Finetech's Syringe Filter Advantages

Finetech Research and Innovation Corporation

11 Syringe Filter Advantages	Finetech Brand	Low Priced Filter (China)
1. Produced in class 7/10,000 clean room environment to ensure the product's cleanliness and to prevent contamination.	○	X
2. The inlet and outlet meets the requirements of ISO 594-1. The tight connection between syringe and filter prevents any leakage.	○	X
3. Number on filter housing for traceability and quality control.	○	X
4. Compliance with ISO13485 to ensure standard production process and management.	○	X
5. Patented drainage design of outlet that makes the liquid flow easily.	○	X
6. 25mm syringe filters available with **double/triple layers** for filtering samples with high solid content.	○	X
7. Syringe filter does not contain plasticizer.	○	X
8. Filter housing made of medical grade (USP Plastic Class VI) PP.	○	X
9. HPLC extractables tested against Millipore's syringe filter.	○	X
10. Residual volume test meets international requirement.	○	X
11. Burst test greater than 5 kg/cm^2.	○	X

1. Produced in Class 7 Clean Room (Fed. Std-209E Class 10,000 Equivalent)

ISO 14644-1:2015 Cleanroom Standard

Class		Maximum Particles (/m³)					
ISO14644-1	Fed. Std-209E	0.1 μm	0.2 μm	0.3 μm	0.5 μm	1.0 μm	5.0 μm
Class 1		10					
Class 2		100	24	10			
Class 3	Class 1	1,000	237	102	35		
Class 4	Class 10	10,000	2,370	1,020	352	83	
Class 5	Class 100	100,000	23,700	10,200	3,520	832	
Class 6	Class 1,000	1,000,000	237,000	102,000	35,200	8,320	293
Class 7	Class 10,000				352,000	83,200	2,930
Class 8	Class100,000				3,520,000	832,000	29,300
Class 9					35,200,000	8,320,000	293,000

Start Time: 2019-07-03 13:00:53
Start Time: 2019-07-03 13:20:22

Location	Status	Sampling Time (Sec)	Times	0.3um	0.5um	5.0um	Unit
1	OK	60	1	235000	58300	9890	/m3
2	OK	60	1	214000	55100	6710	/m3
3	OK	60	1	209000	30400	4240	/m3
4	OK	60	1	286000	48400	8120	/m3
5	OK	60	1	346000	138000	28300	/m3
6	OK	60	1	135000	14500	1770	/m3
7	OK	60	1	167000	31800	6000	/m3
8	OK	60	1	215000	57200	14800	/m3
9	OK	60	1	251000	53000	8480	/m3
10	OK	60	1	208000	52600	5300	/m3
11	OK	60	1	364000	102000	13800	/m3
12	OK	60	1	213000	45200	7420	/m3
13	OK	60	1	201000	60000	2120	/m3

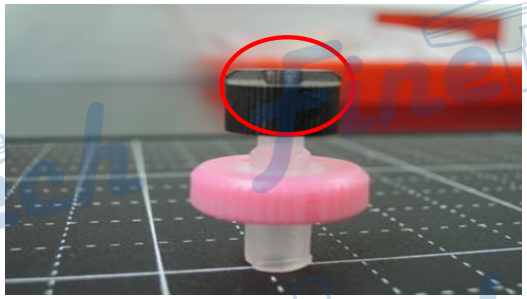
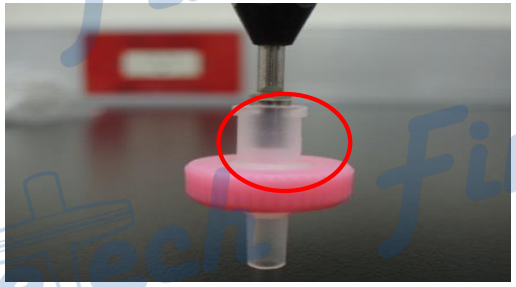
1. Clean room environment prevents dust and hair contamination.
2. Reduces particles especially from the outlet of the filter, which will protect columns from damage

2. Complies with ISO 594-1

- Inlet and Outlet connects tightly with syringes and needles.

  Meets all the requirements of ISO 594-1 (6% Luer)

  (*Luer locks are used in a variety of medical devices and drug delivery applications)

	
Finetech Filter Pass	**Lower quality brand** Fail
	
Finetech Filter	**Lower quality brand**

Disadvantages of not complying with ISO 594-1 :

1. Difficult to conform to internationally standardized components and instruments.
2. Easy to leak and lose sample
3. Solvents can also spray out from the inlet, putting the operator at risk.

3. Syringe Filter Housing QC Number

* Easy for tracing back and quality control management

4. ISO13485 Certified

CISQ is a member of IQNet

www.iqnet-certification.com

ICIM

Certificate No. / *Certificato N.* 9392/0

WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY
SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI

Finetech Research And Innovation Corp.
No. 29, Anle St., Xiushui Township, Changhua County,
Taiwan, R.O.C.

IS IN COMPLIANCE WITH THE STANDARD/ *È CONFORME ALLA NORMA*

UNI CEI EN ISO 13485:2016

Quality Management System / *Sistema di gestione per la qualità*

FOR THE FOLLOWING ACTIVITIES / *PER LE SEGUENTI ATTIVITÀ*

EA: 19

Design, Manufacture, Sales and Trading of Transducer Protector, Recirculation Connector, Female Luer Lock Cap, Suction Unit, Air Vent Filter and Feeding Set for Medical Use

Refer to the documentation of the Quality Management System for details of application to reference standard requirements.
Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.
Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.
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FIRST ISSUE / *DATA EMISSIONE*	CURRENT ISSUE / *EMISSIONE CORRENTE*	EXPIRING DATE / *DATA DI SCADENZA*
18/03/2019	18/03/2019	17/03/2022

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FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

- A tougher and more rigorous standard for medical devices safety and effectiveness, compared to the more customer satisfaction based ISO 9001.

5. Patented Drainage Design of Outlet

中 華 民 國 專 利 證 書

新型第 M 417540 號

新 型 名 稱：針頭過濾器

專 利 權 人：李國鈺

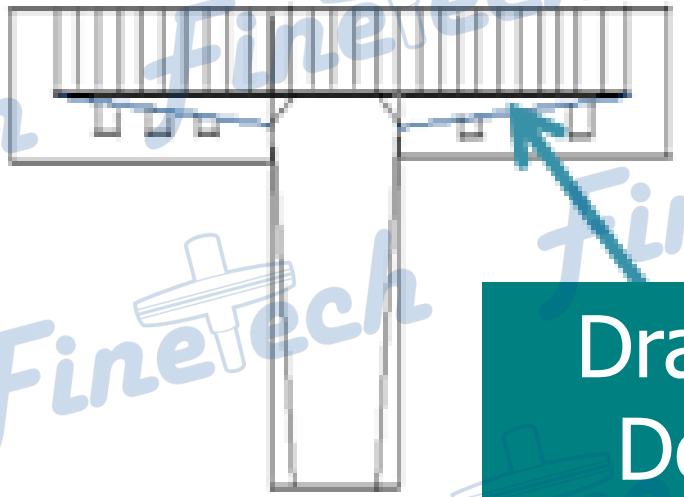
創 作 人：李國鈺

專利權期間：自 2011 年 12 月 1 日至 2021 年 7 月 7 日止

上開新型業依專利法規定通過形式審查取得專利權
行使專利權依法應提示新型專利技術報告進行警告

經濟部智慧財產局
局 長 王美花

中 華 民 國 100 年 12 月 1 日



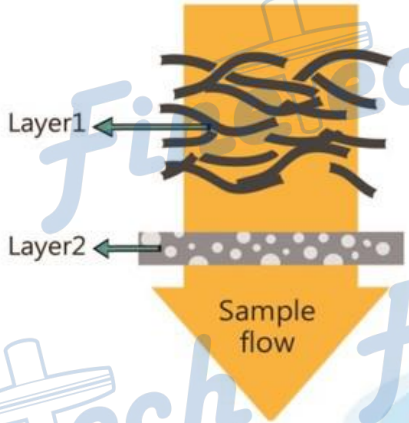
Drainage Design

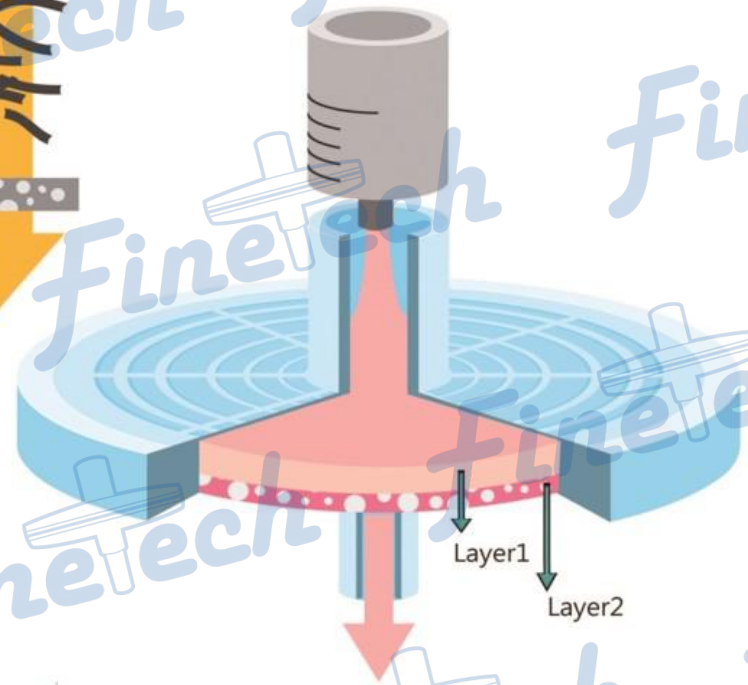
Allows liquids to easily flow out, lowering the “Hold-up Volume”.

6. Double Layer Filter Design (DualTech)

Layer 1
Glass prefilter(GF)
down to 1 µm

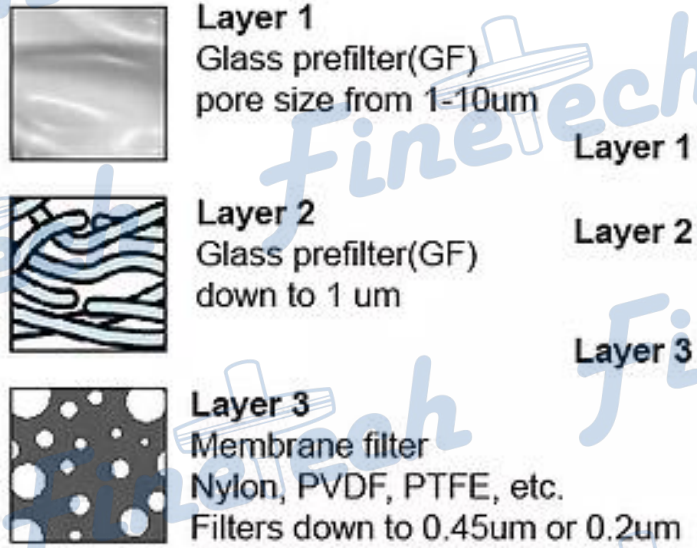
Layer 2
Membrane filter
Nylon, PVDF, PTFE, etc.
Filters down to 0.45 µm or 0.2 µm





- Increased filter durability.
- Filters high particulate samples.
- Higher volume throughput.

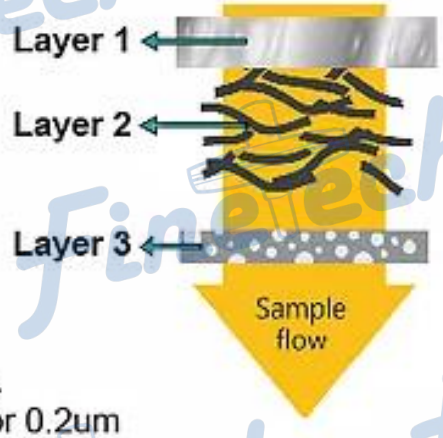
6. Triple Layer Filter Design (TriTech)

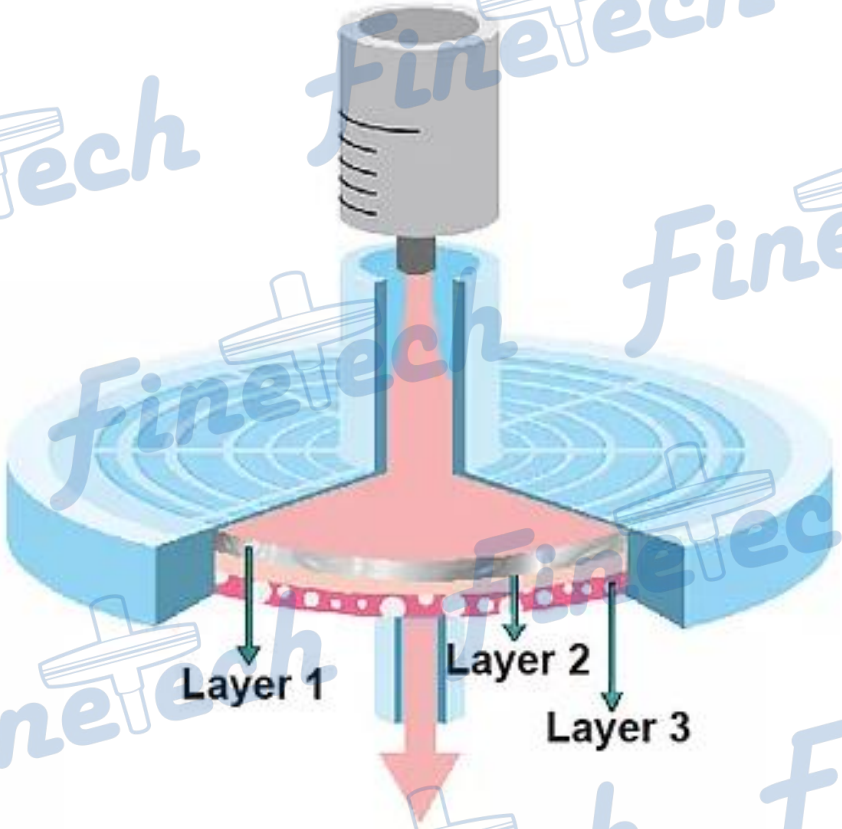


Layer 1
Glass prefilter(GF)
pore size from 1-10um

Layer 2
Glass prefilter(GF)
down to 1 um

Layer 3
Membrane filter
Nylon, PVDF, PTFE, etc.
Filters down to 0.45um or 0.2um





- Able to filter samples with much higher solid concentrations.
- Increased volume throughput over dual layer and other filters.

7. Plasticizer (Phthalate) Test Report

測試結果(Test Results)

測試部位(PART NAME) No.1 : 整體混測 (MIXED ALL PARTS)

測試項目 (Test Items)	單位 (Unit)	測試方法 (Method)	方法偵測極限值 (MDL)	結果 (Result) No.1
可塑劑定量分析 / Phthalates				
鄰苯二甲酸甲苯基丁酯 / BBP (Benzyl butyl phthalate) (CAS No.: 85-68-7)	%	參考EN 14372, 以氣相層析儀/質譜儀檢測之. / With reference to EN 14372. Analysis was performed by GC/MS.	0.003	n.d.
鄰苯二甲酸二 (2-乙基己基)酯 / DEHP (Di- (2-ethylhexyl) phthalate) (CAS No.: 117-81-7)	%		0.003	n.d.
鄰苯二甲酸二異癸酯 / DIDP (Di-isodecyl phthalate) (CAS No.: 26761-40-0)	%		0.01	n.d.
鄰苯二甲酸二異壬酯 / DINP (Di-isononyl phthalate) (CAS No.: 28553-12-0)	%		0.01	n.d.
鄰苯二甲酸二正辛酯 / DNOP (Di-n-octyl phthalate) (CAS No.: 117-84-0)	%		0.003	n.d.
鄰苯二甲酸二丁酯 / DBP (Dibutyl phthalate) (CAS No.: 84-74-2)	%		0.003	n.d.

備註(Note):

1. mg/kg = ppm ; 0.1wt% = 1000ppm
2. n.d. = Not Detected (未檢出)
3. MDL = Method Detection Limit (方法偵測極限值)
4. 樣品的測試是基於申請人要求混合測試，報告中的混合測試結果不代表其中個別單一材質的含量.
   (The samples was/were analyzed on behalf of the applicant as mixing sample in one testing. The above results was/were only given as the informality value.)

8. Medical Grade PP Material Certification

Confidential
TCLVI_EO7

C.F. Tsai
Formosa Plastics Corporation
1 Hsin-Hwa 1st Road
Lin-Yuan Village
Kaohsiung Hsien,
Taiwan

Lab No. 07T_41446_11
P.O. No. 75708007
Test Facility: NAMSA
6750 Wales Road
Northwood, OH 43619

REISSUED REPORT

CERTIFICATE OF COMPLIANCE
USP BIOLOGICAL REACTIVITY TESTS, *IN VIVO*

USP PLASTIC CLASS VI

Test Article: Polypropylene Pellets, YOUNGSOX 5090T
ID No. See Test Article

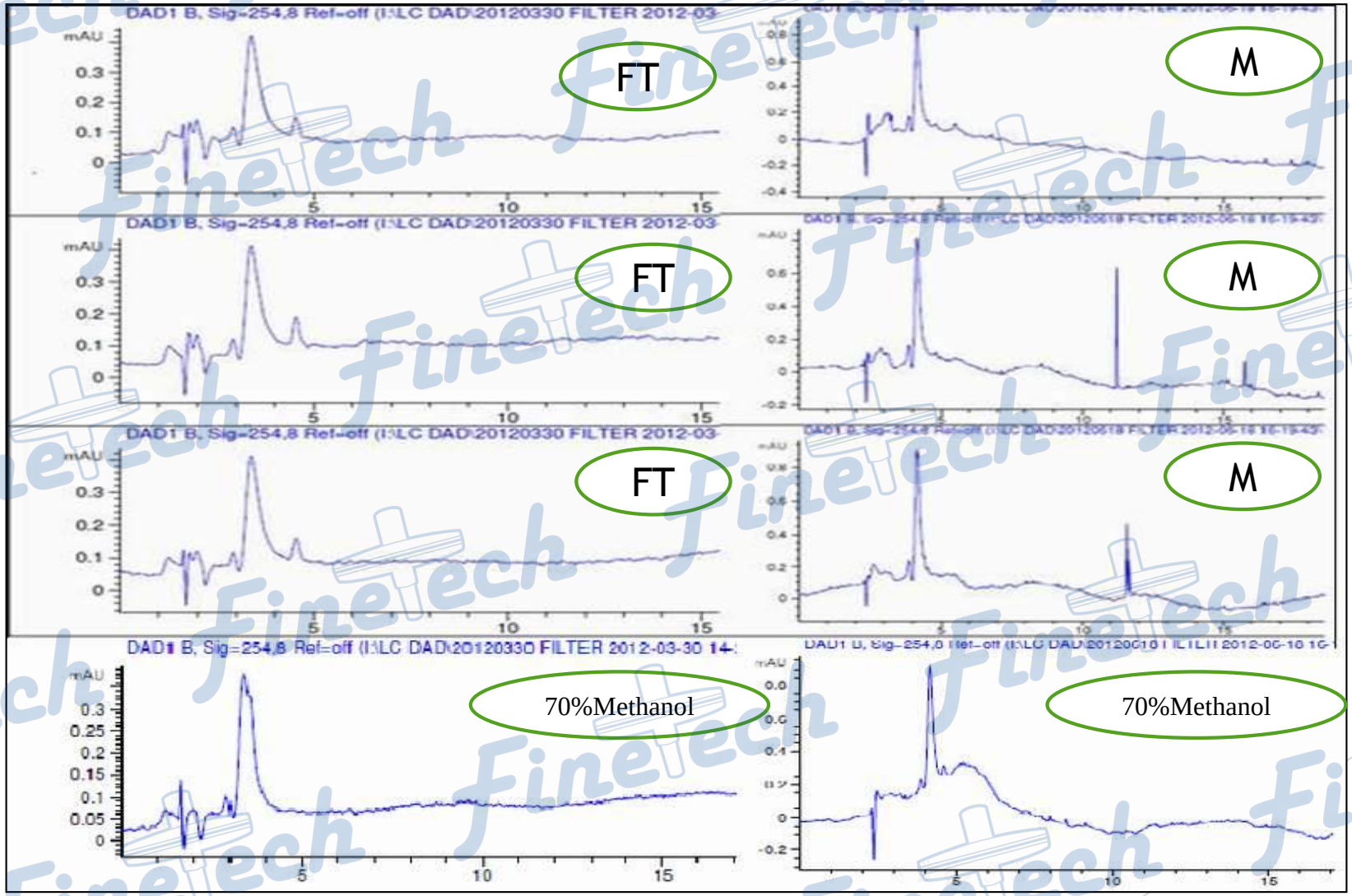
USP Systemic Toxicity Study in the Mouse: The test article was prepared as indicated below and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extractants.

USP Intracutaneous Toxicity Study in the Rabbit: The test article was prepared as indicated below and injected intracutaneously into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater tissue reaction than the blank extractants.

USP Muscle Implantation Study in the Rabbit: The macroscopic reaction of the test article, implanted in rabbit muscle for 1 week, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 4 g:20 ml and extracted at 70°C for 24 hours. The test article extracts met the requirements of a USP Plastic Class VI.

9. HPLC Extractables Test: Finetech vs M Brand Report



10. Finetech and Millipore Volume Residual Test

Product	Company	Sample 1 Residual Volume (mL)	Sample 2 Residual Volume (mL)	Sample 3 Residual Volume (mL)	Average Residual Volume (mL)
33mm (Hydophilic) PVDF0.22µm	Millipore	0.0558	0.0581	0.0443	0.0527
25mm (Hydophilic) PVDF0.22µm	FT Brand	0.0857	0.0933	0.0889	0.0893
25mm (Hydrophobic) PTFE0.22µm	Millipore	0.1272	0.1443	0.1103	0.1273
25mm (Hydrophobic) PTFE0.22µm	FT Brand	0.0555	0.0596	0.1645	0.0932
33mm (Hydophilic) Nylon0.45µm	Millipore	0.0850	0.0912	0.0677	0.0813
25mm (Hydophilic) Nylon0.45µm	FT Brand	0.0599	0.0760	0.0614	0.0658
33mm (Hydophilic) Nylon0.2µm	Millipore	0.0928	0.0942	0.0738	0.0869
25mm (Hydophilic) Nylon0.2µm	FT Brand	0.0584	0.0743	0.0876	0.0734

11. Burst Test

*Our syringe filters can withstand 5 kg/cm^2 of pressure

END