

Validation Document for  
FCVA SERIES  
Pharmaceutical Grade  
Cartridges

**SIEMENS**

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## 1 Introduction

Sterilization grade filters used to sterilize gases that come into contact with pharmaceutical products must conform to strictly defined quality standards.

By using filter technology that conforms to the standards laid down by the various certifying bodies, the quality of the final product can be assured. Contamination can also be prevented from entering the final product by its comprehensive removal at each stage of the primary and secondary process.

When sterilising grade filters are used in the manufacture of products, the interactions between product, filter and process must be fully investigated and validated.

Guidelines for validation can be sourced from publications issued by the FDA, EMEA, USP, EP, BP, PDA<sup>1</sup> etc. This Validation Document has been produced with these guidelines in mind to enable the end user to incorporate this information within their own validation documentation or standard operating instructions for the process.

This Validation Document shows that FCVA surpasses the product specification requirements that have to be imposed on sterilising grade filters.

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<sup>1</sup> FDA, EMEA, USP, EP, BP, PDA – Food and Drug Administration, European Medicines Evaluation Agency, United States, European, and British Pharmacopoeia, Parenteral Drugs Association.

## **2 Quality Policy**

### **2.1 Quality Assurance**

The filtration products are manufactured under controlled environmental conditions to the highest quality regimes and are subjected to a demanding program of Quality Assurance. Inspection and test protocols are implemented from vendor assessment, specification and receipt of raw materials, through every stage of the manufacturing process culminating in a non-destructive integrity test of the filter prior to packing and release.

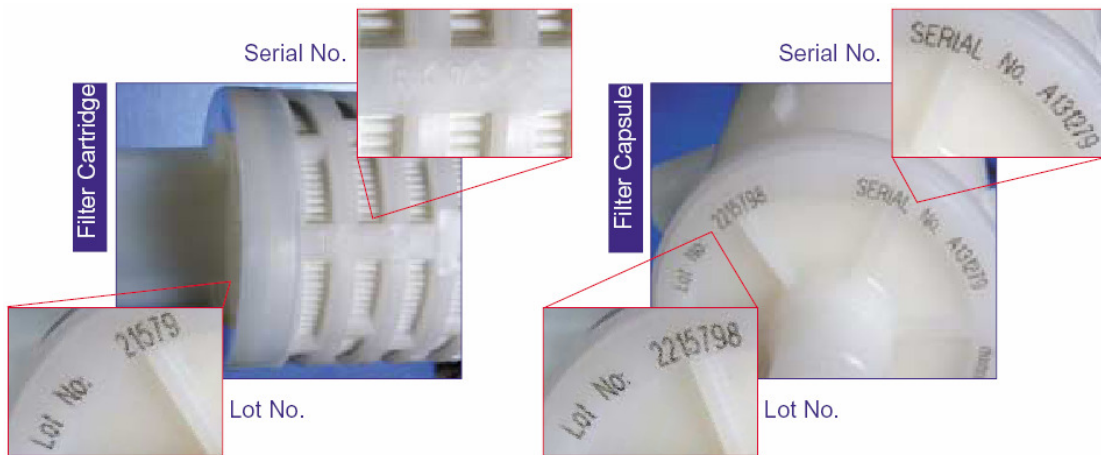
Every stage of the manufacturing process has well defined assembly protocols laid down thus ensuring operational repeatability.

The Quality Assurance Department operates with a well-equipped Laboratory Services Department, in which specialized personnel are employed to perform the essential quality inspections. The manufacturer of the filter cartridges has been assessed by the British Standards Institution and is registered to BS EN ISO 9001:2000, which defines the standards for quality systems, model for quality assurance in design, development, production, installation and servicing.

### 3 Product Traceability

All pharmaceutical grade filters are non-destructively integrity tested and flushed with Purified Water. They are then dried using HEPA filtered air and sealed in a protective polyethylene bag within the controlled manufacturing environment prior to despatch.

To enable full traceability of all pharmaceutical grade filter products, each filter module is marked with an individual serial number. In addition, each filter product is marked with a lot number, product code and general description which is also shown on both the protective polyethylene bag in which the filter is sealed and on the outer surface of the final product packaging.



### 4 Summary of Test Methods

A number of the critical procedures used within this validation document are based on external methods sourced from publications issued by the USP, EP, FDA, ISO<sup>2</sup> and ASTM<sup>3</sup>. The remaining procedures are in-house methods prepared using the manufacturer's relevant experience and industry accepted standards in the fine filtration field. The comprehensive nature of these procedures ensures high batch to batch compliance to the specification.

Membrane Validation		Filter Validation and Testing				
Physical	Chemical / Biological	Integrity Testing	Retention	Flow Parameters	Durability	Chemical / Biological
Bubble Point	Chemical Compatibility	Bubble Point	Liquid Bacterial Challenge	Clean Air Flow	Max Allowable Steam life	Chemical Compatibility
Water / IPA Flow	Extractables	Pressure Hold	Particle / Fibre Shedding		Max continuous running Temperature	Extractables
Thickness	Pyrogen Extractables	Diffusional Flow			Max Allowable Differential Pressure	Bio-Compatibility
Bacterial Challenge	Oxidisables	Aerosol Challenge				Pyrogen Extractables
Burst Strength	Bio-Compatibility	Water Intrusion				Oxidisables
Autoclavability						
Pore Size Analysis						

<sup>2</sup> ISO – International Organisation for Standardisation  
<sup>3</sup> ASTM – American Society for Testing and Materials

## 5 Preparation of Pharmaceutical Grade Filters

### 5.1 *Pharmaceutical Grade Standard*

FCVA filters must meet stringent standards to be certified P-grade. The standards that must be met are:-

- Conformance to the requirements for non-fibre releasing filters as laid down in the United States Food and Drug Administration Regulations 21CFR211.72 and 210.3(b), (6).
- Effluent quality following a purified water flush must also be met as determined by the following tests:
  - ◇ Test for oxidisable material per USP 23 Purified Water.
  - ◇ Test for bacterial endotoxins using a gel clot LAL (Limulus Amoebocyte Lysate).
  - ◇ Test for particulates.
  - ◇ Test for TOC (Total Organic Carbon).
  - ◇ Test for Conductivity.
- All components conform to the Biological Safety Standards identified in USP <88> to Class VI-121 °C levels.
- All filters must meet minimum defined integrity test values prior to despatch, defined from a correlation against an appropriate bacterial challenge.
- All filters are flushed with a high flux of purified water prior to despatch, as a guarantee of product cleanliness.

### 5.2 *Quality of Purified Water used in the preparation of Pharmaceutical Grade Filters*

The current USP and EP standards for Purified Water and Highly Purified Water specify a maximum conductivity of 1.1  $\mu\text{S}/\text{cm}$  @ 20 °C (68 °F) and a maximum TOC (Total Organic Carbon) content of 0.5 mg (500ppb) of carbon per litre.

The water used in the flushing stages of pharmaceutical grade filters exceeds these Pharmacopoeial requirements.

In addition, two other tests are carried out on samples taken from point of use and from a number of points in the supply pipework: -

- A Membrane Filtration Method Standard Plate Count Technique, to establish the microbial content.
- A gel clot LAL (Limulus Amoebocyte Lysate) test, for detection of bacterial endotoxins at 0.125 EU/ml sensitivity.

## 6 Certificate of Conformance

To certify that the **Siemens** FCVA filter products meet the highest pharmaceutical quality and performance requirements, a Certificate of Conformance is issued.

The example following is for FCVA cartridge filters.<sup>4</sup>

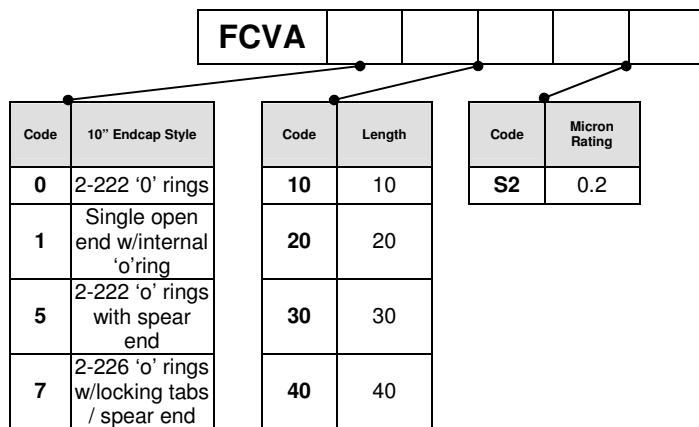
<b>Certificate of Conformance</b>			
For Pharmaceutical Grade Filters			
Rated To	Micron(s)		
<i>This certifies that the Siemens filter</i>			
Recorded Lot Number			
has been manufactured in a purpose-built facility within a controlled environment and subjected to a purified water flush.			
<b>Materials of Construction</b>			
All components of the cartridge are manufactured from materials suitable for contact with food and conform to the biological safety requirements laid down in the current USP Class VI - 121°C Plastics. They also conform with the requirements for non fibre releasing filters as laid down in the United States FDA Title 21 CFR 211.72 and 210.3(b), (6).			
The filters also meet the Siemens quality control and assurance standards.			
<b>Product Integrity</b>			
This product has successfully passed a non-destructive integrity test, which for sterilising grade cartridges is correlated to a bacterial challenge which gave a sterile effluent when challenged with a minimum of 10 <sup>7</sup> organisms per sq cm.			
The maximum diffusional flow value for this product is      mL/min at a test pressure of      mbar.			
During validation, filter samples underwent the following tests and satisfactorily met the respective criteria specified:-			
<b>Effluent Quality</b>			
<b>TOC</b>			
Met the requirements of USP Total Organic Carbon <643>			
<b>Bacterial Endotoxins</b>			
Cartridge aqueous extraction contains less than 0.125 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test, which meets the requirements of USP Water for Injection.			
<b>Water Conductivity</b>			
Met the requirements of USP Water Conductivity <645>			
<b>Particle Release</b>			
Met the requirements of USP Particulate Matter in Injections <788>			
<b>Thermal Stability</b>			
Integrity was maintained after      steam cycles of      minutes at      °C			
<b>SIEMENS</b>		<b>SIEMENS</b>	
Robert Dudek (Regulatory Compliance Manager)			
Siemens – 10 Technology Drive, Lowell, MA 01851			

<sup>4</sup> A specific Certificate of Conformance is issued for DEMICAP capsules.

## 7 Product Coding and Range for FCVA Cartridges

Represented below are details of the product code structure for FCVA cartridges. This product code structure indicates cartridge sizes, micron ratings, endcap configurations and O’rings that are available within the product range.

Example: FCVA720S2      500mm (20”) 0.2 micron FCVA filter cartridge, pharmaceutical grade with ‘C’ style endcap and Silicone O’rings.



## 8 Product Specification

### 8.1 Application

All products within the FCVA range, cartridge, capsule and disc have been designed for use in pharmaceutical applications for sterilisation duties, evaluated using ASTM Standard Test Method F838-83, or for prefiltration applications.

### 8.2 Materials of Construction for FCVA Cartridges and Capsules

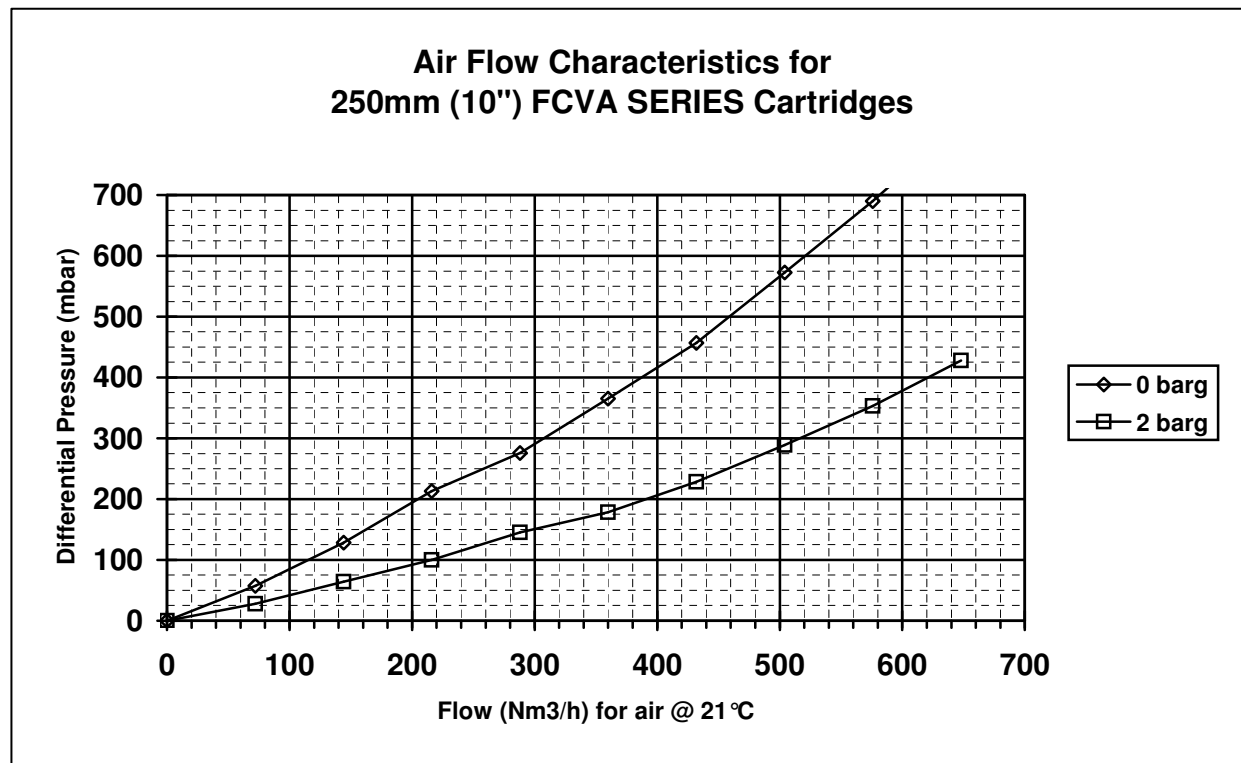
All materials used in the construction of FCVA products that have product contact have met the requirements of the current USP Biological Reactivity Tests, In Vivo to Plastics Class VI-121 °C.

All jointed surfaces are assembled by the use of heat sealing technology. No resins or binders are used in the manufacture of the filter and no surfactants are added to aid wetting.

Component	Material of Construction
Filtration Membrane	Polytetrafluoroethylene (PTFE)
Upstream Support	Polypropylene
Downstream Support	Polypropylene
Inner Support Core	Polypropylene
Outer Protection Cage	Polypropylene
Endcaps	Polypropylene
Endcap Insert	316 Stainless Steel /
Standard O-rings	Silicone

### 8.3 Flow Characteristics

The effective filtration area of a standard 250mm (10") module is 0.75 m<sup>2</sup> (7.9 ft<sup>2</sup>).



### 8.4 Operating Temperatures and Pressures

Below are the recommended maximum differential operating pressures at various temperatures: -

Temperature		Differential Pressure Cartridges		Operating Pressure Capsules Liquids (gases)	
°C	°F	bar	psi	barg	psig
20	68	5.00	72.5	5.00 (4.00)	72.5 (58.0)
40	104	4.00	58.0	5.00 (4.00)	72.5 (58.0)
50	122	3.00	43.5	3.00 (3.00)	43.5 (43.5)
70	158	2.00	29.0	Not Recommended	

**8.5 Steam Sterilization***Autoclave*

Product Format	Autoclave Temp		Number of Cycles	Cycle Time (minutes at temperature)
	°C	°F		
Cartridges	142	288	120	30

To maximize cartridge and capsule life, a slow exhaust cycle is recommended.

*Steam in Place (SIP)*

Product Format	SIP Temp		Number of Cycles	Cycle Time (minutes at temperature)
	°C	°F		
Cartridges	142	288	120	30

To maximize the life of the cartridge, the differential pressure across the cartridge should not exceed 0.30 bar (4.4 psi) at 142 °C (288 °F). For new applications it is recommended that the manufacturer's guidance for the method of steam sterilization be followed.

### 8.6 Tests for BioCompatibility

An independent research establishment has assessed the biological safety associated with the use of FCVA filters designed for processing pharmaceutical products. The materials used in the construction of FCVA products meet the requirements of the current USP <88> *Biological Reactivity* tests at Plastics Class VI – 121 °C.

### 8.7 Extractables

All pharmaceutical grade filters are designed and manufactured to yield a minimum of extractables. Testing of a purified water filtrate with FCVA is documented below.

#### Test Method (1)

Non-volatile extractables from purified water samples after flowing through an autoclaved 250mm (10”) FCVA cartridge are listed below. The levels shown are the quantities present in 100ml samples of filtrate which were taken at stages throughout a 10-litre flush.

**Cartridge Serial No. S000136**

Flush Quantity (litres)	Non-volatile Extract (mg per 100ml)	Oxidisables (per USP 23 Test Method)
1	0.5	PASS
2	0.1	PASS
4	<0.1	PASS
6	0.1	PASS
8	<0.1	PASS
10	<0.1	PASS

#### Test Method (2)

Non-volatile extractables from an autoclaved 250mm (10”) FCVA cartridge and a B-size FCVA capsule following a 4-hour dynamic immersion in a variety of commonly used solvents. Solvent volume used 1500ml.

Solvent	Serial No. Cartridge	Weight of extract (mg)	Serial No. Capsule	Weight of extract (mg)
Water	M41711	2.2	A022783	<0.2
Iso Propyl Alcohol (IPA)	M41719	17.6	A022782	0.38
Ethanol	M41729	9.8	A022777	0.11
Methanol	M41717	12.0	A022773	3.00
Ammonium Hydroxide (pH12)	M41708	0.8	A022776	<0.2
Hydrochloric Acid (pH3)	M41714	8.3	A022774	<0.2

### 8.8 Integrity Testing Data

The following is the integrity test information for the micron ratings available within the FCVA product range. Diffusional flow and bubble point values are given for cartridges wetted in 60:40<sub>v/v</sub> IPA:Water solution.

Micron Rating	Minimum Bubble Point <sup>5</sup>		Diffusional Flow Test Pressure		Maximum Diffusional Flow (ml/min)		
	bar	psi	bar	psi	10"	20"	30"
0.2 / 0.01	1.00	14.5	0.80	11.6	18.0	36.0	54.0
			Water Intrusion Test Pressure		Maximum Water Intrusion (ml/10min)		
			bar	psi	10"	20"	30"
			2.50	36.3	16.0	32.0	48.0

## 9 Correlation of Non-Destructive Integrity Testing to Liquid Bacterial Challenge with *Brevundimonas diminuta* (ATCC 19146) for 0.20 µm Sterilising Grade Filters

To guarantee filter performance a filter must be capable of being non-destructively integrity tested. This was recognized by the FDA in the "Guideline on Sterile Drug Products produced by Aseptic Processing" (June 1987), which states:

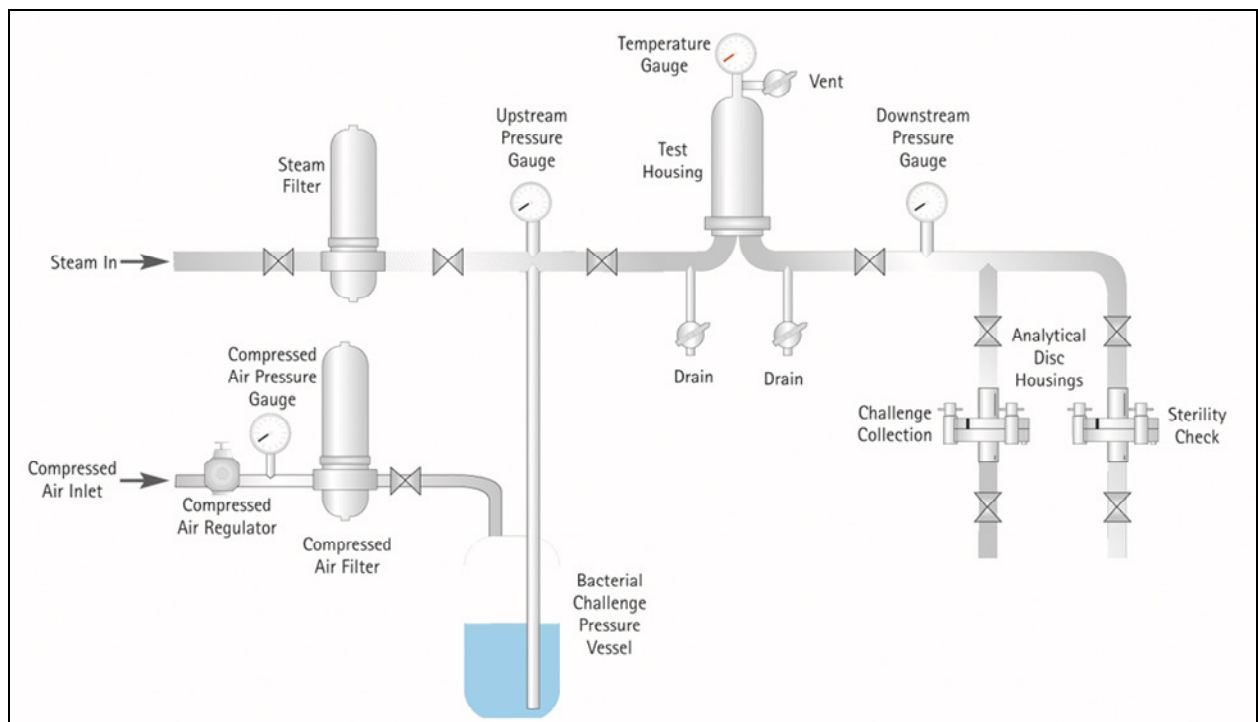
*"After a filtration process is properly validated for a given product process and filter, it is important to assure that identical filter replacements (membrane or cartridge) used in production runs will perform in the same manner. One way of achieving this is to correlate filter performance data with filter integrity testing data. Normally, integrity testing of the filter is performed after the filter unit is assembled and sterilized prior to use. More importantly, however, such testing should be conducted after the filter is used in order to detect any filter leaks or perforations that may have occurred during the filtration."*

To achieve this objective the correlation between bacterial challenge retention and a non-destructive integrity test must be proven. The procedure documented in ASTM F838-83, 'Standard Test Method for Determining Bacterial Retention Of Membrane Filters Utilized For Liquid Filtration', is used to test the manufactured product<sup>6</sup>. The filter must be challenged with a minimum of 10<sup>7</sup> viable *Brevundimonas diminuta* (ATCC 19146) per cm<sup>2</sup> of effective filtration area.

<sup>5</sup> Bubble point is not recommended as an integrity test method for cartridges, but values are given for use as an indicator of product integrity.

<sup>6</sup> Previous reference to the guidance document *Microbial Evaluation of Filters for Sterilising Liquids*, HIMA Document No. 3 Vol. 4, April 1982, referred to in USP<1211> *Sterilisation by Filtration* has been superseded by the equivalent ASTM F838-83.

## 9.1 Liquid Bacterial Challenge Schematic



Any organisms that pass through the test filter are collected and cultured on the surface of analytical discs. In this way colonies may be counted and bacterial species identified. The bacterial challenge is quantified by expressing the filters' efficiency to remove the challenge organism from the challenge suspension as a Log Reduction Value (LRV). To be classed as a sterilising grade filter the test filter must produce a sterile filtrate and  $LRV > 7.0$ .

$$LRV = \text{Log}_{10} \left( \frac{\text{Number of organisms in the challenge}}{\text{Number of organisms in the filtrate}} \right)$$

## 9.2 Diffusional Flow Correlation

Table 1 lists FCVA 0.2  $\mu\text{m}$  cartridges that were diffusional flow integrity tested before and after bacterial challenge. The bacterial challenge was conducted using ASTM F838-83 so providing the necessary correlation between a bacterial challenge and a non-destructive diffusional flow test.

Table 1 indicates that a 250mm (10") FCVA 0.2  $\mu\text{m}$  filter exhibiting a diffusional flow of  $<22.0 \text{ ml/min}$  when completely wet out in 60:40<sub>v/v</sub> IPA:Water, at a test pressure of 0.80 barg (11.6 psig) at 20°C (68°F) will produce a sterile filtrate. To build in an added level of security, the allowable diffusional flow has been reduced.

**A 250mm (10") FCVA 0.2  $\mu\text{m}$  filter, that is completely wet out in 60:40<sub>v/v</sub> IPA:Water, has a maximum diffusional flow value of:**

**18.0 ml/min at a test pressure of 0.80 barg (11.6 psig) at 20°C (68°F).**

The maximum diffusional flow for other FCVA filters is based upon the ratio of the surface area compared to that of a 250mm (10") cartridge.

**Table 1: Diffusional Flow Correlation Data**

Filter Type: FCVA710S2      FCVA 0.2µm 10" Cartridge

Challenge Organism: *Brevundimonas diminuta* (ATCC 19146)

Serial No.	Diffusional Flow (Air in 60:40 <sub>v/v</sub> IPA:Water) @ 0.80 barg (11.6 psig) <i>ml/min</i>	Challenge Level (x 10 <sup>11</sup> )	Organisms Passed	LRV <sup>7</sup>
M32898	0.5	1.70	0	11.23
M36067	2.0	2.50	0	11.40
M32903	2.2	1.34	0	11.13
M32914	2.2	2.64	0	11.42
M36065	2.3	0.31	0	10.49
M32894	3.1	1.64	0	11.21
M32902	3.1	1.77	0	11.25
M41707	3.5	0.14	0	10.15
M32908	3.7	2.41	0	11.38
M41710	5.1	0.15	0	10.18
M36069	6.1	1.57	0	11.20
N008205	6.6	2.88	0	11.46
M37703	6.7	3.25	0	11.51
M32916	6.7	2.32	0	11.37
M32910	6.8	1.65	0	11.22
M41722	6.8	0.13	0	10.11
N008204	7.0	1.99	0	11.30
M37700	7.2	3.08	0	11.49
J29578	7.9	1.80	0	11.26
J29577	7.9	3.02	0	11.48
S000143	9.9	2.87	0	11.46
M36064	11.0	3.11	0	11.49
M37710	11.0	2.01	0	11.30
E92447	22.0	0.52	0	10.72
M38639	22.4	3.29	15	10.34
M41723	36.5	0.40	333	8.08

<sup>7</sup> Where Organisms passed = 0, LRV is stated as *greater than*.

### 9.3 Water Intrusion Correlation

Table 2 proves the correlation that a 250mm (10") FCVA 0.2um filter with a Water Intrusion value of <20.0 ml / 10min at a test pressure of 2.50 barg (36.3 psig) at 20°C (68°F) will produce a sterile filtrate. To build in an added level of security, the allowable Water Intrusion value has reduced.

**A 250mm (10") FCVA 0.2 um filter has a maximum allowable Water Intrusion value of:**

**16.0 ml/10min at a test pressure of 2.50 barg (36.3 psig) at 20°C (68°F).**

The Water Intrusion and Water Flow values for other FCVA filters are based upon the ratio of the surface area compared to that of a 250mm (10") cartridge.

**Table 2: Water Intrusion Correlation Data**

Filter Type: FCVA710S2 FCVA 0.2µm 10" Cartridge

Challenge Organism: *Brevundimonas diminuta* (ATCC 19146)

Serial No.	WI @ 2.50 barg (36.3 psig) ml/10min	Challenge Level (x 10 <sup>11</sup> )	Organisms Passed	LRV <sup>8</sup>
M36064	6.0	3.11	0	11.49
M36067	7.7	2.50	0	11.40
M36069	7.9	1.57	0	11.20
M32894	10.3	1.64	0	11.21
M32898	11.2	1.70	0	11.23
M32907	11.8	2.04	0	11.31
M32908	12.1	2.41	0	11.38
M32910	12.7	1.65	0	11.22
M32902	13.3	1.77	0	11.25
N008204	13.3	1.99	0	11.30
M32896	15.4	1.93	0	11.29
M32916	16.0	2.32	0	11.37
M32915	20.1	1.99	0	11.30
N008200	29.3	1.19	TNTC <sup>9</sup>	<7.00
M38638	38.4	1.62	2083	7.89
M38636	74.2	3.29	16	10.31

<sup>8</sup> Where Organisms passed = 0, LRV is stated as *greater than*.

<sup>9</sup> TNTC – Too Numerous To Count

## 10 Retention to Aerosolized *Brevundimonas Diminuta*

Tests have shown that FCVA is fully retentive to aerosolized *Brevundimonas diminuta* (ATCC 19146) bacteria when challenged with a total of  $2 \times 10^9$  cfu over a 1-hr test at the rated flow of the cartridge.

## 11 Chemical Compatibility

Testing has been carried out that shows FCVA filters and capsules have a broad range of chemical compatibility with chemicals commonly used in the pharmaceutical industry.

### 11.1 Chemical Compatibility Summary Chart for Pharmaceutical Products

Acetic acid 3.5N	C	Methylene Chloride @ 40°C	-
Acetic acid 8.75N	C	Nitric acid 2N 14.4%	C
Acetic acid conc.17.5N	C	Nitric acid 15.8N	C
Acetone	C	Ozone	-
Acetonitrile	C	Paraffin yellow	C
Acidbrite 4 (Diversey) 3.0% <sub>v/v</sub>	-	Pentane	-
Ammonium Hydroxide 8N	C	Peracetic acid 0.5% (10 wk test)	C
Ammonium Oxalate 0.07N	C	Peracetic acid 4%	C
Amyl Acetate	C	Perchloroethylene	-
Aqueous Ammonia 15.5N	C	Petroleum spirits	C
Benzyl Alcohol	C	Phenol (aq) 0.5N	NC
Benzalkonium Chloride 0.1%	C	Phenol 5%	-
Boric acid, saturated	C	Phenol 0.25%	-
Butan-1-ol	LC	Polyethylene Glycol 600	C
Butan-2-ol	C	Polyglycol 2000-E	-
Carbon Tetrachloride	C	Potassium Dichromate 0.1N	C
Chloroform	C	Potassium Iodine 0.6N	C
Cyclohexane	-	Potassium Hydroxide 10N	C
1,4 – Dioxane	C	Potassium Permanganate 0.1N	C
Diverflow (Diversey) 3% <sub>v/v</sub>	-	Propan-1-ol	C
Diversey 212G 0.6% <sub>v/v</sub>	-	Propan-2-ol	C
Divosan Forte 0.5% <sub>v/v</sub>	-	Propan-2-ol, 60:40 H <sub>2</sub> O	C
Divosan XT 1% <sub>v/v</sub>	-	Pyridine	C
Ethanol	C	Sodium Chloride 0.5N	C
Ethanol 45%	-	Saline Lactose Broth	C
Ethyl Acetate	LC	Sodium Hydroxide 2N 8%	C
Formaldehyde 0.3%	C	Sodium Hydroxide 7N 28%	C
Formaldehyde 37%	C	Sodium Hypochlorite (14% Free Cl <sub>2</sub> )	C
Formic acid conc.	C	Sodium thiosulphate 0.1N	C
Glycerol	C	Sulphuric acid 1N	C
Hexane	C	Sulphuric acid conc.	LC
Hydrochloric acid 1N	-	Sulphurous acid	-
Hydrochloric acid conc.	-	Toluene	NC
Hydrochloric acid conc.13%	C	1,1,1 Trichloroethane	-
Hydrogen Peroxide	-	1,1,2 Trichloroethane	C
Hydrogen Peroxide 10% Volume	-	Trichloroacetic Acid 80%	-
Hydrogen Peroxide 100% Volume	C	Trichloroacetic Acid 5N	C
Methanol	C	Toluene	-
Methyl-Iso-Butylketone	C	Xylene	LC

### **11.2 Chemical Compatibility User Instructions and Notes**

- The chemicals are arranged in alphabetical order using their most common or trade names. If the chemical in question does not appear to be listed, it may be found elsewhere in the table under a pseudonym, in particular its IUPAC<sup>10</sup> name.
- With regard to compatibility:
  - ◇ Any product that has Limited Compatibility (LC) at ambient temperatures should not be used at a higher temperature.
  - ◇ The list of compatibilities does not take into account any synergistic effects of more than one chemical present in the solution to be filtered.
  - ◇ Test Conditions – 72 hrs at ambient temperature and pressure, unless otherwise stated.

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<sup>10</sup> IUPAC – International Union of Pure and Applied Chemistry