

## SUPER LABORATORY CO., LTD.

### TESTING CENTER TEST REPORT



#### CUSTOMER

### Finetech Research & Innovation Corp.

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

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Sample name: Vacuum driven sterile filter cup

Manufacturer: Finetech Research & Innovation Corp.

Manufacture Date: 2020.01.15

Lot number: 0155CA20I

Sample Condition: Room Temperature

Sample delivering: By applicant Contact Person: Ms. Yeh

Phone Number: (04)768-7839

Sample expiry Date: 2023.01.15

Country of origin: Taiwan

Test sample packaging: as Appendix

Number of Samples: 1 Piece Report purpose: Retail sale

------ The sample information provided above was confirmed by the customer ------

Sample Received: 2021/05/17

Date of Testing: 2021/05/18

Date of Report : 2021/06/04

LOQ / LOD Method Item (s) Result (s) Unit

Endotoxin Test (Kinetic < 0.005

Chromogenic Assay)

EU/mL According to USP 44 (2021) <85> Bacterial endotoxins test.

0.005 EU/mL

----- Null below -----

#### Remark (s):

- · All inspection contents in this inspection report are inspected according to the entrusted items. If there is any fa-Isehood, we are willing to take full responsibility.
- Used 500 mL pyrogen-free water for extraction. The spike recovery value was 89%. Calculation formula of spiked recovery rate: [Detection value of spiked recovery group (EU/mL) Detection value of test group (EU/mL)] ÷ 0.5 EU/mL (Spiked standard concentration) x 100%.
- · Please note if the tests do not involve sampling, then the test report is only responsible for the test sample provided by the customer. And the report is invalid if not presented in full and for reference only; it shall not be used for advertising, sales promotions, or notarial purposes. Also, when the target is below the limit of detection (LOD) or the limit of quantification (LOQ), the test results will be expressed as "Negative" or "ND" (Not detected).



This report is used only for providing the testing results of commissioned items, not for determining the legality of the product.





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# **Appendix**

Test article Number: M61-210500825

Study item: Endotoxin Study date: 2021/05/18

#### Result:

Test article Number	Detection value (EU/mL)ª	Extraction volume (mL) <sup>b</sup>	Dilution factor	Result (EU/mL)	Spike recovery (%)°
M61-210500825	< 0.005	500	_	-	89

<sup>&</sup>lt;sup>a</sup> Limit of detection: 0.005 EU/mL.

<sup>&</sup>lt;sup>b</sup> Used 500 mL pyrogen-free water for extraction.

<sup>&</sup>lt;sup>c</sup> The spike recovery value was 89%. Calculation formula of spiked - recovery rate: [Detection value of spiked - recovery group (EU/mL) - Detection value of test group (EU/mL)] ÷ 0.5 EU/mL (Spiked standard concentration) x 100%.