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FINAL REPORT

BACTERIAL FILTRATION EFFICIENCY TEST (BFE) AT AN INCREASED CHALLENGE LEVEL

PROCEDURE NO. STP0009 REV 02

LABORATORY NO. 500236

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BACTERIAL FILTRATION EFFICIENCY TEST (BFE) AT AN INCREASED CHALLENGE LEVEL

LABORATORY NUMBER:	500236
PROCEDURE NUMBER:	STP0009 REV 02
SAMPLE SOURCE:	Piston Ltd.
SAMPLE IDENTIFICATION:	Refer to Table 1 P.O. #CsL-PO-046-1-2009
DEVIATIONS:	None
SAMPLE RECEIVED DATE:	02 Nov 2009
LAB PHASE START DATE:	11 Nov 2009
LAB PHASE COMPLETION DATE:	23 Nov 2009
REPORT ISSUE DATE:	23 Nov 2009

INTRODUCTION:

This report describes the procedure and results of the bacterial filtration efficiency (BFE) at increased challenge level testing. This procedure was performed to determine the filtration efficiency of the test materials using a ratio of the challenge to effluent to determine percent efficiency. This procedure allowed a reproducible aerosol challenge to be delivered to each of the test materials. This test procedure employed a challenge level of greater than 10^6 colony forming units (CFU) per test sample, providing a higher challenge than would be expected in normal use. This method was adapted from ASTM F2101.

ACCEPTANCE CRITERIA:

The mean particle size of the challenge aerosol must be maintained at 3.0 ± 0.3 µm.

The average percent bacterial filtration efficiency (%BFE) for the reference material must be within the upper and lower control limits established for the BFE test.

The BFE challenge level must be ≥ 1 x 10^6 CFU/test article when the flow rate is ≥ 30 Liters per minute (Lpm).

JUSTIFICATION:

This BFE test provides a number of advantages over other filtration efficiency tests. The use of all glass impingers (AGIs) in the collection process allowed a high concentration of challenge to be delivered to each test material. The aerosol challenge particle size can be tightly controlled by monitoring the airflow and challenge flow through the nebulizer. The aerosol particles can be sized using a six-stage viable particle Andersen sampler.

PROCEDURE:

Approximately 100 mL of soybean casein digest broth (SCDB) was inoculated with *Staphylococcus aureus*, ATCC #6538, and incubated with mild shaking for 24 ± 4 hours at 37 ± 2°C. The culture suspension was pumped through a 'Chicago' nebulizer using a peristaltic pump at a controlled flow rate and fixed air pressure. The constant challenge delivery formed aerosol droplets of defined size. The challenge level was adjusted to provide a consistent challenge of greater than 10^6 CFU per test sample.

The droplets were generated in a glass aerosol chamber and drawn through the sample holder and into AGIs in parallel. The AGIs contained 30 mL aliquots of sterile peptone water (PEPW) to collect the aerosol droplets. The aerosol challenge flow rate through the test filter was maintained at 30 Lpm.

The challenge was delivered for a 1 minute interval and sampling through the AGIs was conducted for 2 minutes to clear the aerosol chamber. Control runs (no media in sample holder) were performed after every 5-7 test samples to determine the number of viable particles being generated in the challenge aerosol.

The assay fluid in the AGIs was assayed using standard plate count or membrane filtration techniques. All plates were incubated at 37 ± 2°C for 48 ± 4 hours prior to counting.

RESULTS:

The filtration efficiencies were calculated using the following equation:

$$\% \, BFE = \frac{C - T}{C} \, x \, 100$$

Where: C = Average of control values.
T = Count total for test material.

The mean particle size (MPS) of the challenge aerosol was determined using a six-stage Andersen sampler. The challenge level, MPS, and filtration efficiencies of the samples are summarized in Table 1. Testing met the acceptance criteria previously stated in this report.

Piston Ltd.
Lab Number 500236

BFE at an Increased Challenge Level

STATEMENT OF UNCERTAINTY:

If applicable, the statement of uncertainty is available to sponsors upon request.

Adrianne Sandall

Adrianne Sandall, B.S.
Study Director

23 Nov 2009

Study Completion Date

tp

TABLE 1. Results
Sample Identification: Bacterial and viral filter, Type: PBF-100

SAMPLE IDENTIFICATION	TOTAL CFU RECOVERED	FILTRATION EFFICIENCY
Lot #20091021/1	3.5×10^1	99.99948%
Lot #20091021/2	1.2×10^1	99.99982%
Lot #20091021/3	6	99.999911%
Lot #20091021/4	1.7×10^1	99.99975%
Lot #20091021/5	7	99.99990%

Challenge Level: 6.7×10^6 CFU

Mean Particle Size (MPS): 2.7 µm

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