

TEST REPORT

Number: HKGT05112613-S1

This is to supersede report no. HKGT05112613 dated Apr 21,

Number: HKGT05112613-S1

2020

Applicant: CURIE LIMITED Date: Apr 22, 2020

B3-1 G/F

SUPERLUCK INDL CTR PHASE 2 57 SHA TSUI RD

TSUEN WAN NT HK

Attn: ALDRIN OR

Sample Description As Declared :

No. Of Sample : Several

Buyer's Name : -Agent's Name : -

Manufacturer's Name: Curie Limited

Sample Description : Curie Ultrahigh-Efficiency Viral Filter超高效病毒濾材

Colour : White Style No. : 1001 Order No. / PO No. : - Product End Uses : -

Fibre Content : Nonwoven Fabric/GMT Weight : 20g

Ref. : -

Date Received/Date Test Started : Apr 15, 2020 Applicant's Provided Care Instruction/Label :

intertek Total Quality. Assured.

TEST REPORT

Original Sample Photo:



For any queries on this report, you are welcome to contact our customer service representatives:

<u>US3</u>

Angie Yu (852) 98639123 or email to angie.yu@intertek.com



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Tests Conducted (As Requested By The Applicant)

1 Evaluation of Viral Filtration Efficiency (VFE):

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage Φ X174 was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at $1.1-3.3 \times 10^3$ plaque forming units (PFU) with a mean particle size (MPS) of $3.0 \pm 0.3~\mu$ m. The aerosols droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test side: Either

Test Area: ~40 cm²

VFE Flow Rate: 28.3 Liters per minute (L/min)

Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5 °C for a minimum of 4 hours

Positive Control Average: 1.6 x 10³ PFU

Negative Monitor Count: <1 PFU

MPS: 2.9 μ m



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Tests Conducted (As Requested By The Applicant)

Evaluation of Viral Filtration Efficiency (Cont'd)

Result:

Test Article Number	Percent VFE (%)
1	>99.9 ^a
2	>99.9ª
3	>99.9 ^a
4	>99.9ª
5	>99.9ª

^a There were no detected plaques on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

$$\%VFE = \frac{C - T}{C}x100$$

C= Positive control average

T= Plate count total recovered downstream of the test article Note: The plate count total is available upon request

Remark: The test was conducted by competent subcontractor lab.