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BIOSAFETY INVESTIGATION UNIT
QUALITY, SAFETY AND SCIENTIFIC RESOURCES DIVISION

TEST REPORT

DESCRIPTION OF EQUIPMENT: Bact HME ThermoFlo Filter 6000

TEST: Cross contamination bacterial test

COMMERCIAL IN CONFIDENCE

REPORT PREPARED FOR: Pharma Systems AB
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OPERATOR	WRITTEN BY	OPERATING HEAD	DATE
			11 03 96

SUMMARY

The mean percentage efficiency of the Bact HME ThermoFlo filter 6000 (two units placed in series) against bacterial aerosol challenge at 30 litres per minute at relative humidity of 96% or over was found to be 99.99986% (ranging between 99.99972% and 99.99994%). The tests were carried out at room temperature (21±2°C). this is equivalent to a penetration of 13.6±7.5 per 10^7 bacteria. This is equivalent to a titre reduction of 7.4 x 10^5.

METHODS AND MATERIALS

The methods and materials used were essentially similar to that described in Part 1 of this report.

The filters to be tested are designed to prevent cross contamination between the breathing system and the patient. Five units were individually wrapped in cellophane. Each unit consisted of the two Bact HME ThermoFlo filters 6000 arranged in series.

Assay of *B.subtilis* in the collection fluids was carried out as follows:-

After pooling the impinger collecting fluids, the numbers of spores in the pooled fluid was determined by filtering 10ml through a sterile 0.2µ pore, 47mm diameter polycarbonate membrane filter (Whatman International, Maidstone, Kent - catalogue number 7060/4702) placed on a sterilized sintered surface of a sterile Pyrex filter holder. The filter

membranes were transferred to a Tryptone Soya Broth Agar (TSBA) plate and were incubated at 37°C for 18 - 20 hours. Any orange colonies formed were counted.

RESULTS

The results of the tests are shown in Table 1. The mean efficiency of this system against the bacterial challenge was 99.99986%. The pressures measured across each of the filters assemblies are shown in Table 2.

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TABLE 1: FILTER INTEGRITY TESTS USING MICRO-ORGANISMS

Date	06.03.96	Apparatus	Henderson Apparatus
Operator	J E Benbough	Challenge Micro-organisms	*Bacillus subtilis* var niger spores (NCTC 10073)
Batch No.	-	Suspension Fluid	Distilled water
Spray	3-jet Collison	Concentration	2×10^9 cfu/ml

Relative humidity (RH):

Temperature: Dry bulb 70.5°F:- wet bulb 70°F:- RH (from tables) 98%

Filter Tested: Bact HME ThermoFlo filter 6000
(Pharma Systems AB designed to prevent cross contamination [5 identical samples])

Sampling Time [1] min at [30] litres/min Samplers [3 Porton All-Glass Impingers]

Filter Type	Colony Forming Units (cfu)	Volume collected (ml)	Total cfu collected	% Efficiency	Penetration n/10^7
No filter	54.5 per 0.1ml Dilution 10^3	30	1.635×10^7	-	-
1	7 per 10ml Neat	30	21	99.99987	12.8
2	15 per 10ml Neat	30	45	99.99972	27.5
3	7 per 10ml Neat	30	21	99.99987	12.8
4	5 per 10ml Neat	30	15	99.99991	9.2
5	3 per 10ml Neat	30	9	99.99994	5.5

TABLE 2: **The pressure measured in Pascals across Bact HME ThermoFlo filter 6000 (designed to prevent cross contamination) at an airflow of 30 litres per minute and 96% relative humidity and room temperature (21 ± 2°C)**

Filter No.	Pressure (Pascals)
1	245
2	241
3	243
4	247
5	252