Life Sciences

# Validation Guide

USTR 2324

# Pall® Ultipor® VF Grade DV20 AB Ultipleat® Style Virus Removal Filter Cartridges

An addendum to "VG-DV20 - Validation Guide for Pall® Ultipor® VF Grade DV20 AB Style Virus Removal Filter Cartridges"

*Filtration. Separation. Solution.SM*

# CONTENTS

# 1. Introduction

This document contains validation data applicable to **Pall Ultipor** VF Grade DV20 Virus Removal Filters in AB **Ultipleat** cartridge style configurations, part numbers AB1UDV207PH4, AB2UDV207PH4 and AB3UDV207PH4. This document is intended to be used in conjunction with the Pall document VG-DV20 "Validation Guide for Pall® Ultipor® VF Grade DV20 AB Style Virus Removal Filter Cartridges".

The test program included the following investigations:

- **Forward Flow Integrity Test correlated with Bacteriophage Retention Tests**
- **Extractables Tests**
- **Steam Sterilization**
- **Biological Reactivity Tests**

The letter "P" in the part numbering code indicates that these cartridges are intended for pharmaceutical service, that they are manufactured in controlled environments and are subject to stringent quality control including in-process controls and testing of the filter elements as follows:

(1) Forward Flow Test, on a 100% basis, and, on a sampling basis,

(2) Total Organic Carbon (TOC), Conductivity and pH Tests,

(3) Effluent Cleanliness Test,

(4) Limulus Amebocyte Lysate Test, and

(5) Viral Challenge Tests.

Materials of construction and performance parameters of the **Ultipor** VF filters are described in detail in **Pall** Data Sheet USD 2329 "Ultipor® VF Grade DV20 Cartridge Filter", which is to be used in conjunction with this document.

Further information may be obtained from Pall.

# 2. Validation of Pall Ultipor VF Grade DV20 Virus Reduction Filters in AB Ultipleat Cartridge Style Configuration

## 2.1 Introduction

Manufacturers of biological and biotherapeutical products are mandated by regulatory agencies to incorporate adequate virus contamination-control strategies to ensure the virological safety of their final product. Multiple virus inactivation and removal methods are recommended to ensure complementary levels of protection (ICH Harmonized Tripartite Guideline, 1997). A wide range of virus removal and inactivation techniques has been developed and is available to the pharmaceutical manufacturer. Filtration is often one of the least invasive processes that can be employed as a virus control step. It does not require the use of additives; it does not alter the configuration of the target protein, and is generally very amenable to inclusion into the manufacturing process.

The application of filtration for critical process steps requires demonstration and documentation of the filter's performance through a physical test. The correlation between a non-destructive integrity test and assurance of microbial and/or viral retention is extremely important.

Pall uses the Forward Flow Test method on a 100% production basis for the non-destructive integrity testing of membrane filter elements. For integral filters, these Forward Flow values are measured air volume flow rates (mL/min) due to diffusion of air through a suitable liquid film wetting the pores of the filter membrane. Forward Flow measurement may be performed downstream of the wetted filter membrane under constant test pressure, or on the upstream side of the wetted filter membrane by measuring the air flow required to maintain constant test pressure.

The Pressure Hold Test is a modified form of upstream Forward Flow testing, in which the filter housing is pressurized to a pre-determined setting, then isolated from the pressure source. The diffusion of air across the wetted membrane is quantitatively measured as decay in pressure over a specified period of time. Upstream integrity tests are particularly useful in critical fluid processes since they can be performed without compromising the sterility of the downstream system.

Correlating filter integrity test values with microbial (and/or viral) challenge testing is an empirical process resulting in validation data applicable to the test parameters and fluid attributes utilized. This document provides data from the viral challenges for the bacteriophages PR772 (sized at 53-82 nm) and PP7 (sized at 25 nm) versus Forward Flow validation studies. Typical retention data for mammalian viruses, such as Parvoviruses and other viruses, are available from Pall upon request.

## 2.2 Parameter Determination

Based on viral challenge and Forward Flow integrity tests during the development of the **Pall Ultipor** VF Grade DV20 filters in AB **Ultipleat** cartridge style configuration, it was determined that a Forward Flow integrity test air pressure of 5.86 bar (85 psi) is suitable for integrity testing **Ultipor** VF Grade DV20 filters in AB **Ultipleat** cartridge style configuration when wet with dilute (30% by vol.) isopropyl alcohol (IPA). Under these test conditions, the maximum allowable Forward Flow value for one 254 mm (10-inch) filter cartridge (AB1UDV20) was set at 14.2 mL of air per minute, based on pro-rata area calculation compared with **Pall Ultipor** VF Grade DV20 filter in AB style, which has the same membrane and sealing mechanisms and therefore on a Forward Flow test basis differs only in filter area.

In order to validate the use of 5.86 bar (85 psi) air pressure and the maximum allowable flow of 14.2 mL/min for 30% IPA/water, filter elements were sampled from three production lots and tested as described below. Bacteriophage PP7, which is sized at 25 nm, is often used as a surrogate for mammalian viruses such as Parvovirus and Poliovirus, which are similar in size range *(Aranha-Creado and Brandwein, 1999)*. Bacteriophage PP7 is a non-enveloped icosahedral phage with cubic symmetry. The method of assembly of PP7 within the bacterial host and its cubic symmetry preclude aggregation. Bacteriophage PR772 is an icosahedral bacteriophage sized at 53-82 nm.

## 2.3 Summary of Viral Challenge Validation Procedure

**Pall Ultipor** VF Grade DV20 filter cartridges in AB **Ultipleat** cartridge style configuration, part number AB1UDV207PH4 (effective filter area 2.0 $m^2$ [21.5 $ft^2$]), were tested using the following procedure:

1. Install the filter in the housing.

2. Perform a pre-autoclave, pre-challenge integrity test of the filter as follows: Immerse the filter vertically, with the open end facing upwards, slowly into a solution of 0.1 µm-filtered 30% (by vol.) isopropyl alcohol, allowing air to be expelled as the filter becomes wetted. Hold the filter submerged in the liquid for at least 25 minutes. Perform Forward Flow integrity test at a test pressure 5.86 bar (85 psi). Record the integrity test value in mL/min.

3. Flush the filter with 0.1 µm filtered de-ionized water for 20 minutes using 3.44 bar (50 psi) upstream pressure and 1.38 bar (20 psi) back pressure.

4. Sterilize the wet filter, in the housing, by autoclaving at 121°C (250°F) for 60 minutes on a slow exhaust cycle.

5. Flush the filter with 0.1 µm-filtered, de-ionized water for 20 minutes using 3.44 bar (50 psi) upstream pressure and 1.38 bar (20 psi) back pressure. Perform a post-autoclave aseptic Forward Flow installation test *in-situ* at 5.86 bar (85 psi).

6. Perform the viral challenge as follows:

    a. Fill a sterile pressure vessel with a pre-filtered carrier fluid (BSA/PBS [10 mg/mL]) inoculated with bacteriophages PR772 and PP7 at a concentration of approximately $10^6$ plaque forming units (PFU)/mL.

    b. Aseptically remove a sample of the challenge suspension from the pressure vessel for assay.

    c. Connect the outlet port of the pressure vessel to the inlet port of the filter housing, and the inlet port of the pressure vessel to a regulated air source.

    d. Adjust the air pressure to the pressure vessel via the pressure regulator to maintain 2 bar (30 psi) differential pressure across the filter during challenge.

    e. Allow 1 liter of effluent to pass through the filter. Collect an aliquot for viral assays.

    f. Stop the challenge flow by clamping the downstream tubing and releasing the pressure from the pressure vessel.

    g. Remove the filter from the housing and sanitize by submerging in 1% sodium hypochlorite overnight.

7. Assay the input and effluent samples for virus content using the agar overlay method. Prepare serial dilutions of the input samples to confirm the initial concentration of PP7 and PR772. Assay ten 1 mL aliquots of the undiluted effluent to determine any low level PR772 transmission, while using 10-fold serial dilutions of the effluent to assay for PP7 transmission.

8. Incubate the plaque assay plates at 37± 2°C (99°F) overnight, count for plaques and calculate the virus removal efficiency of the filter as follows:

$$\text{Log Titer Reduction } (T_R) = \frac{\text{Concentration of challenge virus in input (PFU/mL)}}{\text{Concentration of challenge virus in effluent (PFU/mL)}}$$

If no challenge virus is detected downstream of the filter (and the effluent aliquots tested are sterile), the zero value for virus concentration in the effluent is replaced by 1 in the equation and the Log Titer Reduction is expressed as "greater than" ("≥") the calculated value.

9. Drain the sanitizing agent from the filter, install the filter in a filter housing and flush with 0.1 µm-filtered, de-ionized water for 20 minutes using 3.44 bar (50 psi) upstream pressure and 1.38 bar (20 psi) back pressure.

10. Perform a post-challenge integrity test of the filter as follows: flush with 3 liters of 0.1 µm-filtered 30% (by vol.) isopropyl alcohol using a pressure of 3.1 bar (45 psi). Perform Forward Flow integrity test at a test pressure 5.86 bar (85 psi). Record the integrity test value in mL/min.

**NB:** A detailed description of the procedure can be found in the **Pall** document VG-DV20 "Validation Guide for Pall® Ultipor® VF Grade DV20 AB Style Virus Removal Filter Cartridges".

## 2.4 Results

The data from the viral retention versus Forward Flow validation study are listed in Table 1. **Ultipor** VF grade DV20 AB1UDV207PH4 filter (254 mm, 10 inch) cartridges with Forward Flow values from 6.6 to 10.3 mL/min – when wet with 30% (by vol.) isopropyl alcohol and tested at 5.86 bar (85 psi) – gave titer reductions for bacteriophages PR772 (53-82 nm) and PP7 (25 nm) of ≥ 6 logs and ≥ 3 logs, respectively, under the test conditions. The test conditions included challenges with bacteriophage viruses at concentrations of ≥ $10^6$ PFU/mL in an isotonic protein solution (phosphate buffered saline + 10 mg/mL bovine serum albumin) with an applied differential pressure of 2 bar (30 psi). Effluent was sampled and analyzed post-filtration after a 1-liter challenge throughput volume.

## 2.5 Conclusions

The AB1UDV20 cartridges have been shown to provide titer reductions of ≥ 6 logs for bacteriophages PR772 (53-82 nm) and ≥ 3 logs for bacteriophages PP7 (25 nm) under the specified test conditions. The Forward Flow integrity test performed at 5.86 bar (85 psi) in 30% (by vol.) isopropyl alcohol demonstrates that AB **Ultipleat** cartridge style **Ultipor** VF Grade DV20 filter cartridges with Forward Flow values within the limit of 14.2 mL/min are retentive for bacteriophages PR772 (53-82 nm) and PP7 (25 nm) with a titer reduction of ≥ 6 logs and ≥ 3 logs respectively, under the test conditions.

**Table 1. Correlation of Forward Flow Values of Ultipor VF Grade DV20 AB1UDV20 (Ultipleat Cartridge Style) Filter Cartridges with Retention of Bacteriophages PR772 (sized at 53-82 nm) and PP7 (sized at 25 nm)**

| Filter Element Serial Number | Forward Flow* at 85 psi (5.86 bar) 30% (by vol.) IPA/water wet [mL/min] | Titer Reduction for Phage PR772 (53-82 nm) | Titer Reduction for Phage PP7 (25 nm) |
|---|---|---|---|
| **PB1073005** | 6.6 | $> 10^6$ | $4.8 \times 10^4$ |
| **IG7213034** | 7.8 | $> 10^6$ | $8.2 \times 10^3$ |
| **IG7213015** | 8.3 | $> 10^6$ | $1.0 \times 10^4$ |
| **IG7213006** | 8.4 | $> 10^6$ | $5.1 \times 10^4$ |
| **PB1074002** | 8.5 | $> 10^6$ | $1.7 \times 10^4$ |
| **PB1075008** | 9.2 | $> 10^6$ | $1.3 \times 10^4$ |
| **PB1075006** | 9.3 | $> 10^6$ | $1.1 \times 10^4$ |
| **PB1075007** | 9.3 | $> 10^6$ | $1.2 \times 10^4$ |
| **PB1075009** | 10.2 | $> 10^6$ | $2.4 \times 10^4$ |
| **IG7213025** | 10.3 | $> 10^6$ | $1.7 \times 10^4$ |

* Forward Flow data reported for the higher of the two Forward Flow values (pre- versus post- challenge FF values)

# 3. Extractables Report for Ultipor VF Grade DV20 Virus Reduction Filters in AB Ultipleat Style Cartridge Configuration

## 3.1 Introduction

The purpose of these tests was to quantify and characterize the materials that may be extracted from an **Ultipor** VF Grade DV20 filter cartridge in AB **Ultipleat** style configuration into aqueous products, when the filter is used in accordance with the procedures validated by Pall. **Ultipor** VF Grade DV20 filter cartridges in AB **Ultipleat** cartridge style configuration are constructed from a hydrophilic acrylate-modified polyvinylidene fluoride (PVDF) filter membrane, polyester non-woven support and drainage layers, and polypropylene molded components. In these tests, four 254 mm (10 inch) **Ultipor** VF Grade DV20 filter in AB **Ultipleat** cartridge style configuration (effective filter area 2.0 $m^2$ [21.5 $ft^2$]) from three production lots were tested for non-volatile, water-soluble extractables. These extractables were then analyzed by Infrared and Ultraviolet spectrophotometry.

## 3.2 Summary of Methods

The **Ultipor** VF Grade DV20 filter cartridges in AB **Ultipleat** cartridge style configuration were obtained from production inventory and were tested for extractable matter in a state the filters would typically be in at the onset of filtration. Whenever the **Ultipor** VF Grade DV20 filter cartridge in AB **Ultipleat** cartridge style configuration is used in the processing of pharmaceutical or biological products, the filter would normally be integrity tested and sterilized before filtration is begun. Therefore all these steps were carried out according to the following procedure:

1. Integrity test the filter after wetting with 30% (by vol.) isopropyl alcohol.

2. Flush filters with 0.1 µm filtered de-ionized water.

3. Steam sterilize at ≥ 121°C (250°F) for 1 hour.

4. Flush with 0.2 µm filtered water and (optionally) perform a post-autoclave aseptic integrity test, water-wet.

Each test filter was then extracted by submerging the filters (open end upwards) in 1500 mL de-ionized water at ambient temperature and gently moving the filter up and down in the liquid at a rate of 20 cycles per minute for a period of 24 hours. In each cycle the top of the filter cartridge is brought above the liquid level, causing flow of the extracting liquid through the filter. At the end of the 24 hour period the Ultraviolet absorption spectrum of the eluate was measured over the range of 200-360 nm. 1000 mL of the eluate was evaporated to dryness and the amount of non-volatile residue was determined gravimetrically.

**NB:** A detailed description of the procedure can be found in the **Pall** document VG-DV20 "Validation Guide for Pall® Ultipor® VF Grade DV20 AB Style Virus Removal Filter Cartridges".

## 3.3 Results

After the recommended procedures for integrity testing and sterilization, the AB1UDV20 filters tested showed a maximum of 14 mg of non-volatile materials when extracted with water at ambient temperature.

The **Pall** document VG-DV20 "Validation Guide for Pall® Ultipor® VF Grade DV20 AB Style Virus Removal Filter Cartridges" contains additional information on the characterization of the non-volatile materials from **Ultipor** VF Grade DV20 AB1DV20 cartridges. These results are also applicable to **Ultipor** VF Grade DV20 cartridges in AB **Ultipleat** cartridge style configuration (AB1UDV20), since **Ultipor** VF Grade DV20 cartridges in AB style configuration (AB1DV20) consist of the same materials of construction as **Ultipor** VF Grade DV20 in AB **Ultipleat** cartridge style configuration (AB1UDV20).

An Ultraviolet absorption spectrum of the eluate was measured using a Hewlett-Packard Model 8452A Diode Array Spectrophotometer. The eluate showed a maximum absorbance of about 0.065A at 200 nm and a small secondary maximum (0.02A) at about 240 nm. This is due to the presence of small amounts of water-soluble terephthalate and isophthalate oligomers originating from the polyester drainage materials of the filter.

The Infrared spectrum of the non-volatile residue was measured for sample in the form of a potassium bromide pellet using a Nicolet Model 510P Fourier Transform Infrared Spectrophotometer. The Infrared adsorption pattern from approx. 1700 $cm^{-1}$ to 1730 $cm^{-1}$, 1651 $cm^{-1}$, 1558 $cm^{-1}$, at 1270 $cm^{-1}$ and at 1127 $cm^{-1}$ indicates that the material consists mainly of a mixture of the therephthalate and isophthalate oligomers from the polyester support and drainage layers, and acrylate residues from the chemically bonded polymer coating which makes the filter membrane surface hydrophilic.

## 3.4 Conclusions

The level of aqueous extractables from **Ultipor** VF Grade DV20 filter cartridges in AB **Ultipleat** cartridge style configuration is very low. Actual service may impose different conditions, such as different fluids, exposure times and temperatures. Evaluation under process conditions is suggested. For assistance in reporting product and process-related extractables, contact Pall.

# 4. Biological Reactivity Tests for Ultipor VF Grade DV20 Virus Reduction Filters in AB Ultipleat Style Cartridge Configuration

## 4.1 Introduction

The purpose of these tests was to evaluate the biological suitability of the materials of construction of the **Ultipor** VF Grade DV20 filter cartridges. This was done by performing the Biological Reactivity Tests, *In Vivo*, for Plastics, as described in the *United States Pharmacopeia (USP), Chapter <88>*.

The tests were performed using **Pall Ultipor** VF Grade DV20 cartridges in AB style configuration (AB1DV20), which consist of the same materials of construction as **Pall Ultipor** VF Grade DV20 in AB **Ultipleat** cartridge style configuration (AB1UDV20).

## 4.2 Summary

The testing procedures described in the *USP* include injection of extracts of plastic material, as well as implantation of the material itself into animal tissue. Four extracting media are listed which simulate parenteral solutions and body fluids. These include: Sodium Chloride Injection, 1 in 20 Solution of Alcohol in Sodium Chloride Injection, Polyethylene Glycol 400 and Vegetable Oil (sesame or cottonseed oil). Extracts are 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. Since **Ultipor** VF Grade DV20 membrane filters will be autoclaved before use and since the most stringent condition not resulting in physical changes in the plastic is recommended, they were extracted at 121°C (250°F).

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 extracts were injected intravenously. Vegetable Oil extract and Polyethylene Glycol 400 extract were injected intraperitoneally.

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

Implantation was 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 filter cartridges was implanted separately.

## 4.3 Results

The tests were conducted by Gibraltar Laboratories, 122 Fairfield Road, Fairfield, New Jersey 07004-2405. Copies of the test reports can be found in the **Pall** document VG-DV20 "Validation Guide for Pall® Ultipor® VF Grade DV20 AB Style Virus Removal Filter Cartridges", or be obtained from Pall.

## 4.4 Conclusions

The **Ultipor** VF Grade DV20 Virus Reduction filter cartridges were found to meet the requirements of the *USP* for Class VI-121°C Plastics.

# 5. Steam Sterilization Cycle Report for Ultipor VF Grade DV20 Virus Reduction Filters in AB Ultipleat Style Cartridge Configuration

## 5.1 Introduction

The purpose of these tests was to demonstrate that the **Pall Ultipor** VF Grade DV20 filters in AB **Ultipleat** cartridge style configuration reliably retain integrity after steam sterilization, performed to the procedures recommended by Pall. These tests included repeated *in-situ* steaming at 125°C (257°F) (6 cycles for the duration of 1 hour) and autoclaving at 125°C (257°F) (3 cycles for the duration of 1 hour). In the case of *in-situ* steaming, 5 filters from 4 production lots were tested. In the case of autoclaving, 6 filters from 4 production lots were tested. The integrity of the filters was verified at the beginning and at the end of the sterilization tests.

## 5.2 Summary of Methods

### 5.2.1 *In-Situ* Wet Steaming

The **Pall Ultipor** VF Grade DV20 filters in **Ultipleat** cartridge style configuration were submitted to the following procedure:

1. Install the filter in a housing and integrity test after wetting with 30% (by vol.) isopropyl alcohol.
2. Flush the filter with de-ionized water.
3. Steam sterilize the filter at ≥ 125°C (257°F) for 1 hour.
4. Dry the filter at 65°C (149°F) for 36 hours.
5. Repeat steps 1 - 4 until the desired cycle number is completed.
6. Integrity test the filter after wetting with 30% (by vol.) isopropyl alcohol.

### 5.2.2 Autoclaving

The **Pall Ultipor** VF Grade DV20 filters in AB **Ultipleat** cartridge style configuration were submitted to the following procedure:

1. Install the filter in a housing and integrity test after wetting with 25% (by vol.) tertiary butanol/water.
2. Flush the filter with de-ionized water.
3. Autoclave the filter at 125°C (257°F) for 1 hour. Repeat autoclave cycle twice.
4. Dry the filter at 65°C (149°F) for 36 hours.
5. Integrity test the filter after wetting with 25% (by vol.) tertiary butanol/water.

## 5.3 Results

### 5.3.1 *In-Situ* Steaming

All filters tested were integral at the onset of the test and remained integral and fully functional as indicated by the virus-correlated 30% (by vol.) isopropyl alcohol wetted Forward Flow test after the six *in-situ* steam sterilization cycles.

**Table 2. Forward Flow Results Prior and After *In-situ* Wet Steaming**

| Filter Element Serial Number | Forward Flow Pre-Steaming at 85 psi (5.86 bar) 30% (by vol.) IPA/water wet [mL/min] | Forward Flow Post-Steaming at 85 psi (5.86 bar) 30% (by vol.) IPA/water wet [mL/min] |
|---|---|---|
| **IG7213017** | 9.7 | 9.2 |
| **IG7213013** | 10.2 | 10.4 |
| **PB1073012** | 10.0 | 9.8 |
| **PB1074013** | 9.8 | 9.5 |
| **PB1075015** | 10.3 | 11.1 |

### 5.3.2 Autoclaving

All filters tested were integral at the onset of the test and remained integral as indicated by the 25% (by vol.) tertiary butanol/water wetted Forward Flow test after the three autoclave cycles.

**Table 3. Forward Flow Results Prior and After Wet Autoclaving**

| Filter Element Serial Number | Forward Flow Pre-Steaming at 85 psi (5.86 bar) 25% (by vol.) tert. butanol/water wet [mL/min] | Forward Flow Post-Steaming at 85 psi (5.86 bar) 25% (by vol.) tert. butanol/water wet [mL/min] |
|---|---|---|
| **IG7213005** | 6.8 | 7.6 |
| **IG7213008** | 6.9 | 7.4 |
| **PB1073007** | 3.8 | 6.9 |
| **PB1074010** | 7.8 | 7.9 |
| **PB1075016** | 8.2 | 7.1 |
| **PB1075024** | 7.1 | 6.8 |

## 5.4 Conclusions

At the beginning of these tests and after exposure to the sterilization cycles, the Forward Flow values of the filters tested remained at or below the Forward Flow limit of 14.2 mL/min for 30% (by vol.) IPA/water and 25% (by vol.) tertiary butanol/water.

## 6. References

ICH harmonized tripartite guideline: "Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin", pp. 1-27, IFPMA, Geneva, Switzerland (1997).

Aranha-Creado, H. and Brandwein, H. (1999): "Application of bacteriophages as surrogates for mammalian viruses: a case for use in filter validation based on precedents and current practices in medical and environmental virology", PDA J. Pharm. Sci. Technol. 53: 75-82.

*United States Pharmacopeia* XXIV, The United States Pharmacopeial Convention, Rockville, Maryland, 1994.

2200 Northern Boulevard
East Hills, New York 11548-1289

+1 516 484 5400 phone
+1 516 801 9548 fax
pharmafilter@pall.com e-mail

Europa House, Havant Street
Portsmouth PO1 3PD, United Kingdom
+44 (0)23 9230 3303 phone
+44 (0)23 9230 2506 fax
BioPharmUK@europe.pall.com e-mail

**Visit us on the web at www.pall.com/biopharmaceutical**

**Pall Corporation has offices and plants throughout the world in locations including:** Argentina, Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, India, Indonesia, Ireland, Italy, Japan, Korea, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Poland, Puerto Rico, Russia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, United Kingdom, the United States and Venezuela. Distributors are located in all major industrial areas of the world.



02.2005

*Filtration. Separation. Solution.SM*