



# Why You Should Choose Syringe Filters from Finetech

**Finetech Research and Innovation Corporation**



## 11 Finetech Syringe Filter Advantages

	Finetech	Low Priced Filter (China)
1. Produced in class 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 ISO9001, ISO13485, and GMP (Good Manufacturing Practice) certification to ensure standard production process and management.	○	X
5. Patented drainage design of outlet that makes the liquid flow easily.	○	X
6. The 25mm syringe filters are double layer for filtering large particles and highly viscous samples.	○	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 between Finetech and Millipore.	○	X
10. Residual volume test meets international requirement.	○	X
11. Burst test greater than 5 kg/cm <sup>2</sup> .	○	X

# 1. Produced in Class 10,000 Clean Room

Airborne Particulate Cleanliness Classes  
Clean room which meets the American Federal Standard 209E

Class	Level limit										
	0.3µm		0.5µm		1µm		3µm		5µm		
IS	数量	单位	数量	单位	数量	单位	数量	单位	数量	单位	
M4.5	1000	(/F)	---	(/F)	---	(/F)	15300	(/F)	1000	247	7.38
M5	---	(/F)	---	(/F)	---	(/F)	100000	(/F)	2800	618	17.5
M5.5	10001	(/F)	---	(/F)	---	(/F)	153000	(/F)	10000	2470	70.6
M6	---	(/F)	---	(/F)	---	(/F)	1000000	(/F)	28300	6180	173
M6.5	100000	(/F)	---	(/F)	---	(/F)	1530000	(/F)	100000	24700	700
M7	---	(/F)	---	(/F)	---	(/F)	10000000	(/F)	283000	61800	1750

Standard (AFS)	Biological Particles Per cu. ft.	Biological Particles Per sq. ft. week
Class 100	0.1	1,200
Class 10,000	0.5	6,000
Class 100,000	2.5	30,000

Clean Room : Class M5.5



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

Federal Standard 209E

Mode: Single  
Start Time: 2015-07-15 14:09:10  
Stop Time: 2015-07-15 14:24:00

Location	Status	Sampling Time(Sec)	Times	0.3µm	0.5µm	5.0µm	Unit
1	OK	60	1	7580	400	20	cf
2	OK	60	1	2320	540	0	cf
3	OK	60	1	770	50	10	cf
4	OK	60	1	8540	200	0	cf
5	OK	60	1	6030	360	0	cf
6	OK	60	1	10400	270	0	cf
7	OK	60	1	7020	180	0	cf
8	OK	60	1	5810	300	10	cf







## 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)

	
<b>Finetech Filter</b> <span style="border: 1px solid red; padding: 2px;">Pass</span>	<b>Lower quality brand</b> <span style="border: 1px solid red; padding: 2px;">Fail</span>
	
<b>Finetech Filter</b>	<b>Lower quality brand</b>

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. ISO9001, ISO13485 Certified



\*Finetech's production and management are under accordance with ISO 9001, ISO 13485, and GMP

## 4. GMP (Good Manufacturing Practice) Certified

### MANAGEMENT SYSTEM CERTIFICATE

Certificate No: 201347-2016-AQ-80C-NA Initial certification date: 31 August, 2016 Valid: 31 August, 2016 – 28 February, 2019

This is to certify that the management system of

**Finetech Research and Innovation Corp.**

No. 29, Anle St., Xiushui Township, Changhua County 504, Taiwan

has been found to conform to the management system standard:

**ISO 13485:2003**

This certificate is valid for the following Scope:

**Design, Manufacture, Sales and Trading of Transducer Protector, Recirculation Connector and Female Luer Lock Cap for Medical Use.**

Place and date:  
Havik, 31 August, 2016



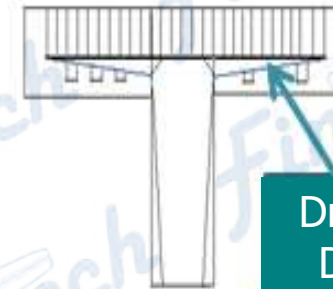
For the issuing office:  
DNV GL Business Assurance Norway AS  
Veritetsveien 1, 1322 Havik, Norway

*Eugenia Winger Husebye*  
Eugenia Winger Husebye  
Management Representative

Law of Norway and standards as set out in the Contract Agreement may apply to this Certificate issued.  
ACCREDITED UNIT: DNV GL Business Assurance Norway AS - Veritetsveien 1, 1322 Havik, Norway. Tel: +47 67 57 91 00 Fax: +47 67 57 91 11  
[www.dnv.com](http://www.dnv.com)

Manufacturing  
process of  
GMP  
guarantees  
perfect quality

## 5. Patented Drainage Design of Outlet



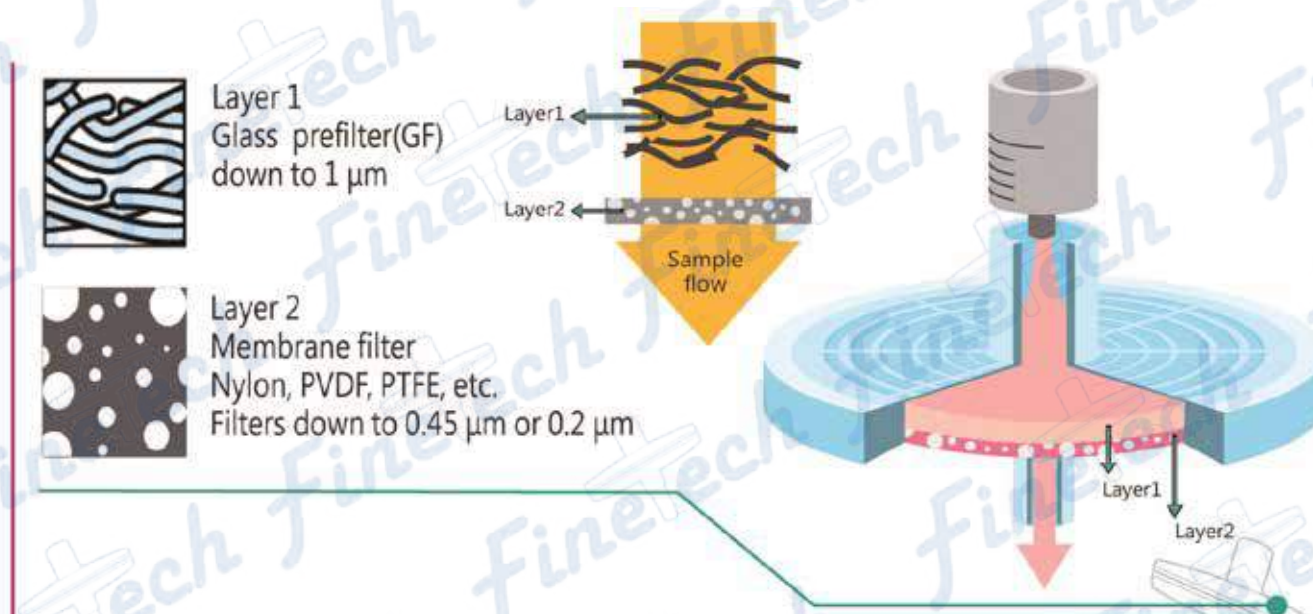
Drainage  
Design

\*Allows liquids to easily flow out.  
Which lowers the "Hold-up  
Volume".

- Syringe Filter Patent
- Patent No.: M417540



## 6. Double Layer Filter Design



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

\*The added PP or GF membrane prefilter allows for the filtering of larger particles and viscous liquids.

# 7. Plasticizer (Phthalate) Test Report



## 測試報告 Test Report

號碼(No.) : CY/2011/71539 日期(Date) : 2011/07/26 頁數(Page) : 2 of 3

波特多科技有限公司  
PROTECTOR FILTER TECHNOLOGY CORP.  
臺中市南屯區文山九街72號  
NO. 72, WEN-SHAN 9TH STREET, NAN-TUN DISTRICT, TAI-CHUNG CITY TAIWAN



### 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				
鄰苯二甲酸甲苄基丁酯 / 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.)

Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This test report cannot be reproduced, except in full, without prior written permission of the Company. 除非另有說明, 此報告結果僅對測試的樣品負責。本報告未經本公司書面許可, 不可部份複製。  
This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at [www.sgs.com/terms\\_and\\_conditions.htm](http://www.sgs.com/terms_and_conditions.htm) and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at [www.sgs.com/terms\\_e-document.htm](http://www.sgs.com/terms_e-document.htm). Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

SGS Taiwan Ltd.  
台灣檢驗科技股份有限公司 | Chemical-Taipei | 33 WuChyuan Road, Wuku Industrial Zone, New Taipei City, Taiwan / 新北市五股工業區五祥路33號 +886 (02)2299 3279 f + 886 (02)2299 3237 [www.sgs.com](http://www.sgs.com)

Member of the SGS Group (SGS SA)

# 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

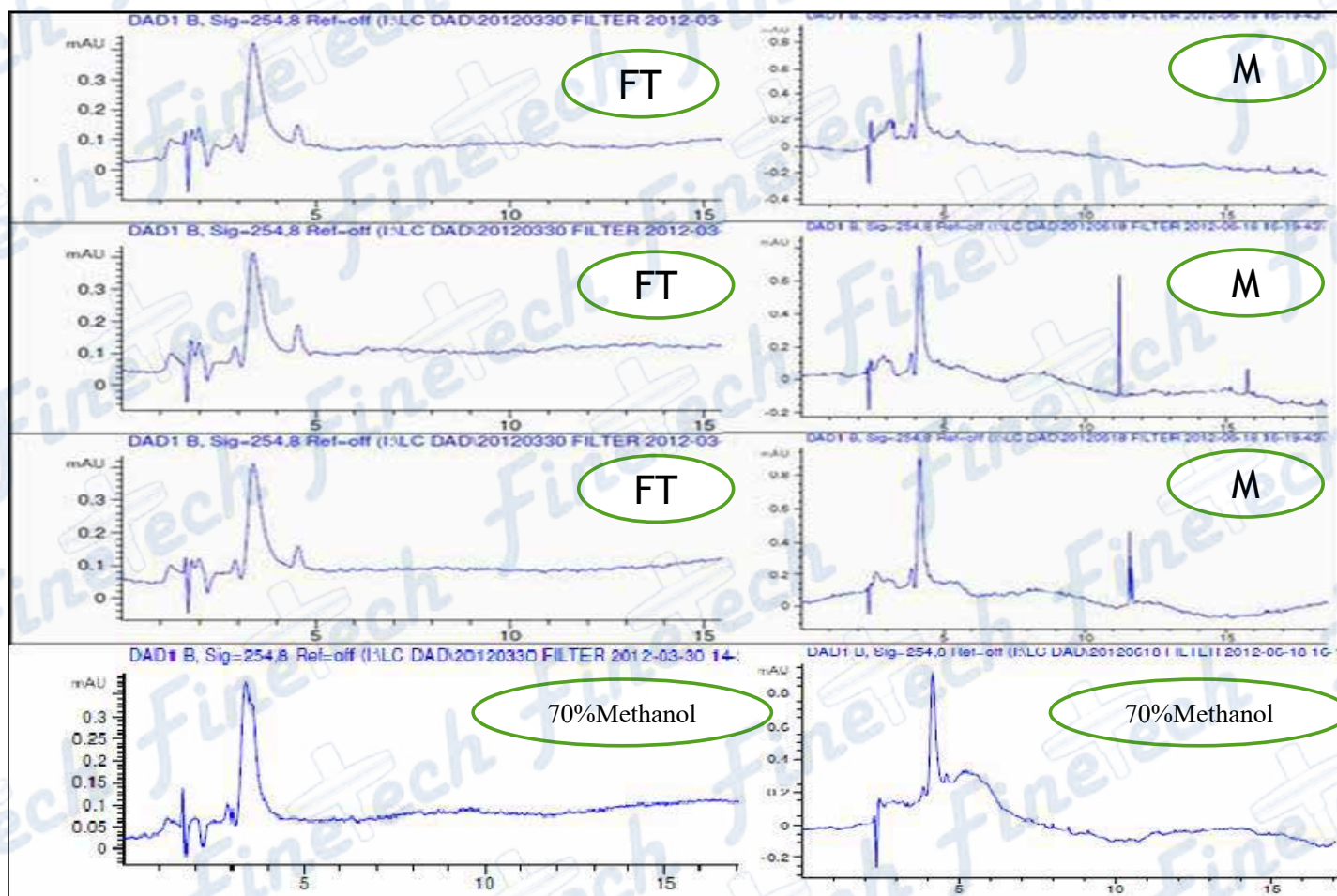
USP Systemic Toxicity Study in the Mouse: The test article was prepared as indicated below and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extractants.

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 (tested by National Chung Hsing University)



## 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	Finetech	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	Finetech	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	Finetech	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	Finetech	0.0584	0.0743	0.0876	0.0734

# 11. Burst Test



\*Finetech's syringe filters can withstand 5 kg/cm<sup>2</sup> of pressure

**END**