



**VALIDATION  
FOR  
ULTRAPOLYPLEA P-PP/P-PP 100  
FILTER CARTRIDGE**



REG. NO. 234 Q1



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# INTRODUCTION

This validation guide summarizes the extensive testing and evaluation program prepared by ultrafilter AG. This data includes USP XXI plastics, cytotoxicity, and pyrogenicity test reports as well as performance parameters and specifications for the ultrapolyplea P-PP and P-PP 100 filter cartridge.

ultrapolyplea P-PP and P-PP 100 filters are constructed in a clean room under controlled conditions using sophisticated, highly specialized machinery. Every effort is directed toward quality and consistency while meticulous quality control procedures insure reliability. The ultrapolyplea P-PP and P-PP 100 filter cartridge offer reliable performance in a wide range of applications.



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# MATERIALS OF CONSTRUCTION

The ultrapolyplea P-PP and P-PP 100 filter cartridge is manufactured from high quality components which are non-toxic, biologically inert raw materials. In addition, all components of the ultrapolyplea P-PP and P-PP 100 filter cartridge are FDA listed for food contact use in the Code of Federal Regulations (CFR), Title 21 as listed below:

**The ultrapolyplea P-PP and P-PP 100 filter cartridge is manufactured from high quality components which are non-toxic, biologically inert raw materials.**

## A. Components:

Media:	Polypropylene	CFR Title 21, 177.1520
Upstream Support:	Polypropylene	CFR Title 21, 177.1520
Downstream Support:	Polypropylene	CFR Title 21, 177.1520
Outer Guard:	Polypropylene	CFR Title 21, 177.1520
Core:	Polypropylene	CFR Title 21, 177.1520
End Caps:	Polypropylene	CFR Title 21, 177.1520
Sealing Method:	Thermal Bonding	

## B. Cartridge Dimensions:

Diameter: 2.75" (7 cm)  
Lengths: 10, 20 and 30 inches (nominal)  
25, 50 and 75 centimeters (nominal)

## C. Operating Characteristics:

37°C at 5.6 bar (100°F at 80 psid)  
65°C at 4.2 bar (150°F at 60 psid)  
82°C at 2.1 bar (180°F at 30 psid)

## D. Quality Assurance:

ultrapolyplea P-PP and P-PP 100 filter cartridges are manufactured in a clean room to exacting specifications by skilled technicians. All ultrapolyplea P-PP and P-PP 100 filter cartridges are clearly marked with type and lot number. To further ensure product reliability, our Quality Assurance staff continually audits the manufacturing process for conformance to our written standards.



## A. In-Line Steam Sterilization Procedure

This procedure outlines the steps required to steam sterilize the ultrapolyplea P-PP and P-PP 100 filter cartridge and system using saturated steam. This procedure is frequently used in critical applications where a sterile effluent is desired. The ultrapolyplea P-PP and P-PP 100 filter cartridge is capable of repeated steam sterilization cycles without loss of integrity.

The steam should be free of rust and other particulates. The housing should be clean before installing the cartridge. To assure sterilization, steam pressure in the assembly must not be allowed to fall below 2.03 bar (15 psig) abs. 121°C (249.8°F). Condensate should be drained from the system before sterilizing. A typical piping schematic is outlined in figure 1.

### Procedure:

1. Close all valves.
2. Open valve  $V_4$ .
3. Slowly open  $V_2$ .
  - a. Crack open  $V_7$  to vent trapped air.
  - b. Crack open  $V_6$  allowing steam to flow through the system.
  - c. Leave drain  $V_8$  cracked during sterilization to drain condensate.
4. Steam sterilize for a minimum of 1 hour at 2.05 to 2.41 bar (15 to 20 psig) or as long as experience dictates.
5. When sterilization is complete, close  $V_2$ .
6. Open  $V_3$  and introduce sterile air or nitrogen regulated to the same pressure as the steam.
7. Close  $V_6$ .
8. Allow the system to cool to room temperature. Close  $V_3$ .
9. Crack vent  $V_7$  and allow the system pressure to equalize. The filtration process may now be started.

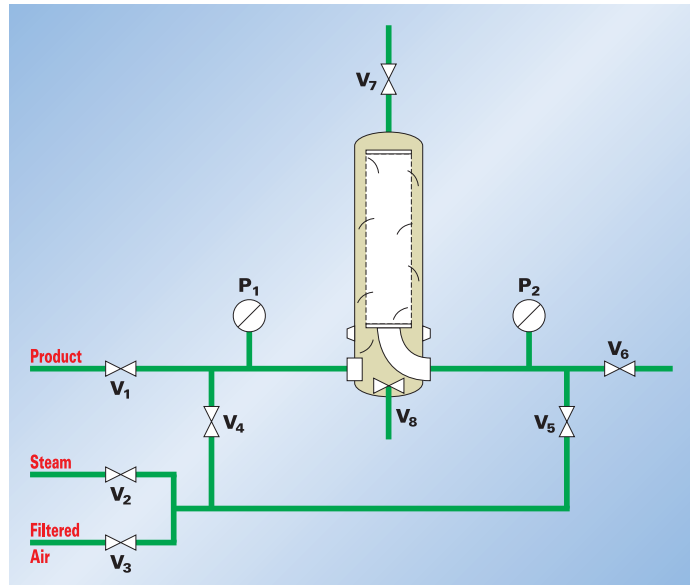


Figure 1: Steam Sterilization Schematic



### C. Autoclave Procedure

This procedure outlines the steps required to autoclave the ultrapolyplea P-PP and P-PP 100 filter cartridge and housing assembly. The ultrapolyplea P-PP and P-PP 100 filter cartridge is capable of repeated sterilization cycles without loss of integrity.

#### Procedure:

1. Using sterile water, pre-wet the cartridge o-rings and install cartridge in housing. Autoclave the sump separately from the filter cartridge/head assembly is not recommended due to increased risk of contamination and or damage to the filter element.
2. Open all vents.
3. Wrap all openings loosely with Kraft paper or other appropriate covering.
4. Using the slow exhaust cycle, autoclave at 121°C (249.8°F) for 30 minutes.  
As autoclaves may vary, sterilization cycles should be validated under actual system or autoclave loading conditions.
5. Allow assembly to cool.
6. Install assembly in system using aseptic techniques.



# ULTRAFILTER

## ultrapolyplea filter element

### Resistance to chemicals

The following suggestions are based on technical data and other information which we consider to be reliable and is now proposed as a general guideline. The data to the chemicals resistance mentioned here, is based on statistical exposure of the test fluid to room temperature. If not otherwise mentioned for all the chemicals listed here it is compulsory that they are provided as full concentrations or as saturated solutions of a common purity degree. In some cases the actual performance can be changed due to temperature changes, differences in the concentration, combination of the chemicals, time and frequency of exposure or other application factors that we can not influence. If there should be doubt the materials should be tested prior to use. Please contact ultrafilter if you should require assistance with regards to some specific applications or chemicals.

In this guideline to tolerance the chemical resistance of ultrapolyplea will be indicated by the following lettering:

- A Recommendable. No significant changes of the flow rate or the Bubble-point is detected.
- B Limited recommendation. Suitable for most applications, but extra tests are recommended as arching, changing of color or some small changes could occur.
- C Not recommendable. Distinct changes in the flow rate and/or the Bubble-point could be expected.

The use of small lettering (a, b, c) means that ultrapolyplea was not specially tested with the corresponding chemical, but the result can be predicted according to tests with similar chemicals.



Chemical	Result
Acetone.....	A
Aluminium salts .....	A
Ammonium chloride 10% .....	A
Ammonium hydroxide 10% .....	A
Amyl Acetate .....	A
Anilin .....	B
Apple juice .....	A
Barium salts .....	A
Petrol.....	B
Benzol .....	C
Benzylalcohol .....	A
Beer .....	A
Bleach .....	A
Boric acid .....	A
Butane .....	A
Butanol.....	A
Butylacetate.....	B
Chloroform.....	B
Chloro sulphon acid .....	C
Chromic acid .....	A
Cyclohexane.....	A
Cyclohexanol.....	A
Cyclohexanone.....	A
Steam.....	A
Dichloromethane.....	B
Diethyl.....	B
Di.....	A
E.....	A
F.....	A
Fe.....	A

Chemical	Result
Ferric-(II)-nitrate .....	A
Ferric-(II)-sulphate .....	A
Ferric-(III)-chloride.....	A
Ferric-(III)-nitrate .....	A
Ferric-(III)-sulphate .....	A
Acetic acid, 10% .....	A
Ethan.....	A
Ethanol.....	A
Ethylene acetate .....	A
Ethylene glycol.....	A
Ethylene nitrate.....	A
Ethylene oxide .....	A
Ethylene sulphate .....	A
Hydrofluoric acid 40%.....	A
Formaldehyde .....	A
Freon 113 .....	A
Glycerine .....	A
Hexane.....	B
Fluosilicic acid 50% .....	B
Hydraulic liquid.....	A
Isopropyl acetate.....	A
Isopropanol .....	A
Caustic potash 10% .....	A
Caustic potash 50%.....	A
Potassium -Aluminium -Sulphate 5% .....	C
Potassium hydroxide.....	A
Calcium hypo chloride.....	A
Calcium carbonate .....	A
Calcium nitrate .....	A
Kerosene.....	A



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Chemical	Result
Magnesium chloride .....	A
Magnesium sulphate .....	A
Seawater .....	A
Methanol.....	A
Methyl acetate .....	A
Methylen chloride .....	B
Methyl ethyl ketone .....	B
Methyl iso butyl ketone .....	B
Milk acid.....	A
Mineral oil .....	A
Engine oil .....	A
N-methyl-2-pyrrolidon.....	C
Sodium chloride .....	A
Sodium hypochlorite .....	A
Sodium salts .....	A
Sodium hydroxide 10% .....	A
Sodium hydroxide 50% .....	A
Nickel salts .....	A
Pentanol .....	A
Perchlor ethylene .....	B
Perchloric acid 25% .....	A
Petrolether .....	B
Petroleum.....	A
Photo paint Kodak (KTFR, KEMER, Microresist) .....	A
Phenol.....	A
Phosph.....	B
Pro.....	A
Pr.....	A
Py.....	A
Py.....	B



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Chemical	Result
Nitric acid 10% .....	A
Nitric acid conc.....	A
Hydrochloric acid 10% .....	A
Hydrochloric acid conc. ....	A
Lubricating oil.....	A
Sulphuric acid 10% .....	A
Sulphuric acid conc. ....	B
Sulphurous acid.....	A
Silikon liquid .....	A
Sole .....	A
Edible oil.....	A
Tetrachlorocarbon.....	B
Tetrahydrofuran .....	B
Trichloroethylene .....	B
Trichlorotrifluorethan .....	B
Wax.....	A
Hydrogen peroxide 5% .....	A
Wine .....	A
Wine acid .....	A
Xylene .....	C
Zinc salts .....	A
Citric acid .....	A

# BIOLOGICAL SAFETY

In order to assure that ultrapolyplea P-PP / P-PP 100 is biologically inert and safe for critical pharmaceutical applications, all of the ultrapolyplea P-PP / P-PP 100 components were tested according to USP Class VI plastics procedures. In addition, ultrapolyplea P-PP / P-PP 100 meets the requirements as specified by USP Physio Chemical tests. No binders, adhesives or surfactants are used in its construction.

ultrapolyplea P-PP / P-PP 100 was also subjected to oxidizable substances and cytotoxicity tests. The oxidizable substances tests is used to detect the presence of surfactants. The cytotoxicity test is used to determine biocompatibility of materials intended for use in medical devices.

ultrapolyplea P-PP / P-PP 100 passed all of the above mentioned tests. A summary of the procedures and results are presented in the following pages.

**ultrapolyplea P-PP / P-PP 100: biologically safe for critical applications.**



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**STUDY COMPLETION DATE:** February 26, 1991  
**STUDY INITIATION DATE:** February 11, 1991  
**DATE SAMPLE RECEIVED:** January 17, 1991  
**SAMPLE IDENTIFICATION:** Polypropylene Components

**SUMMARY SHEET  
USP XXII PLASTICS CLASSIFICATION TEST**

**Specimen Description:** Polypropylene Components

**Reference:** The United States Pharmacopeia, XXII (1990), pp. 1497-1500.

**Result summary:** NVP No. 16E-03 Systemic Injection Toxicity Test Extracts

Sodium Chloride Injection	PASS
1 in 20 Solution of Alcohol in SCI	PASS
Cottonseed Oil	PASS
Polyethylene Glycol 400	PASS

NVP No. 16E-04 Intracuneous Reactivity Test Extracts

Sodium Chloride Injection	PASS
1 in 20 Solution of Alcohol in SCI	PASS
Cottonseed Oil	PASS
Polyethylene Glycol 400	PASS

NVP No. 16E-05 Intramuscular Implantation Test

Duration: 5 Days PASS

**Conclusion:** From the results of testing and in accordance with the definitions in the above cited documents, the sample as described above PASSES the USP XXII Class VI-70C Plastics Test.



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Verified by: \_\_\_\_\_

Mary Jane Deenihan,  
Manager In vivo Laboratory Services

Northview Pacific Laboratories, Inc.



**SUMMARY SHEET  
USP PLASTICS CLASSIFICATION TEST**

**Specimen Description:** Polypropylene Adaptor

**Reference:** BTP 2-3-093-86; The United States Pharmacopeia, XXI(1984), pp. 1235-1237.

**Result Summary:**

BTR Nos. 1-3-27517-1 and 1-3-27587	
Systemic Injection Toxicity Test Extracts	
Sodium Chloride Injection	PASS
5% Ethanolic Sodium Chloride Injection	PASS
Cottonseed Oil	PASS
Polyethylene Glycol 400	PASS
BTR Nos. 1-3-27517-2 and 1-3-27587	
Intracutaneous Reactivity Test Extracts	
Sodium Chloride Injection	PASS
5% Ethanolic Sodium Chloride Injection	PASS
Cottonseed Oil	PASS
Polyethylene Glycol 400	PASS
BTR No. 1-3-27517-3 Intramuscular Implantation Test	
Duration: 5 Days	PASS

**Conclusion:** From the results of testing and in accordance with the definitions in the above cited documents, the sample as described above PASSES the USP Class VI-70 deg C Plastics Test.

Summary Verified by: \_\_\_\_\_

Terry L. Brown, B.A.  
Manager, Biology

FEB 16, 1988



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Los Angeles, California 90019

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(800) 331-9958

SUMMARY SHEET  
USP PLASTICS CLASSIFICATION TEST

Specimen Description: Polypropylene Support Layer

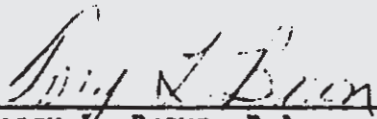
Reference: BTP 2-3-093-86; The United States Pharmacopeia, XXI(1984), pp. 1235-1237.

Result Summary:

BTR No. 1-3-27515-1 Systemic Injection Toxicity Test Extracts	
Sodium Chloride Injection	PASS
5% Ethanolic Sodium Chloride Injection	PASS
Cottonseed Oil	PASS
Polyethylene Glycol 400	PASS
BTR No. 1-3-27515-2 Intracutaneous Reactivity Test Extracts	
Sodium Chloride Injection	PASS
5% Ethanolic Sodium Chloride Injection	PASS
Cottonseed Oil	PASS
Polyethylene Glycol 400	PASS
BTR No. 1-3-27515-3 Intramuscular Implantation Test	
Duration: 5 Days	PASS

Conclusion: From the results of testing and in accordance with the definitions in the above cited documents, the sample as described above PASSES the USP Class VI-70 deg C Plastics Test.

Summary Verified by:

  
Terry M. Brown, B.A.  
Manager, Biology

MAY 12, 1988



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MEM ELUTION

LABORATORY NUMBER: 53604G  
PROCEDURE NUMBER: SOP/CTX/003B  
SAMPLE SOURCE:  
SAMPLE IDENTIFICATION: Polypropylene Meltblown Media  
P.O. #F-4313  
CELL LINE: Mouse Heteroploid Connective  
Tissue (L-929)  
INCUBATION PERIOD: 48 ± 3 hour at 37°C  
METHOD OF SCORING: Cytopathic Effect (0-4)  
AMOUNT TESTED: 120 CM<sup>2</sup>  
DATE STARTED: 09 Aug 93  
COMPLETION DATE: 12 Aug 93  
REPORT DATE: 16 Aug 93

INTRODUCTION:

The MEM Elution test is designed to determine the cytotoxicity of extractable substances exposed to cellular monolayers. The appearance of cellular destruction by these extracts is evidence of varying degrees of cytotoxicity.

PROCEDURE:

The amount of test material to be extracted is based on USP surface area recommendations or by weight (4.0 g/20 mL extract fluid for polymers and plastic, 2.0 g/20 mL extract fluid for other materials). The prepared sample is normally extracted for 24 hours ± 1 hour at 37°C in MEM.

The test extracts were filtered. Two mL of test material was added to each test well (35 x 14 mm) with 70-90% confluent cell monolayer. The test was performed in triplicate for each test extract. The prepared test wells were incubated at 37°C for 48 hours.



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monolayers were examined microscopically. The as to the degree of discernable morphological relative scale of 0 to 4:

MEM Elution  
 Lab Number 53604G  
 Page 2

CONDITIONS OF ALL CULTURES	REACTIVITY	GRADE
No cell lysis, intracytoplasmic granules.	NONE	0
Not more than 20% rounding, occasional lysed cells.	SLIGHT	1
Not more than 50% rounding, extensive cell lysis	MILD	2
Not more than 70% rounding and lysed cells.	MODERATE	3
Nearly complete cell destruction	SEVERE	4

The results from the three wells were averaged to give a final cytopathic effect (CPE).

**RESULTS:**

IDENTIFICATION	SCORE #1	SCORE #2	SCORE #3	AVERAGE
NEGATIVE CONTROL	0	0	0	0
POSITIVE CONTROL	4	4	4	4
SAMPLE	0	0	0	0



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*[Signature]*  
 \_\_\_\_\_  
 Technician

*[Signature]*  
 \_\_\_\_\_  
 Teri A. Roming, M.S. RM(AAM)  
 Study Director

MEM ELUTION

LABORATORY NUMBER: 53604C  
PROCEDURE NUMBER: SOP/CTX/003B  
SAMPLE SOURCE:  
SAMPLE IDENTIFICATION: Polypropylene Support Layer  
P.O. #F-4313  
CELL LINE: Mouse Heteroploid Connective  
Tissue (L-929)  
INCUBATION PERIOD: 48 ± 3 hour at 37°C  
METHOD OF SCORING: Cytopathic Effect (0-4)  
AMOUNT TESTED: 120 CM<sup>2</sup>  
DATE STARTED: 09 Aug 93  
COMPLETION DATE: 12 Aug 93  
REPORT DATE: 16 Aug 93

INTRODUCTION:

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Monolayers were examined microscopically. The test results were scored as to the degree of discernable morphological changes on a relative scale of 0 to 4:

MEM Elution  
 Lab Number 53604C  
 Page 2

CONDITIONS OF ALL CULTURES	REACTIVITY	GRADE
No cell lysis, intracytoplasmic granules.	NONE	0
Not more than 20% rounding, occasional lysed cells.	SLIGHT	1
Not more than 50% rounding, extensive cell lysis	MILD	2
Not more than 70% rounding and lysed cells.	MODERATE	3
Nearly complete cell destruction	SEVERE	4

The results from the three wells were averaged to give a final cytopathic effect (CPE).

RESULTS:

IDENTIFICATION	SCORE #1	SCORE #2	SCORE #3	AVERAGE
NEGATIVE CONTROL	0	0	0	0
POSITIVE CONTROL	4	4	4	4
SAMPLE	0	0	0	0



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*[Signature]*  
 Technician

*[Signature]*  
 Teri A. Roming, M.S. RM(AAM)  
 Study Director

MEM ELUTION

LABORATORY NUMBER: 53604B  
PROCEDURE NUMBER: SOP/CTX/003B  
SAMPLE SOURCE:  
SAMPLE IDENTIFICATION: Polypropylene Components  
P.O. #F-4313  
CELL LINE: Mouse Heteroploid Connective  
Tissue (L-929)  
INCUBATION PERIOD: 48 ± 3 hour at 37°C  
METHOD OF SCORING: Cytopathic Effect (0-4)  
AMOUNT TESTED: A-11.5 g, B-11.7 g  
DATE STARTED: 09 Aug 93  
COMPLETION DATE: 12 Aug 93  
REPORT DATE: 16 Aug 93

INTRODUCTION:

The MEM Elution test is designed to determine the cytotoxicity of extractable substances exposed to cellular monolayers. The appearance of cellular destruction by these extracts is evidence of varying degrees of cytotoxicity.

PROCEDURE:

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monolayers were examined microscopically. The as to the degree of discernable morphological relative scale of 0 to 4:

MEM Elution  
 Lab Number 53604B  
 Page 2

CONDITIONS OF ALL CULTURES	REACTIVITY	GRADE
No cell lysis, intracytoplasmic granules.	NONE	0
Not more than 20% rounding, occasional lysed cells.	SLIGHT	1
Not more than 50% rounding, extensive cell lysis	MILD	2
Not more than 70% rounding and lysed cells.	MODERATE	3
Nearly complete cell destruction	SEVERE	4

The results from the three wells were averaged to give a final cytopathic effect (CPE).

**RESULTS:**

IDENTIFICATION	SCORE #1	SCORE #2	SCORE #3	AVERAGE
NEGATIVE CONTROL	0	0	0	0
POSITIVE CONTROL	4	4	4	4
SAMPLE A	0	0	0	0
SAMPLE B	0	0	0	0



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*[Signature]*  
 Technician

*[Signature]*  
 Teri A. Roming, M.S. RM(AAM)  
 Study Director

MEM ELUTION

LABORATORY NUMBER: 53604A  
PROCEDURE NUMBER: SOP/CTX/003B  
SAMPLE SOURCE:  
SAMPLE IDENTIFICATION: Polypropylene Adaptors  
P.O. #F-4313  
CELL LINE: Mouse Heteroploid Connective  
Tissue (L-929)  
INCUBATION PERIOD: 48 ± 3 hour at 37°C  
METHOD OF SCORING: Cytopathic Effect (0-4)  
AMOUNT TESTED: A-3 g, B-3.3 g  
DATE STARTED: 09 Aug 93  
COMPLETION DATE: 12 Aug 93  
REPORT DATE: 16 Aug 93

INTRODUCTION:

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monolayers were examined microscopically. The test results were scored as to the degree of discernable morphological changes on a relative scale of 0 to 4:

MEM Elution  
 Lab Number 53604A  
 Page 2

CONDITIONS OF ALL CULTURES	REACTIVITY	GRADE
No cell lysis, intracytoplasmic granules.	NONE	0
Not more than 20% rounding, occasional lysed cells.	SLIGHT	1
Not more than 50% rounding, extensive cell lysis	MILD	2
Not more than 70% rounding and lysed cells.	MODERATE	3
Nearly complete cell destruction	SEVERE	4

The results from the three wells were averaged to give a final cytopathic effect (CPE).

RESULTS:

IDENTIFICATION	SCORE #1	SCORE #2	SCORE #3	AVERAGE
NEGATIVE CONTROL	0	0	0	0
POSITIVE CONTROL	4	4	4	4
SAMPLE A	0	0	0	0
SAMPLE B	0	0	0	0



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 Technician

*[Signature]*  
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 Study Director

\*\*\* CERTIFICATION OF ANALYSIS \*\*\*

Test Report No. 1-3-29819-2  
Date Received: 4/12/88  
Date Initiated: 4/15/88  
Date Completed: 4/15/88

Type of Examination: PYROGEN TEST

Specimen Description: One (1) sample Cartridge.

Reference: BTP No. 2-3-001-85, Pyrogen Test.  
(The United States Pharmacopeia, 21st Rev., pp 1181-3,1984)

Specimen Preparation: The unit was rinsed in 400 mL of sterile, pyrogen-free saline.

Tabular Results: Injected at a Dosage of 10.0 ml / kg.

Rabbit No.	Weight gms	Temperature Pre-Inject	Dose (ml)	Temperature (Deg. Celsius)			
				1hr	2hr	3hr	Rise
7968	3710	39.6	37.1	39.6	39.5	39.3	0.0
7969	3750	39.5	37.5	39.3	39.5	39.6	0.1
7970	3530	39.3	35.3	39.5	39.4	39.2	0.2

Conclusion: In accordance with the above cited documents, the product, tested as described, was found to be Non-Pyrogenic.

Examination by: Virginia Uy, B.S.  
Biologist

Approved by: Regina M. Fernando, B.S.  
Biology Team Leader



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by:

*Regina M. Fernando*  
Regina M. Fernando, B.S.  
Biology Team Leader

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