

## Syringe Filter Comparing Test Report

### 1. Test purpose:

Testing the performance of incoming syringe filters and comparing them with OT syringe filters (2 batches of each OT series, 3 samples from each batch).

### 2. Test items:

2.1 Appearance (luer, taper).

2.2 General performance (bubble point, flow rate, pressure resistance).

2.3 Particle retention performance.

2.4 Extractable test.

### 3. Test conditions & methods:

3.1 Appearance test methods: visual inspection of filter appearance, caliper measurement of luer diameter, standard plug gauge test taper.

3.2 General performance test methods:

3.2.1 Flow rate test: After the filter is wetted with pure water, the volume of liquid passing through the filter is tested for one minute at 25°C and 0.07Mpa.

3.2.2 Bubble point test: the filter is slowly pressurized with pure water until the first series of continuous bubbles appear, at which time the pressure value is the bubble point value.

3.2.3 Pressure resistance test: seal the outlet of the filter, pressurize it to 0.6Mpa from the inlet, keep it for 5S to see if the filter is intact.

3.3 Particle retention test methods:

3.3.1 Liquid was collected as a solution of 0.001% TritonX-100 through the filter to be tested and the absorbance value was zeroed as a blank sample. A tube of 0.002% 0.3  $\mu\text{m}$  or 0.46  $\mu\text{m}$  latex sphere was passed through all filters and collected every 3 ml. Test the absorbance.

3.3.2 Instrument used: UV-visible spectrophotometer.

3.3.3 Solvents and reagents: 0.3  $\mu\text{m}$  and 0.46  $\mu\text{m}$  latex sphere standard particles, dispersant Triton X-100.

3.3.4 Detection wavelength: 272nm.

3.3.5 Standard particle selection: 0.22 $\mu\text{m}$  membrane filter tested with 0.3 $\mu\text{m}$  standard particles, 0.45 $\mu\text{m}$  membrane filter tested with 0.46 $\mu\text{m}$  standard particles.

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### 3.4 Extractable test method

Filter with acetonitrile/water (70/30) solution

Instruments: waters UPLC H Class

Column: C18 column (1.6 $\mu$ m, 4.6\*50mm)







Mobile phase: acetonitrile/water gradient elution

Detection wavelength: 254nm

Injection volume: 10 $\mu$ l

## 4. Test results:




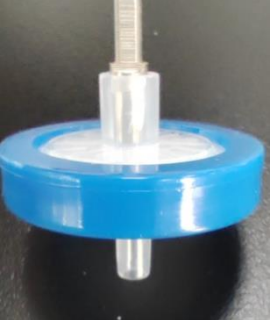

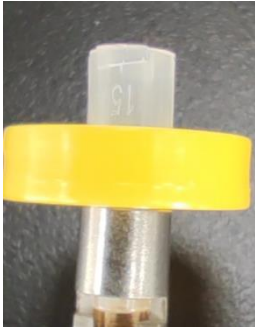


### 4.1 Appearance test results:

Green Union Sample Filter Appearance	Green Union 13mm luer diameter	Green Union 25mm luer diameter
		
Appearance of OT's corresponding filter	OT 13mm luer diameter	OT 25mm luer diameter
		

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Green Union 13mm Inlet Taper	OT 13mm Inlet Taper	Green Union 25mm Inlet Taper	OT 25mm Inlet Taper
			
Green Union 13mm outlet taper	OT 13mm outlet taper	Green Union 25mm outlet taper	OT 25mm outlet taper
			

4.1.1 The Green Union sample has a slightly blackened appearance.

4.1.2 The diameter of OT Luer meets the SS-EN 1707 EU standard (the standard requirement is  $7.8 \pm 0.1$ ), and the size of Green Union is **smaller**.

4.1.3 OT taper in line with GB-T 1962-1 national standards, Green Union products measured with a standard plug gauge, in which the inlet fails to fully insert the plug gauge, judging the **inlet taper is smaller**. The outlet failed to reveal, judging the **outlet taper is bigger**.

#### 4.2 General Performance Test Results:

Part no	Bubble Point mpa			Flow rate mL/min			Pressure Resistance mpa	Average Bubble Point	Average Flow Rate	OT Standard
Green UnionNY1322	0.38	0.32	0.29	7	7	8	>0.6	0.33	7	Bubble Point≥0.26mpa Flow Rate≥4ml/min Pressure Resistance≥0.6mpa
OT1322-361208001	0.4	0.38	0.37	6	8	7	>0.6	0.38	7	
OT1322-361229010	0.35	0.4	0.36	10	11	9	>0.6	0.37	10	
Green Union NY1345	0.2	0.26	0.21	16	14	15	>0.6	0.22	15	Bubble Point≥0.16mpa Flow Rate≥8ml/min Pressure Resistance≥0.6mpa
OT1345-361220007	0.23	0.23	0.21	25	27	24	>0.6	0.22	25	
OT1345-361206005	0.21	0.23	0.21	24	26	24	>0.6	0.22	25	
Green Union NY2545	0.27	0.26	0.24	46	52	48	>0.6	0.26	49	Bubble Point≥0.16mpa Flow Rate≥32ml/min Pressure Resistance≥0.6mpa
OT2545-360908003	0.22	0.23	0.21	90	89	98	>0.6	0.22	92	
OT2545-361103008	0.21	0.23	0.22	87	85	90	>0.6	0.22	87	

4.2.1The structure of Green Union samples and OT products are: upper cage + membrane + lower cage.

4.2.2Green Union NY0.22 general performance is close to OT's.

4.2.3Green Union NY0.45 bubble point is close to OT's, with a lower flow rate of about 50-60% of OT's.

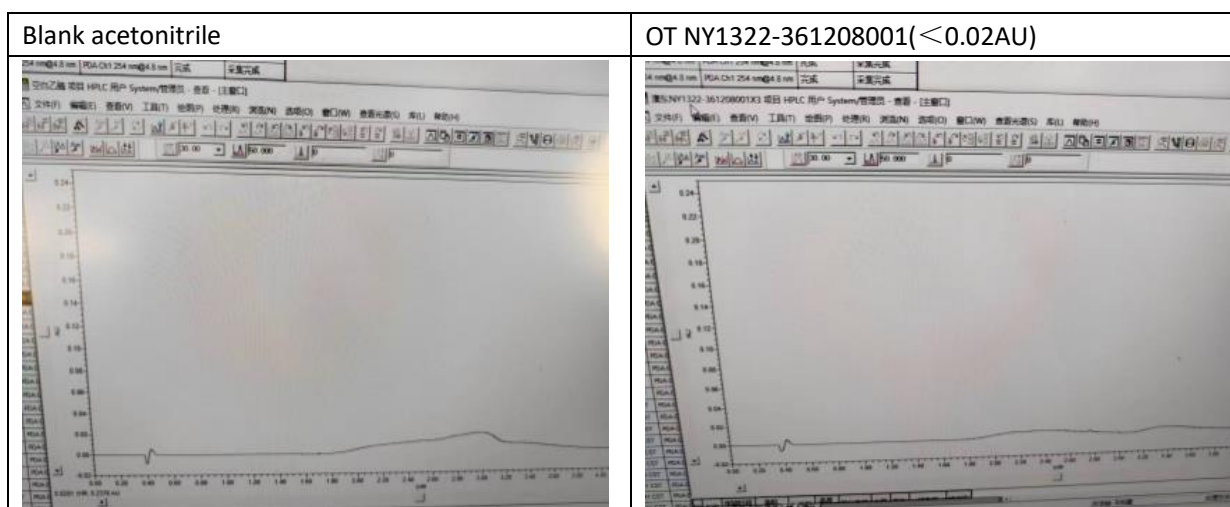
#### 4.3 Retention & Extractable results:

Part No.	Retention Rate			Extractable
Green Union NY1322	99.17%	99.48%	99.48%	≈0.07AU
OT NY1322-361208001	99.58%	99.58%	99.58%	<0.02AU
OT NY1322-361229010	99.48%	99.58%	99.48%	<0.02AU
Green Union NY1345	100%	99.82%	99.91%	<0.02AU
OT NY1345-361220007	99.30%	99.73%	99.82%	<0.02AU
OT NY1345-361206005	99.91%	99.91%	100%	<0.02AU
Green Union NY2545	99.82%	99.73%	99.73%	≈0.03AU
OT NY2545-360908003	100%	100%	99.82%	<0.02AU
OT NY2545-361103008	100%	100%	100%	<0.02AU

4.3.1 The particle retention performance of Green Union is basically close to that of OT's.

**4.3.2 Extractable test:** Green Union NY1322 and NY2545 have a small amount of extractable, and the rest of the samples have only a small amount of extractable, as well as the OT samples.

4.3.3 Extractable spectrum is shown below

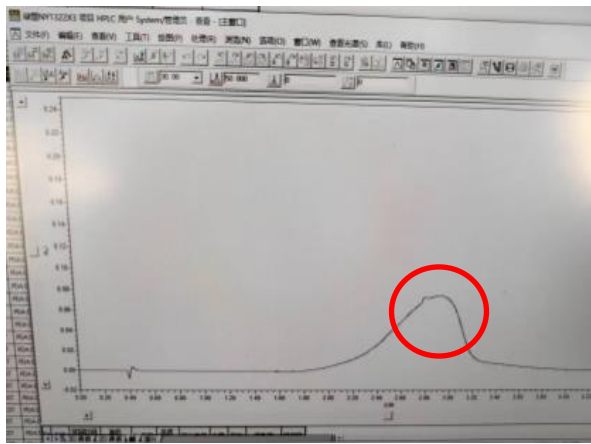
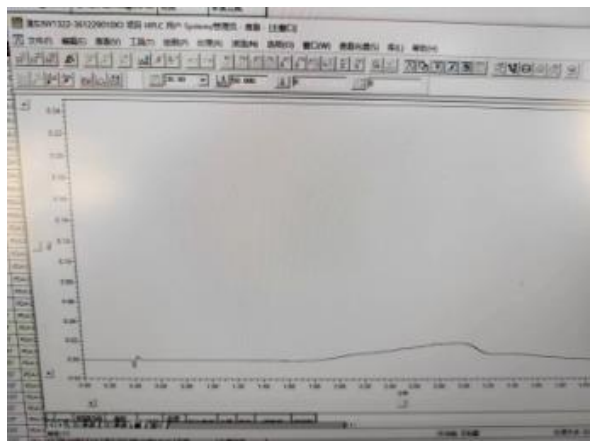
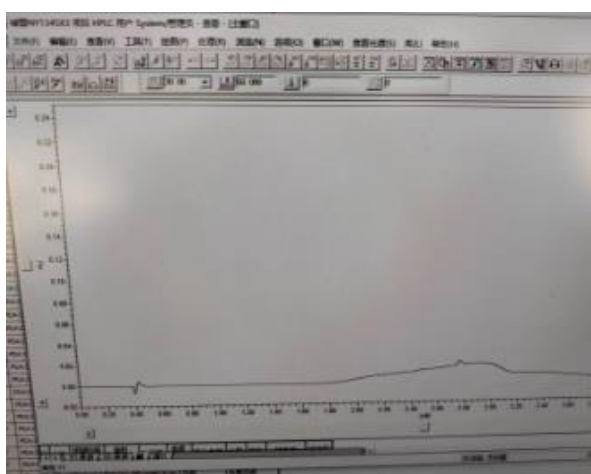
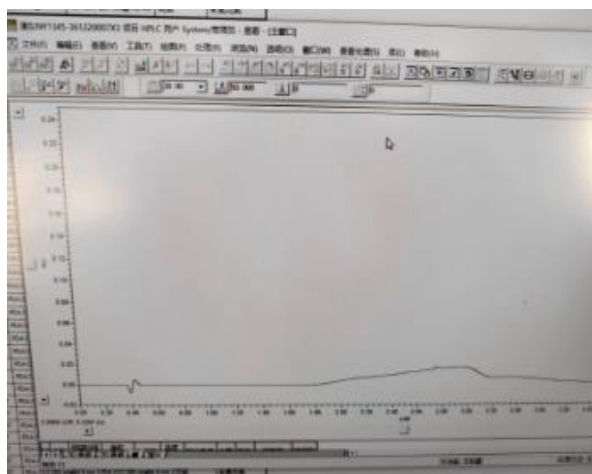
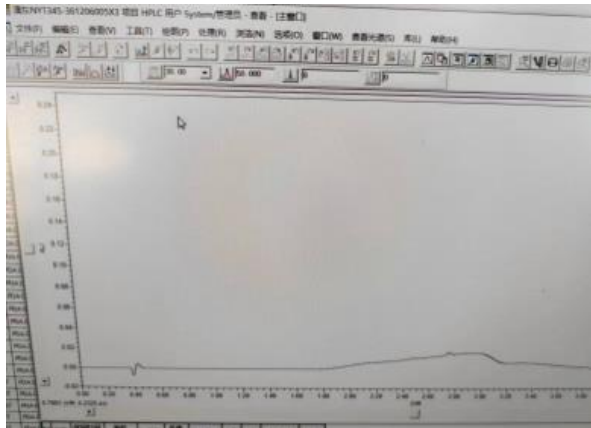
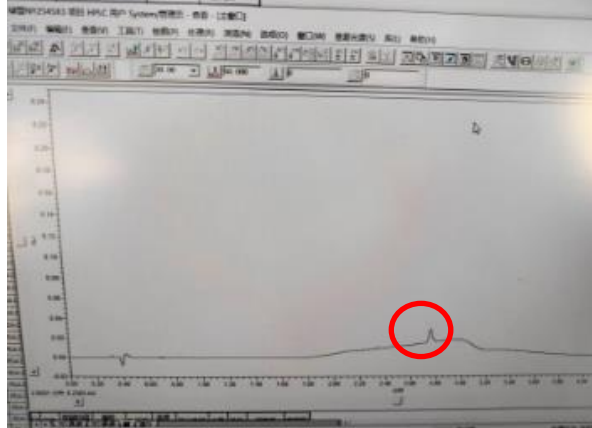




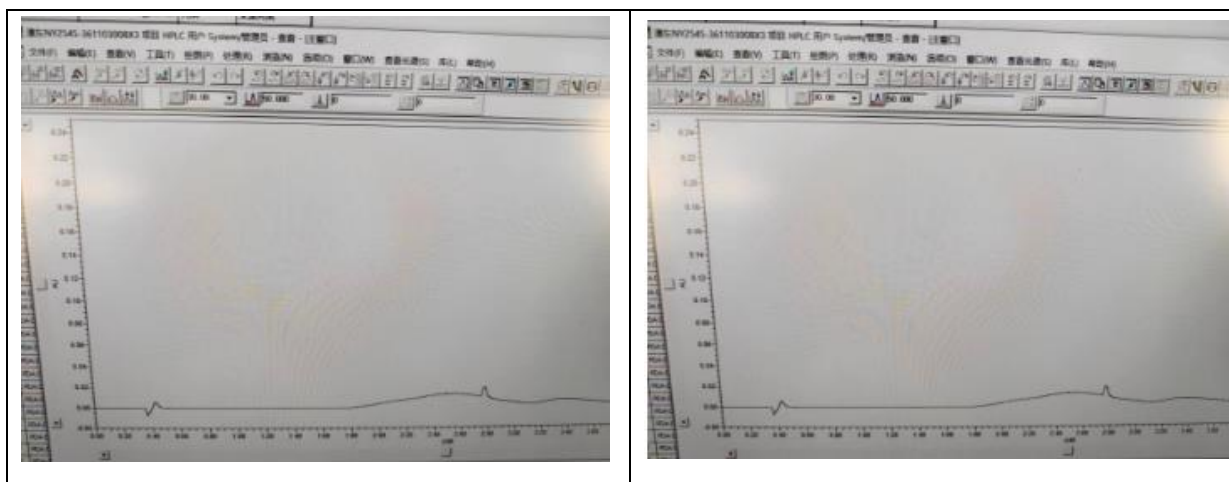
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<p>Green Union NY1322(<math>\approx 0.07\text{AU}</math>)</p> 	<p>OT NY1322-361229010(<math>&lt; 0.02\text{AU}</math>)</p> 
<p>Green Union NY1345(<math>&lt; 0.02\text{AU}</math>)</p> 	<p>OT NY1345-361220007(<math>&lt; 0.02\text{AU}</math>)</p> 
<p>OT NY1345-361206005(<math>&lt; 0.02\text{AU}</math>)</p> 	<p>Green Union NY2545(<math>\approx 0.03\text{AU}</math>)</p> 
<p>OT NY2545-360908003(<math>&lt; 0.02\text{AU}</math>)</p> 	<p>OT NY2545-361103008(<math>&lt; 0.02\text{AU}</math>)</p> 



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