Messrs
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Zola Predosa, 12/05/2020

Ref. Your Order del 2020

Test Report N°20-0508-01

DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)

Sample description

Denomination: 3ply-adult
Code: ID2
Lot: FM2003
Sterilization: No
Receipt number: 15766
Receipt date: 06/05/2020
Sampling carried out by: PERFECT CARE DISTRIBUTION SRL

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 11-05-2020 and was completed on 12-05-2020

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

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 3000 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.

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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℃ 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			
Positive control run 1	2843			
Positive control run 2	2773			
Positive control average	2808			
Test 1	17			
Test 2	16			
Test 3	16			
Test 4	20			
Test 5	6			
Sample average	**15.0**	**99.5**	**≥ 95**	**≥ 98**

The present test report exclusively refers to the referenced test sample.
If the sample has been sampled by the Customer, the results are referred to the sample as received.
The present test report may not be partially reproduced without Biochem authorization.

(#) Data provided by the Customer. The laboratory declines responsibility for such data.

Test verified by: Buriani Giampaolo, PhD.

Issue authorized by:
Head of Laboratory, Giovanni Bassini, Ch. Eng.

END OF TEST REPORT

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