FONdation pour le DEveloppement de la REcherche PHARmaceutique

Toulouse, July 7th 2023

ASSAY REPORT N° 23-2081

STUDY 23-3455

STANDARD NF EN 17272 (Avril 2020)
Chemical disinfectants and antiseptics –
Methods of airborne room disinfection by automated process – Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities

Medical area
Clean conditions
Additional microorganisms: ***S. aureus* ATCC 33591 (MRSA) and *P. aeruginosa* CIP 106817 (MDRP)**

Client	**Company registration SIREN 448974253** **829 rue Marcel Paul** **94500 CHAMPIGNY SUR MARNE** **FRANCE**
Assay laboratory	**FONDEREPHAR** **Faculté des Sciences Pharmaceutiques** **35 Chemin des Maraîchers** **31062 TOULOUSE cedex 9** **FRANCE**

Dr **Catherine FEUILLOLAY** Study Manager	Dr **Jocelyne BACARIA** Quality Manager
Catherine FEUILLOLAY Signature numérique de Catherine FEUILLOLAY Date : 2023.07.20 15:45:42 +02'00'	Jocelyne BACARIA Signature numérique de Jocelyne BACARIA Date : 2023.07.20 15:52:45 +02'00'

1. Test Laboratory

FONDEREPHAR
Faculté des Sciences Pharmaceutiques
35 chemin des Maraîchers
31062 Toulouse cedex 9
France

2. Identification of the aerial disinfection system

Device : **Diffuser PX-00**
Serial number : 172X731

Disinfectant : **Formula N-1**
Batch : A310523N/1
Exp.: May/2025
Receipt : Jun/26/2023
Internal code: **23-3455-1**

Concentration of product: 8mL/m^3
One treatment - Waiting time 120 minutes after the end of diffusion
Amount of disinfectant diffusion: 222g (difference of weight's flask between T_0 and at the end of the diffusion and the waiting time)
Time of diffusion : 15 minutes

Promotor : Company registration SIREN 448974253

Storage conditions: Ambiant temperature

Period of testing: June – July 2023

Active Substance: Hygrogen Peroxide (6%)

NB. Obligatory conditions of the standard (efficacy and distribution) in the test report N° 22-1907 (dated May/29/2022)

3. Experimental Conditions

a. Tests micro-organisms

- Bactericidal activity :
  - *Staphylococcus aureus* ATCC 33591 (MRSA)
  - *Pseudomonas aeruginosa* CIP 106817 (MDRP)

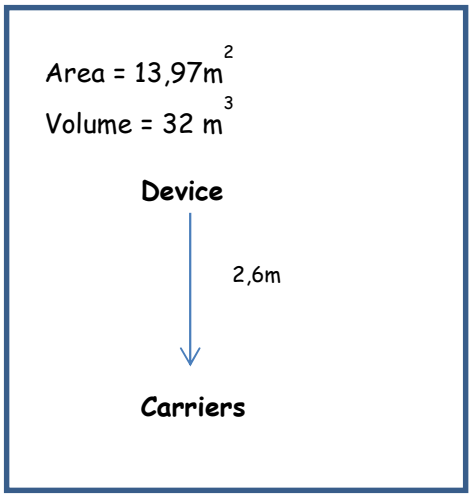
b. Carriers

The selected tests surfaces are stainless steel discs, flats, corresponding to the requirements of paragraph 5.2.3.2 of the standard. The supplier is MERCIER CLAUSSE (France).

4. Efficacy tests

a. Conditions of aerial disinfection system use

- Room :



Relative humidity ranging from 50% (see results).
Initial temperatures ranging from 20,9°C (see results).

Test room volume : 32m³.

Distance between the appartus and the carriers : 2,60m (tableau B.1), 1,15m from floor.

b. Diluants, culture media and membranes

Interfering substances
1/20 reconstituted milk (Internal preparation - Batch 11660 Exp. Jul/26/2023)
BSA fraction V 0,3g/l (Internal preparation - Batches 577 and 579)

Diluants
Suspension preparation : Water for Injectable Preparations (WIP) (interference of product with Tryptone-salt) (Cooper - Batch 19QIAEW0 Exp. Aug/2024)
Recovery solution + 0,5% Tween 80 (Internal preparation – Batch 11601)

Filtration membranes
White nitrocellulose membranes 0,45 µm (Millipore – Batch F2DB43464)

Culture media
Trypcase soy agar (Biomérieux – Batch 1009871570 Exp. Aug/14/2024)

c. Results

- **8 mL / m³ – waiting 120 minutes – Batch A310523N/1**

Tests microorganisms	N Test suspension (CFU/mL)	Preliminary tests			T Control (CFU/spot - 50µL)	n'1 + n'2 CFU / spot 50µL (dilution/filtration – disc in agar)	Log reduction - Mean
		n1/N1	n2/N2	n3/N1			
	5.10^7 – 2.10^9	n1 > 0.5 N1	n2 > 0.5 N2	n3 > 0.5 N1	≈ 10^6		
***S.aureus* ATCC 33591** **Assay Jun/29/23** **20,9°C/RH 50%**	$8,75.10^8$	d1 : 96/88 d2 : 91/88	d1 : 91/84 d2 : 78/84	d1 : 82/88 d2 : 78/88	d1 : $2,04.10^7$ d2 : $2,12.10^7$ **T** = $2,08.10^7$	E1 : 0 + 0 E2 : 0 + 0 E3 : 1 + 0	R1 : 7,32 R2 : 7,32 R3 : 7,32 **R = 7,32**

T: counting of micro-organisms on the discs.
N_1 : counting of test suspension by pour plate technique - N_2 : counting of test suspension by filtration method
n_1 : counting to search inhibitor effect in agar medium - n_2 : counting to search inhibitor effect on membrane filtration - n_3 : counting to search inhibitor effect after inclusion of disc in agar medium
n'_1 : number of survival micro-organisms in 100mL of tryptone-salt - n'_2 : number of micro-organisms after inclusion of the disc in agar medium.
$n'_1 + n'_2$: total number of survival micro-organisms on the carrier surface. d1 : disc N°1 / d2 : disc N°2 / d3 : disc N°3

- **8 mL / m³ – waiting 120 minutes – Batch A310523N/1**

Tests microorganisms	N Test suspension (CFU/mL)	Preliminary tests			T Control (CFU/spot - 50µL)	n'1 + n'2 CFU / spot 50µL (dilution/filtration – disc in agar)	Log reduction - Mean
		n1/N1	n2/N2	n3/N1			
	5.10^7 – 5.10^9	n1 > 0.5 N1	n2 > 0.5 N2	n3 > 0.5 N1	≈ 10^6		
***P.aeruginosa* CIP106817** **Assay Jun/29/23** **20,9°C/RH 50%**	$3,8.10^9$	d1 : 27/38 d2 : 31/38	d1 : 38/31 d2 : 34/31	d1 : 30/38 d2 : 28/38	d1 : $7,5.10^6$ d2 : $2,84.10^6$ **T** = $5,17.10^6$	E1 : 2 + 0 E2 : 67 + 0 E3 : 5 + 0	R1 : 6,41 R2 : 4,88 R3 : 6,01 **R = 5,77**

T: counting of micro-organisms on the discs.
N_1 : counting of test suspension by pour plate technique - N_2 : counting of test suspension by filtration method
n_1 : counting to search inhibitor effect in agar medium - n_2 : counting to search inhibitor effect on membrane filtration - n_3 : counting to search inhibitor effect after inclusion of disc in agar medium
n'_1 : number of survival micro-organisms in 100mL of tryptone-salt - n'_2 : number of micro-organisms after inclusion of the disc in agar medium.
$n'_1 + n'_2$: total number of survival micro-organisms on the carrier surface. d1 : disc N°1 / d2 : disc N°2 / d3 : disc N°3

5. Conclusion

The device/product combination: diffuser PX-00 serial number 172X731 / Formula N-1 (batch A310523N/1), for use in clean conditions, in medical area, meets the criteria of standard NF EN 17272 (April 2020) for bactericidal efficacy test with additional microorganisms (*S. aureus* ATCC 33591 (MRSA) and *P. aeruginosa* CIP106817 (MDRP)) after treatment at 8 mL/m3 and a waiting time of 120 minutes.

The results hold only for the device/product under assay and apply to the sample as received.