Test Report N° 20-0371-04

DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)

Sample description
Denomination: FP5 SAFECOMFORT MASCHERA FACCIALE
Code: 88001
Lot: A00120
Sterilization: No
Receipt number: 15358
Receipt date: 02/04/2020
Sampling carried out by: AXELMED S.R.L.

Further information about the sample
Number of tested samples: 5
Side of the test sample facing the challenge aerosol: the internal part.

Test date
The test was started on 08-04-2020 and was completed on 10-04-2020

Test method
EN 14683:2019 Annex B

Equipments and reagents
Vacuum pump "GEO Air Plus"
Modified Andersen Cascade Impactor "TE-20-830"
MMAD nebulizer 3,0 ± 0,3 μm
Colture plates containing TSA

Summary of method
Before the start of the test, the samples were conditioned at 22 ± 2 ° C in the presence of 80 ± 10% R H for 4 hours. A negative control is performed by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 minutes.
Then the bacterial challenge of Staphylococcus Aureus ATCC 6538, with a concentration of 5280 CFU / ml, is introduced into the spray chamber.
A first positive control is performed, by passing the bacterial challenge through the cascade impactor at a flow rate of 28,3 ± 0,5 l/min for 1 minute. The airflow is maintained through the cascade impactor for 1 additional minute, for a total test time of 2 minutes.
The control plates are removed from the cascade impactor and fresh plates are placed in order to perform the test on the test samples.
The specimen is clamped in place between the first stage of the cascade impactor and the inlet cone of the nebulization collector and the procedure used for the positive control is repeated for each of the 5 specimens to be tested.
After the last specimen has been tested, a further positive control run is performed.
Then all the plates are incubated at 37 ± 2°C for a lenght of time between 24 and 72 hours.
After the incubation, for each specimen and control run, the number of colonies is counted in order to give the total number of CFU collected by the cascade impactor.
The Bacterial Filtration Efficiency (BFE) is calculated for each test specimen, as a percentage, using the following formula:
BFE = [(C - T) / C] x 100
where
C is the mean of the total plate counts for the two positive control runs;
T is the total plate count for the test specimen

Results

Determination	Amount of collected CFU	BFE (%)	BFE (%) Limit Type I	BFE (%) Limit Type II
Negative control	0.0			
Positive control run 1	1964.0			
Positive control run 2	1729.0			
Positive control average	1846.5			
Test 1	1.0			
Test 2	2.0			
Test 3	3.0			
Test 4	0.0			
Test 5	0.0			
Sample average	**1.2**	**99.9**	**≥ 95**	**≥ 98**

Test Report N° 20-0372-02

DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)

Sample description
Denomination: FP5 SAFECOMFORT MASCHERA FACCIALE
(Sample N°2 machine washed for 5 cycles of 1 hour - 40°C)
Code: 88001
Lot: A00120
Sterilization: No
Receipt number: 15359
Receipt date: 02/04/2020
Sampling carried out by: AXELMED S.R.L.

Further information about the sample
Number of tested samples: 1
Side of the test sample facing the challenge aerosol: The internal part

Test date
The test was started on 09-04-2020 and was completed on 11-04-2020

Test method
EN 14683:2019 Annex B

Equipments and reagents
Vacuum pump "GEO Air Plus"
Modified Andersen Cascade Impactor "TE-20-830"
MMAD nebulizer 3,0 ± 0,3 µm
Colture plates containing TSA

Summary of method
Before the start of the test, the samples were conditioned at 25 ± 2 ° C in the presence of 75 ± 10% R H.
A negative control is performed by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 minutes.
Then the bacterial challenge of Staphylococcus Aureus ATCC 6538, with a concentration of 2300 UFC/ml, is introduced into the spray chamber.
A first positive control is performed, by passing the bacterial challenge through the cascade impactor at a flow rate of 28,3 ± 0,5 l/min for 1 minute. The airflow is maintained through the cascade impactor for 1 additional minute, for a total test time of 2 minutes.
The control plates are removed from the cascade impactor and fresh plates are placed in order to perform the test on the test samples.
The specimen is clamped in place between the first stage of the cascade impactor and the inlet cone of the nebulization collector and the procedure used for the positive control is repeated for each of the 5 specimens to be tested.
After the last specimen has been tested, a further positive control run is performed.
Then all the plates are incubated at 37 ± 2°C for a lenght of time between 24 and 72 hours.
After the incubation, for each specimen and control run, the number of colonies is counted in order to give the total number of CFU collected by the cascade impactor.
The Bacterial Filtration Efficiency (BFE) is calculated for each test specimen, as a percentage, using the following formula:
$BFE = [(C - T) / C] \times 100$
where
C is the mean of the total plate counts for the two positive control runs;
T is the total plate count for the test specimen

Results

Determination	Amount of collected CFU	BFE (%)	BFE (%) Limit Type I	BFE (%) Limit Type II
Negative control	0.0			
Positive control run 1	2212.0			
Positive control run 2	2052.0			
Positive control average	2132.0			
Test sample	0.0			
Sample average	**0.0**	**100.0**	**≥ 95**	**≥ 98**

Test Report N° 20-0372-02

DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)

Sample description
Denomination: FP5 SAFECOMFORT MASCHERA FACCIALE
(Sample N°4 with autoclave sterilization for 20 cycles for 28' - 128°C)
Code: 88001
Lot: A00120
Sterilization: No
Receipt number: 15359
Receipt date: 02/04/2020
Sampling carried out by: AXELMED S.R.L.

Further information about the sample
Number of tested samples: 1
Side of the test sample facing the challenge aerosol: The internal part

Test date
The test was started on 09-04-2020 and was completed on 11-04-2020

Test method
EN 14683:2019 Annex B

Equipments and reagents
Vacuum pump "GEO Air Plus"
Modified Andersen Cascade Impactor "TE-20-830"
MMAD nebulizer 3,0 ± 0,3 µm
Colture plates containing TSA

Summary of method
Before the start of the test, the samples were conditioned at 25 ± 2 ° C in the presence of 75 ± 10% R H.
A negative control is performed by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 minutes.
Then the bacterial challenge of Staphylococcus Aureus ATCC 6538, with a concentration of 2300 UFC/ml, is introduced into the spray chamber.
A first positive control is performed, by passing the bacterial challenge through the cascade impactor at a flow rate of 28,3 ± 0,5 l/min for 1 minute. The airflow is maintained through the cascade impactor for 1 additional minute, for a total test time of 2 minutes.
The control plates are removed from the cascade impactor and fresh plates are placed in order to perform the test on the test samples.
The specimen is clamped in place between the first stage of the cascade impactor and the inlet cone of the nebulization collector and the procedure used for the positive control is repeated for each of the 5 specimens to be tested.
After the last specimen has been tested, a further positive control run is performed.
Then all the plates are incubated at 37 ± 2°C for a lenght of time between 24 and 72 hours.
After the incubation, for each specimen and control run, the number of colonies is counted in order to give the total number of CFU collected by the cascade impactor.
The Bacterial Filtration Efficiency (BFE) is calculated for each test specimen, as a percentage, using the following formula:
BFE = [(C - T) / C] x 100
where
C is the mean of the total plate counts for the two positive control runs;
T is the total plate count for the test specimen

Results

Determination	Amount of collected CFU	BFE (%)	BFE (%) Limit Type I	BFE (%) Limit Type II
Negative control	0.0			
Positive control run 1	2212.0			
Positive control run 2	2052.0			
Positive control average	2132.0			
Test sample	0.0			
Sample average	**0.0**	**100.0**	**≥ 95**	**≥ 98**