

Messrs  
PFC Pharma Manufacturing SL  
Calle Osona, 2  
08820, Prat de Llobregat (El), Barcelona  
Cataluña, España

Zola Predosa, 19/05/2020

Ref. Your Order of 2020

### Test Report N°20-0508-02

#### DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

##### Sample description

# Denomination: 3ply-adult  
# Code: ID2  
# Lot: FM2003  
# Sterilization: No  
Receipt number: 15767  
Receipt date: 06/05/2020  
Sampling carried out by: PERFECT CARE DISTRIBUTION SRL

##### Further information about the sample

Number of tested specimens: 5  
Number of tested areas per sample: 5  
General location of the chosen areas to be tested: representative areas are chosen for the test.  
Picture of the sample:



## Test date

15-05-2020

## Test method

EN 14683:2019 Annex c

## Summary of method

Each specimen is conditioned at  $22 \pm 2^\circ\text{C}$  and  $80 \pm 10\%$  relative humidity for a minimum of 4 hours before the test.

A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material. A digital differential manometer is used to measure the differential pressure. A mass flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the test apparatus and a needle valve is used to adjust the airflow rate.

Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 l/min.

The holder is opened and the test specimen is placed across the 25 mm diameter orifice (total area 4,9 cm<sup>2</sup>) between the top and the bottom parts of the holder. Then it is clamped in place using a mechanical clamp with sufficient pressure to avoid air leaks. Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow air. With the specimen in place the flow rate shall be 8 l/min.

The procedure described is carried out on 5 (or appropriate number) different areas of the mask and the readings averaged.

for each test specimen the differential pressure of each tested area is calculated as follows:

$$DP = DP \text{ read} \setminus 4,9$$

where

DP is the Differential Pressure for cm<sup>2</sup> of test material expressed in Pa;

Dp read is the Differential Pressure for specimen;

4,9 is the area (in cm<sup>2</sup>) of the test material.

## Results

Determination	DP Read (Pa)	DP (Pa/cm <sup>2</sup> )	DP (Pa/cm <sup>2</sup> ) Limit Type I	DP (Pa/cm <sup>2</sup> ) Limit Type II
Specimen 1	143	29.2		
Specimen 2	155	31.6		
Specimen 3	142	29.0		
Specimen 4	138	28.2		
Specimen 5	130	26.5		
<b>Total average of specimens</b>		<b>28.9</b>	<b>&lt; 40</b>	<b>&lt; 40</b>

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