125°C (257°F) for 60 minutes	24 hours 24 hours 24 hours 24 hours 24 hours 24 hours	106mg 81mg 88mg 78mg 105mg 86mg
AB1UB7PH4	IC4045030 IC4045010	None	4 hours 4 hours	167mg 156mg
AB1UB7PH4	IC4045031 IC4045047	Autoclaved 125°C (257°F) for 60 minutes	4 hours 4 hours	156mg 147mg

Infra red spectra (Figures 3-2 and 3-3) of the material extracted from Preflow filters indicate the presence of components extracted from the polyester support and drainage materials and also material extracted from the filter membrane (eg silica and binder resins).

Table 3-2. Infra red spectrum of aqueous extracts from Preflow grade UB filter cartridges

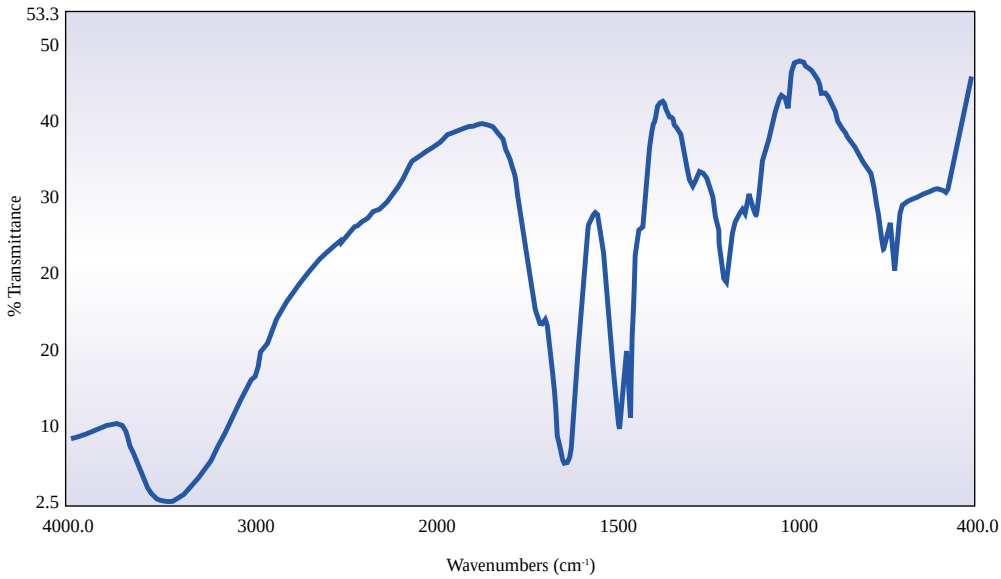
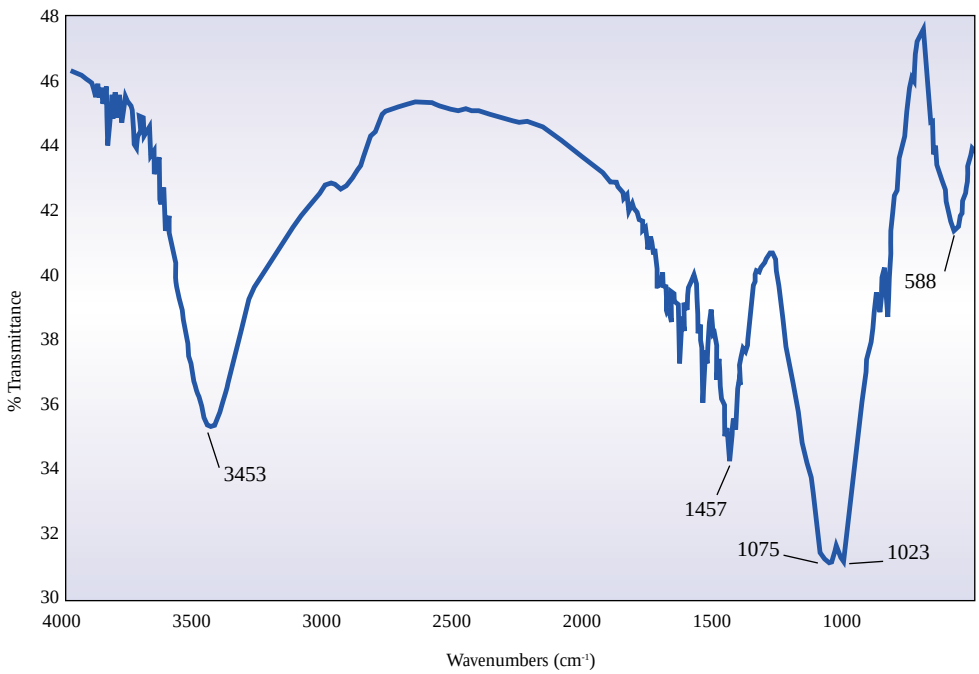


Table 3-3. Infra red spectrum of aqueous extracts from Preflow grade UUA filter cartridges



3.4 Conclusions

For Preflow filter cartridges pre-treated by in-line steam sterilisation or autoclave, the average amount of aqueous extractables were determined to be as follows:

- 91 mg per AB1UUA7PH4 filter cartridge determined over a 24 hour extraction period
- 152 mg per AB1UB7PH4 filter cartridge over a 4 hour extraction period

These levels of aqueous extractables determined for Preflow filters are typical for production elements.

Actual service will impose different conditions, such as different exposure times, temperature, liquid purity etc. Evaluation under process conditions is therefore also recommended.

4. Endurance to steam sterilisation

4.1 Aims

The aim of these tests was to determine the endurance of Preflow filter cartridges to in-line steam sterilisation.

4.2 Summary of methods

Standard Preflow filter cartridges from production (part numbers AB1UUA7PH4 and AB1UB7PH4) were used for these tests. The procedure used was based on the recommended instructions for steam sterilisation described in Pall publication USD805 'Steam Sterilisation of Pall Filter Assemblies which Utilise Replaceable Filter Cartridges'

The filters were installed in a stainless steel housing and steamed in-line using saturated condensate-free steam. In each series of tests the following was performed:

- Filters were subjected to one hour cycles of steam sterilisation at either 125°C (257°F) or 140°C (284°F)
- Steam pressure and temperature was held constant during the sterilisation period
- After each steam cycle the filter assembly was cooled
- After three one hour steam in place cycles had been performed the constructional integrity of the filters was confirmed.

Please contact Pall if further details about the test methods are required.

4.3 Results

The results are shown in Table 4-1. All of the filters were found to retain constructional integrity following exposure to three one-hour steam cycles.

Table 4-1. Integrity of Preflow filters following exposure to three steam in place cycles

Pall filter part number	Pall filter batch number	Steam temperature	Result of post-steam test following 3 cycles
AB1UUA7PH4	EJ082 Sample A EJ082 Sample B EK007 Sample A EK007 Sample B	140°C (284°F)	Pass Pass Pass Pass
AB1UB7PH4	IC7708 Sample A IC7708 Sample B IC7708 Sample C IC7708 Sample D IC7708 Sample E	125°C (257°F)	Pass Pass Pass Pass Pass

4.4 Conclusions

Preflow filters retained constructional integrity following exposure to three one hour steam cycles. These data demonstrate that Preflow filters withstand cumulative steam exposure.

5. Biological safety tests on components of Preflow filter cartridges

5.1 Aims

The aims of this study was to evaluate the biological suitability of the materials of construction of Preflow filter cartridges. The materials of construction of Preflow filters (both UUA and UB grades) are as follows:

Filter membrane	Resin - bonded glass fibre
Support / drainage layers	Non - woven polyester
Core, cage, and endcaps	Natural unpigmented polypropylene homopolymer

5.2 Summary of methods

The tests were performed in accordance with the Biological Reactivity Tests *in vivo* for Class VI - 121°C Plastics as described in the current United States Pharmacopeia.

The tests were conducted by Gibraltar Laboratories Inc., Fairfield, New Jersey.
The testing procedures described in the USP include:

- Injection of extracts of plastic materials
- Implantation of the solid material into animal tissue.

The four extracting media listed in the USP simulate parenteral solutions and body fluids. These include:

- Sodium Chloride Injection
- 1 in 20 Solution of Alcohol in Sodium Chloride Injection
- Polyethylene Glycol 400
- Vegetable Oil (sesame or cottonseed oil).

The USP states that extracts may be prepared at one of three standard conditions: 50°C (122°F) for 72 hours, 70°C (158°F) for 24 hours, or 121°C (250°F) for 1 hour. The most stringent condition not resulting in physical changes in the plastic is recommended, therefore the filters were extracted at 121°C (250°F).

Acute Systemic Injection Tests

An Acute Systemic Injection Test was performed to evaluate the potential of a single injection of an extract to produce systemic toxicity. Sodium Chloride Injection and 1 in 20 Solution of Alcohol in Sodium Chloride Injection were injected intravenously. Vegetable oil extract and Polyethylene Glycol 400 extract were injected intraperitoneally.

Intracutaneous Tests

An Intracutaneous Test was performed to evaluate the potential of a single injection of an extract to produce tissue irritation. All four of the extracts listed above were used for these tests.

Implantation Tests

Implantation tests were also performed, in order to subject the materials of construction to the most stringent conditions included in the USP. Each of the components of the Preflow filter cartridges were implanted separately.

5.3 Results

The components of Preflow filters passed all of the tests specified. See Appendix 1 for copies of the test reports.

5.4 Conclusions

Preflow filter cartridges meet the requirements of the USP for Class VI -121°C Plastics *(in vivo)*.

6. Testing and Certification of 'P' grade filters

6.1 Introduction

P-grade filters are manufactured in a controlled environment and are subject to stringent quality control tests. Samples of filters taken from each manufacturing batch are subjected to the following tests:

- Fabrication integrity
- Cleanliness
- Total organic carbon
- pH shift
- Pyrogens

This section of the report describes a summary of the routine QC tests performed and presents the results obtained from typical manufacturing batches of Preflow filters (part numbers AB1UB7PH4 and AB1UUA7PH4).

6.2 Summary of methods

The tests described below are performed on a sample of filters taken from every batch of Preflow filters that are manufactured.

Cleanliness tests

Cleanliness tests are performed by flushing deionised water through the filter samples at a set flow rate for 15 minutes. The filtrate quality is measured by counting particles and fibres collected on analysis discs positioned on the downstream side of the filter.

The analysis discs are placed on the downstream side of the filters during the initial five minutes and the final five minutes of the 15-minute flush. After the analysis discs have been dried they are examined microscopically for the presence of fibres and particles ≥ 5 µm in size that have been extracted from the filter (particles with an aspect ration of ≥ 3:1 are counted as fibres).

The maximum allowable limits for the cleanliness tests are as follows:

Particles ≥ 5µm	< 250 per ft^2 of membrane per litre of flushed water
Fibres ≥ 5µm	< 50 per ft^2 of membrane per litre of flushed water

Total organic carbon and pH

During the performance of the cleanliness tests, upstream and downstream water samples are taken and Total Organic Carbon (TOC) and pH is determined in each sample. The TOC and pH values measured in the water that has been flushed through the filter is compared with the value determined using the upstream unfiltered water. The tests have passed if the TOC and pH values obtained meet the current USP requirements under purified water and packaged water respectively after flushing.

Pyrogens

The pyrogens test is performed using a wrapped filter that has been autoclaved and then soaked for one hour in endotoxin-negative water. The amount of endotoxins in a sample of the soak water is then determined using the *Limulus amebocyte* lysate gel clot method.

A negative result indicates that there is less than 0.125 endotoxin units (EU)/ml in the sample and that the sample meets the current USP requirements under Bacterial Endotoxins Test.

Please contact Pall if further details about any of the test methods are required.

6.3 Results

Table 6-1 shows the QC test results obtained during the production of typical manufacturing batches.

Table 6-1. 'P' test results from typical batches of Preflow filter cartridges

Pall filter part number and manufacturing batch number	Results of QC testing				
	Particles	Fibres	TOC	pH	Pyrogens
AB1UUA7PH4 EJ079 EJ082 EJ081	 Pass Pass Pass	 Pass Pass Pass	 Pass Pass Pass	 Pass Pass Pass	 Pass Pass Pass
AB1UB7PH4 ID2935 IC9524 IC8471	 Pass Pass Pass	 Pass Pass Pass	 Pass Pass Pass	 Pass Pass Pass	 Pass Pass Pass

6.4 Conclusions

Preflow UUA and UB ‘P’- grade filters are supplied with a certificate of test that confirms that filters have been manufactured in a controlled environment and that the tests described above have been performed on a sample of filters taken from the manufacturing lot provided.

Appendix 1

Independent report on Biological Safety of Pall Preflow filter cartridges

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e-mail: danielprince@gibraltarlabsinc.com • internet: http://www.gibraltarlabsinc.com

REPORT No. G-23636
11/23/99
1 of 2

LABORATORY REPORT

FINAL REPORT

Sponsor:(0850)
Pall Corporation
25 Harbor Park Drive
Port Washington,NY,11050
Attn: Janet Mathus
Purchase Order #:P434807

GBL Ref.: 1410- 196- 7275
GBL Sample No.:12673/A-D.30
Lot #1:1C7708
Lot #2: PN AB1UB7PH4
Lot #3: None
Date Received: 10/27/99
Date Tested: 11/04/99
Date Completed: 11/12/99

USP 23 CLASS VI on Preflow^{R} UB Filter
Interim Report Activity:

Description:
One white plastic filter cartridge with a spike at one end and two orange O-rings at the other. The following components to be tested as a composite for Intracutaneous Irritation and Systemic Toxicity and Individually for Implantation:(1) Polyester drainage material (2) Glass fiber filter media on polyester substrate (3) Polypropylene filter core, endcap or adaptor and (4) Polypropylene cage containing white pigment.

1 Purpose
To determine the reaction of normal animal tissue and living animals to the presence of extracts and/or portions of the test material.

2 Test System
2.1 New Zealand albino rabbits, either sex, 1.91 to 3.39 kg.
Two per extract and two per implant.
2.2 Swiss Webster albino mice, male, 21.1 to 30.7 grams.
Five test and control (intravenous and intraperitoneal injection).

3. Method: Test Material Preparation and Extraction
A composite of the following materials was extracted in 20 mL of each of the below solvents. Each component was tested separately for implantation.
/1 30 cm^2 - Polyester drainage material
/2 30 cm^2 - Glass fiber filter media on polyester substrate
/3 1.0 gram - Polypropylene filter core
/4 1.0 gram - Polypropylene Cage containing white pigment

3.1 Solvents
(X) USP Sodium Chloride for Injection (Saline)
(X) 5% Ethanol in Sodium Chloride (ETOH/Saline)
(X) Cottonseed Oil (CSO)
(X) Polyethylene glycol 400 (PEG)

Conclusion: The material conforms to the requirements of this test.

Respectfully Submitted,
GIBRALTAR LABORATORIES, INC.

Date
Written: 11/23/99 Approved By: J. Chris Knutsen, Ph.D. or Daniel L. Prince, Ph.D.
Analyst: 41
Protocol #: None

AUDIT GBL

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2 of 2

LABORATORY REPORT

3.2 Extraction Conditions
(X) 121C for one hour

3.3 Dosing Procedures
(X) IC Injection - three day observation period
(X) Systemic Injection (IV and IP) - three day observation period
(X) Intramuscular Implantation - seven day observation period

4. Results: See Tables 1 to 7.

Table 1: Intracutaneous Irritation

Extract	Average Test Score	Average Control Score	Difference
Saline	(0.00)	(0.00)	(0.00)
ETOH/Saline	(0.00)	(0.00)	(0.00)
CSO	(1.50)	(2.33)	(0.83)
PEG 400	(0.00)	(0.00)	(0.00)

Table 2: Systemic Toxicity

	(Test Group)		(Control Group)		
Extract	Death	Morbidity	Death	Morbidity	Difference
Saline	0/5	0/5	0/5	0/5	0/5
ETOH/Saline	0/5	0/5	0/5	0/5	0/5
CSO	0/5	0/5	0/5	0/5	0/5
PEG 400	0/5	0/5	0/5	0/5	0/5

Table 3: Intramuscular Implantation - Polyester drainage material

Sample Size	Average Test Score	Average Control Score	Difference
1 x 10 mm	(0.13)	(0.00)	(0.13)

Table 4: Intramuscular Implantation - Glass fiber filter media

Sample Size	Average Test Score	Average Control Score	Difference
1 x 10 mm	(0.25)	(0.00)	(0.25)

Table 5: Intramuscular Implantation - Polypropylene filter core

Sample Size	Average Test Score	Average Control Score	Difference
1 x 10	(0.00)	(0.00)	(0.00)

Table 6: Intramuscular Implantation - Polypropylene cage

Sample Size	Average Test Score	Average Control Score	Difference
1 x 10	(0.00)	(0.00)	(0.00)

Independent report on Biological Safety of Pall Preflow filter cartridges (*continued*)

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25 Harbor Park Drive
Port Washington,NY,11050
Attn: Janet Mathus
Purchase Order #:P434807

GBL Ref.: 1422- 196- 7357
GBL Sample No.:16874/ 1.339
Lot #1:AB1UUA7H4
Lot #2: None
Lot #3: None
Date Received: 03/07/00
Date Tested: 03/13/00
Date Completed: 03/24/00

USP 24 CLASS VI on Preflow^{R} UUA Filter
Interim Report Activity:

Description:
One white plastic filter cartridge with a spike at one end and two orange O-rings at the other end.
/1 = Glass fiber filter membrane
/2 = Polypropylene drainage layer
/3 = Whitened polypropylene cage
/4 = Polypropylene core

1 Purpose
To determine the reaction of normal animal tissue and living animals to the presence of extracts and/or portions of the test material.

2 Test System
2.1 New Zealand albino rabbits, either sex, 1.96 to 3.25 kg.
Two per extract and two per implant.
2.2 Swiss Webster albino mice, male, 16.5 to 23.7 grams.
Five test and control (intravenous and intraperitoneal injection).

3. Method: Test Material Preparation and Extraction
A composite of the following materials was extracted in 20 mL of each of the below solvents. Each component was tested seperatly for implantation.
/1 30 cm^2 - Glass Fiber Filter Membrane
/2 30 cm^2 - Polypropylene Drainage Layer
/3 1.0 gram - Whitened Polypropylene Cage
/4 1.0 gram - Polypropylene Core

3.1 Solvents
(X) USP Sodium Chloride for Injection (Saline)
(X) 5% Ethanol in Sodium Chloride (ETOH/Saline)
(X) Cottonseed Oil (CSO)
(X) Polyethylene glycol 400 (PEG)

Conclusion: The material conforms to the requirements of this test.

Respectfully Submitted,
GIBRALTAR LABORATORIES, INC.

Date
Written: 05/01/00 Approved By: _____
Analyst: 41 J. Chris Knutsen, Ph.D. or Daniel L. Prince, Ph.D.
Protocol #: None

AUDIT rep 5/11/00 GBL

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2 of 2

LABORATORY REPORT

3.2 Extraction Conditions
(X) 121C for one hour

3.3 Dosing Procedures
(X) IC Injection - three day observation period
(X) Systemic Injection (IV and IP) - three day observation period
(X) Intramuscular Implantation - seven day observation period

4. Results: See Tables 1 to 6.

Table 1: Intracutaneous Irritation

Extract	Average Test Score	Average Control Score	Difference
Saline	(0.00)	(0.00)	(0.00)
ETOH/Saline	(0.00)	(0.00)	(0.00)
CSO	(1.67)	(2.17)	(0.50)
PEG 400	(0.00)	(0.00)	(0.00)

Table 2: Systemic Toxicity

	(Test Group)		(Control Group)		
Extract	Death	Morbidity	Death	Morbidity	Difference
Saline	0/5	0/5	0/5	0/5	0/5
ETOH/Saline	0/5	0/5	0/5	0/5	0/5
CSO	0/5	0/5	0/5	0/5	0/5
PEG 400	0/5	0/5	0/5	0/5	0/5

Table 3: Intramuscular Implantation - Polyester drainage material

Sample Size	Average Test Score	Average Control Score	Difference
1 x 10 mm	(0.00)	(0.00)	(0.00)

Table 4: Intramuscular Implantation - Glass fiber filter media

Sample Size	Average Test Score	Average Control Score	Difference
1 x 10 mm	(0.13)	(0.00)	(0.13)

Table 5: Intramuscular Implantation - Polypropylene filter core

Sample Size	Average Test Score	Average Control Score	Difference
1 x 10	(0.00)	(0.00)	(0.00)

Table 6: Intramuscular Implantation - Polypropylene cage

Sample Size	Average Test Score	Average Control Score	Difference
1 x 10	(0.00)	(0.00)	(0.00)

PALL BioPharmaceuticals

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