FONdation pour le DEveloppement de la REcherche PHARmaceutique

Toulouse, June 7th 2022

ASSAY REPORT N° 22-1906

STUDY 20-2793

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

Food industrial, industry and collectivity areas
Clean conditions
Efficacy and distribution tests

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**

Pr **Christine ROQUES** Study Manager Christine ROQUES Signature numérique de Christine ROQUES Date : 2023.01.03 18:17:55 +01'00'	Dr **Jocelyne BACARIA** Quality Manager Jocelyne BACARIA Signature numérique de Jocelyne BACARIA Date : 2023.01.03 18:37:52 +01'00'

1. Test Laboratory

Fondation pour le Développement de la recherche en Pharmacie (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-5**
Batch : A071220FD/1
Exp.: Dec/2022
Receipt : Jan/04/2021

Disinfectant : **Formula N-5**
Batch : A160222FD/1
Exp.: Feb/2024
Receipt : Feb/25/2022

Concentration of product: 5mL/m^3 (efficacy tests) or 6mL/m^3 (distribution test)
One treatment - Waiting time 120 minutes after the end of diffusion
Amount of disinfectant diffusion ≈ 162,5 mL (efficacy tests) – 200 mL (distribution test)
Time of diffusion : 9 minutes 45 seconds (efficacity tests) – 12 minutes (distribution test)

Promotor : Company registration SIREN 448974253

Storage conditions: Ambiant temperature
Period of testing: February 2021 – April 2022

Active Substance: Hydrogen peroxide (7,9%)

3. Experimental Conditions

a. Tests micro-organisms

- Bactericidal activity :
  - *Pseudomonas aeruginosa* CIP 103467
  - *Staphylococcus aureus* CIP 4.83
  - *Enterococcus hirae* CIP 58.55
  - *Escherichia coli* CIP 54.127
- Fungicidal activity :
  - *Candida albicans* DSM 1386
  - *Aspergillus brasiliensis* CBS 733.88
- Sporicidal activity :
  - *Bacillus subtilis* CIP 52.62
- Mycobactericidal activity :
  - *Mycobacterium terrae* ATCC 15755
  - *Mycobacterium avium* ATCC 15769

- Phagocidal activity :
    - Bacteriophage for *Lactococcus lactis* subspecies *lactis* P001 (DSM 4262)
    - Bacteriophage for *Lactococcus lactis* subspecies *lactis* P008 (DSM 10567)

- Virucidal activity (virus/receiving cells):

Adenovirus/HELA Cells

Virus

Origin:	ATCC
ATCC reference:	VR-5
Batch number supplier:	58486654
Internal number Batch:	SS-1-250413 (passage N°1)

Receiving cells

Origin:	ATCC
ATCC reference:	CCL-2
Batch number ATCC:	4440136
Internal number Batch:	WCB-140613 (passage N°39)

Murine Norovirus souche S99/RAW264.7 cells:

Virus

Origin :	Friedrich Loefler Institut Berlin
Supplier reference:	RVB-651
Batch number supplier:	4/200409/220409
Internal number Batch:	SS-5-100516 (passage N°5)

Receiving cells

Origin :	ATCC
ATCC reference:	TIB-71
Batch number ATCC:	5822175
Internal number Batch:	WCB-210916 (passage N°26)

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).

c. Virucidal activity: validation and titration

Control of sensitivity of cells to virus

- Add one volume of solution S or PBS + one volume of cellular suspension at 2.10^5 cells/ml for one hour in water bath at 36°C±1°C
- The cells are centrifuged at 1600trs/min for 10 min and resuspended in culture media
- The virus is diluted from 1/10 to 1/10 on a 96-well microplate (10 dilutions)
- Add 100 µl of cell suspension treated (Solution S) or not treated (PBS control) to each well of the microplate
- Incubate for 72 hours

The difference of title reduction between cells treated by the solution S and cells treated by PBS shall be < 1 lg.

Control of efficiency for suppression of disinfectant activity

- Add 1 volume of BSA + 1 volume of virus suspension + 1 volume of solution S or distilled water
- Leave the mixture in the ice bath for 60 min at room temperature

Titration method

- Titrate the virus (method titration on cell in suspension) by following steps:
- Serial dilutions (1/10) are realized with culture medium in the glass tube
- Transfer 0,1 ml of each dilution into eight wells of a microplate plaque
- The last row of eight wells will receive 0,1 ml of culture medium (control untreated cells)
- Add 0,1 ml of cell suspension at 2.10^5cell/ml.
- Incubate for 72 hours at 36 ° C ± 1 ° C under 5% CO_2 ± 2%.
- The viral cytopathic effect is read by using an inverted microscope

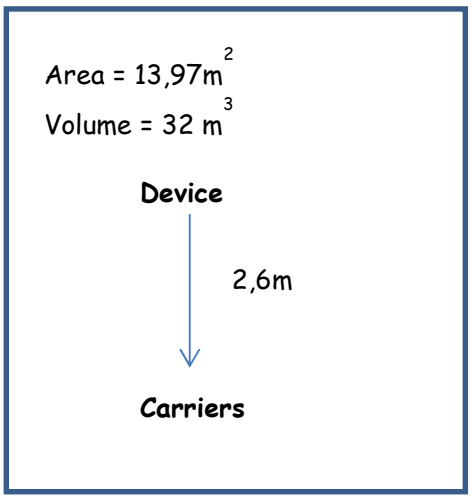
The estimated of infectious unite is determined by method KARBER-SPAERMAN calculating the negative logarithm of 50% endpoint (lgDIC50) by the following formula:

lgDICT50 = negative logarithm of the highest concentration of virus - [(Sum of% affected to each dilution/100 - 0.5) X (lg dilution)]

4. Efficacy tests

a. Conditions of aerial disinfection system use

- Room :



Relative humidity ranging from 50% to 62% (see results).
Initial temperatures ranging from 18,3°C to 20,2°C (see results).
Test room volume : 32m^3.
Distance between the appartus and the carriers : 2,6m (tableau B.1), 1,15m from floor.

b. Diluants, culture media and membranes

Interfering substances
1/20 reconstituted milk (Internal preparation - Batches 10219 Exp. Apr/09/2021 and 10280 Exp. May/13/2021)
BSA fraction V 0,3g/l (Internal preparation - Batches 367, 368, 374, 379, 382, 392)
Acid low-fat milk (Internal preparation – Batch 10 Exp. June/20/2021)

Diluants
Suspension preparation : Water for Injectable Preparations (WIP)* (interference of product with Tryptone-salt) (Cooper - Batch 19MKA300 Exp. Sept/2021)
Diluant for *A. brasiliensis* (Internal preparation - Batch 53 Exp. May/26/21)
Diluant for phages (Internal preparation – Batch 10336 Exp. June/10/21)
Recovery solution + 0,5% Tween80 (Internal preparation - Batches 10096, 10154, 10192, 10201, 10241, 10254 and 10270,10364)
Recovery solution (viruses) EMEM (Internal preparation - batches N°2869, N°2870 and N°2876)

Filtration membranes
Nitrocellulose membranes 0,45 µm (Millipore – white / Batches F0MB14755C and F05B62670C – black / Batches F0KB98880C and F9HA42174)

Culture media
Malt Extract agar (Inetrnal preparation - Batches 10242 Exp. Apr/22/21 and 10252 Exp. Apr/24/21)
Trypcase soy agar (Biomérieux - Lot 1008444040 Exp. June/09/2022)
Middlebrook agar + OADC (Internal preparation - Batches 10147 Exp. Mar/15/2021)
Molt M17 agar (Internal preparation – Batch 10337 Exp. June/10/2021)
M17 agar (Internal preparation – Batches 10362 Exp. June/17/2021 ; 10382 Exp. June/25/2021)
M17 broth (Internal preparation – Batches 10332 Exp. June/10/2021 ; 10381 Exp. June/25/2021)

$CaCl_2$ 50mM/L solution (Internal preparation – Batch 10334 Exp. June/10/2021)
EMEM (Internal preparation - batches N°2869, N°2870 and N°2876)

c. Results

c1. Bactericidal activity

- **5 mL / m³ – waiting 60 minutes – Batch A071220FD/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		
E. coli* **Assay Apr/13/2021** **19,8°C / RH 53%**	$6,15.10^9$	d1 : 59/62 d2 : 53/62	d1 : 42/38 d2 : 41/38	d1 : 49/62 d2 : 51/62	d1 : $2,19.10^6$ d2 : $2,05.10^6$ **T** = $2,12.10^6$	d1 : 0 + 0 d2 : 0 + 0 d3 : 14 + 0	R1 : 6,33 R2 : 6,33 R3 : 5,18 **R = 5,95**
E. hirae* **Assay Mar/24/2021** **19,7°C / RH 50%**	$2,85.10^8$	d1 : 28/27 d2 : 30/27	d1 : 33/32 d2 : 36/32	d1 : 21/27 d2 : 19/27	d1 : $3,00.10^6$ d2 : $1,26.10^7$ T = $7,80.10^6$	d1 : 0 + 0 d2 : 0 + 0 d3 : 0 + 0	R1 : 6,89 R2 : 6,89 R3 : 6,89 **R = 6,89**

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

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* **Assay Mar/10/2021** **18,3°C / RH 50%**	$4,05.10^8$	d1 : 60/41 d2 : 59/41	d1 : 42/47 d2 : 47/47	d1 : 45/41 d2 : 45/41	d1 : $1,40.10^7$ d2 : $1,57.10^7$ **T** = $1,49.10^7$	d1 : 1 + 0 d2 : 0 + 0 d3 : 1 + 0	R1 : 7,17 R2 : 7,17 R3 : 7,17 **R = 7,17**
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* **Assay Apr/13/2021** **19,8°C / RH 53%**	$4,35.10^9$	d1 : 49/44 d2 : 48/44	d1 : 40/41 d2 : 46/41	d1 : 25/44 d2 : 44/44	d1 : $3,01.10^6$ d2 : $5,50.10^6$ **T** = $4,26.10^6$	d1 : 22 + 0 d2 : 0 + 0 d3 : 25 + 0	R1 : 5,29 R2 : 6,63 R3 : 5,23 **R = 5,72**

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

c2. Fungicidal activity

- **Treatment 5 mL / m^3 – waiting 60 minutes – Batch A071220FD/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			
	2.10^7 – 1.10^8	n1 > 0.5 N1	n2 > 0.5 N2	n3 > 0.5 N1	≈ 10^5		
C. albicans **Assay Mar/31/21** **19,0°C / RH 50%**	$5,90.10^7$	d1 : 55/59 d2 : 56/59	d1 : 58/56 d2 : 57/56	d1 : 50/59 d2 : 45/59	d1 : $5,80.10^5$ d2 : $5,05.10^5$ **T** = $5,43.10^5$	d1 : 0 + 0 d2 : 0 + 0 d3 : 0 + 0	R1 : 5,73 R2 : 5,73 R3 : 5,73 **R = 5,73**

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

- **Treatment 5 mL / m³ – waiting 60 minutes – Batch A071220FD/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			
	5.10^6 – 1.10^7	n1 > 0.5 N1	n2 > 0.5 N2	n3 > 0.5 N1	≈ 10^5		
A. brasiliensis **Assay Mar/31/2021** **19,0°C / RH 50%**	$9,95.10^6$	d1 : 55/47 d2 : 43/47	d1 : 33/29 d2 : 23/29	d1 : 27/47 d2 : 29/47	d1 : $1,21.10^6$ d2 : $1,19.10^6$ **T** = $1,20.10^6$	d1 : 0 + 0 d2 : 0 + 0 d3 : 0 + 0	R1 : 6,08 R2 : 6,08 R3 : 6,08 **R = 6,08**

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

c3. Sporicidal activity

- **Treatment 5 mL / m^3 – waiting 60 minutes – Batch A071220FD/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			
	2.10^5 – 5.10^5	n1 > 0.5 N1	n2 > 0.5 N2	n3 > 0.5 N1	≈ 10^4		
B. subtilis* **Assay Mar/24/21** **19,7C/RH 50%**	$3,55.10^5$	d1 : 35/36 d2 : 39/36	d1 : 26/20 d2 : 28/20	d1 : 36/36 d2 : 30/36	d1 : $1,02.10^4$ d2 : $1,17.10^4$ **T** = $1,10.10^4$	d1 : 0 + 0 d2 : 0 + 0 d3 : 0 + 0	R1 : 4,04 R2 : 4,04 R3 : 4,04 **R = 4,04**

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

c4. Mycobactericidal activity

- **Treatment 5 mL / m^3 – waiting 120 minutes – Batch A071220FD/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			
	1.10^7 – 1.10^8	n1 > 0.5 N1	n2 > 0.5 N2	n3 > 0.5 N1	≈ 10^5		
M. terrae **Assay Feb/23/21** **20,2°C/RH 56%**	$2,76.10^7$	d1 : 92/103 d2 : 87/103	d1 : 87/82 d2 : 81/82	d1 : 79/103 d2 : 73/103	d1 : $4,93.10^6$ d2 : $3,44.10^6$ **T** = $4,19.10^6$	d1 : 20 + 0 d2 : 0 + 0 d3 : 0 + 0	R1 : 5,32 R2 : 6,62 R3 : 6,62 **R = 6,19**
M. avium **Assay Feb/16/21** **20,1°C/RH 62%**	$4,10.10^7$	d1 : 39/42 d2 : 22/42	d1 : 25/34 d2 : 26/34	d1 : 27/42 d2 : 31/42	d1 : $5,03.10^5$ d2 : $1,01.10^6$ **T** = $7,57.10^5$	d1 : 0 + 0 d2 : 0 + 0 d3 : 0 + 0	R1 : 5,88 R2 : 5,88 R3 : 5,88 **R = 5,88**

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

c5. Phagocidal activity

- **Treatment 5 mL / m³ - waiting 60 minutes – Batch A071220FD/1**

Strain	N Test suspension (PFU/mL)	Preliminary tests			T Control (PFU/spot - 50µL)	n'1 + n'2 CFU/ spot 50µL (dilution – disc in agar)	Log reduction - Mean
		n1/N1	-	n3/N1			
	8.10^8 – 3.10^9	n1 > 0.5 N1	-	n3 > 0.5 N1	≈ 2.10^5		
P 001 **Assay May/20/21** **20,3°C/RH 54%**	$1,87.10^9$	d1 : 192/178 d2 : 198/178	-	d1 : 184/178 d2 : 197/178	d1 : $1,92.10^7$ d2 : $1,69.10^7$ **T** = $1,81.10^7$	d1 : <100 + 0 d2 : <100 + 0 d3 : 100 + 0	R1 : 5,26 R2 : 5,26 R3 : 5,26 **R = 5,26**
P 008 **Assay May/27/21** **19,8°C/RH 54%**	$1,32.10^9$	d1 : 172/132 d2 : 176/132	-	d1 : 178/132 d2 : 136/132	d1 : $4,35.10^7$ d2 : $2,35.10^7$ **T** = $3,35.10^7$	d1 : <100 + 0 d2 : <100 + 0 d3 : <100 + 0	R1 : 5,53 R2 : 5,53 R3 : 5,53 **R = 5,53**

T: counting of micro-organisms on the discs.
N_1 : counting of S solution
n_1 : counting to search inhibitor effect in agar medium - 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

c6. Virucidal activity

Treatment 5 mL / m^3 – waiting 60 minutes – Batch A071220FD/1

- **Adenovirus type 5**

No cytotoxicity was observed on the carrier without treatment which has been pretreated with the aerial disinfection.

Assay June/07/2021 **18,6°C/RH 54%**	Degree of cytopathogenic effect (lgDICT50)	Logarithmic reduction
Sensitivity of cells to virus		
- With treatment (S1)		
Carrier 1	7.00	
Carrier 2	6.88	Difference <1 lg.
Average	6.94	
- Without traitement (S2)		
Carrier 1	7.13	
Efficiency for suppression of disinfectant activity		
- With treatment (D1)		
Carrier1	6.63	
Carrier 2	6.88	
Average	6.76	Difference <0,5 lg.
- Without traitement (D2)		
Carrier 1	7.00	
Test control		
Carrier1	6.50	
Carrier 2	6.75	
Average	6.63	
Assay		
Support 1	2.50	
Support 2	2.38	**4.13**
Support 3	2.63	
Average	2.50	

- Murine Norovirus

No cytotoxicity was observed on the carrier without treatment which has been pretreated with the aerial disinfection.

Essai du June/10/2021 **20,1°C/RH 54%**	Degree of cytopathogenic effect (lgDICT50)	Logarithmic reduction
Sensitivity of cells to virus		
- With treatment (S1)		
Carrier 1	7.38	
Carrier 2	7.13	
Average	7.25	Difference <1 lg.
- Without traitement (S2)		
Carrier 1	7.50	
Efficiency for suppression of disinfectant activity		
- With treatment (D1)		
Carrier1	7.13	
Carrier 2	7.00	
Average	7.07	Difference <0,5 lg.
- Without traitement (D2)		
Carrier 1	7.13	
Test control		
Carrier1	6.13	
Carrier 2	6.25	
Average	6.19	
Assay		
Support 1	1.50	
Support 2	2.00	**4.48**
Support 3	1.63	
Average	1.71	

5. Distribution test

a. Conditions of aerial disinfection system use

- Room : same room as for the efficacy tests (area = 13,97m^2 ; volume = 32m^3)

Relative humidity: 46% (see results).
Initial temperature: 19°C (see results).

The positioning of the carriers in relation to the apparatus shall be as indicated in Table A.2 of the standard.

b. Diluants, culture media and membranes

Interfering substances
BSA fraction V 0,3g/l (Internal preparation – Batch 461)

Diluants
Suspension preparation : Water for Injectable Preparations (WIP)* (interference of product with Tryptone-salt) (Cooper - Batch 19QEAGF0 Exp. Apr/2024)
Recovery solution + 0,5% Tween80 (Internal preparation – Batch 11024)

Filtration membranes
Nitrocellulose membranes 0,45 µm (Millipore – white / Batch R1MB59701)

Culture media
Trypcase soy agar (Biomérieux – Batch 1009172670 Exp. Jul/19/2023)

c. Results

- **6 mL / m^3 – waiting 120 minutes – Batch A160222FD/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
		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* **Assay Apr/12/22** **19°C / HR 46%**	$5,30.10^8$	d1 : 48/53 d2 : 49/53	d1 : 52/50 d2 : 49/50	d1 : 54/53 d2 : 46/53	d1 : $9,55.10^6$ d2 : $3,50.10^6$ T = $6,53.10^6$	d1 : 0 + 0 d2 : 0 + 0 d3 : 0 + 0 d4 : 0 + 0 d5 : 0 + 0 d6 : 0 + 0 d7 : 2 + 0 d8 : 0 + 0	R1 : 6,81 R2 : 6,81 R3 : 6,81 R4 : 6,81 R5 : 6,81 R6 : 6,81 R7 : 6,51 R8 : 6,81

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 …

6. Conclusion

The device/product combination: diffuser PX-00 serial number 172X731 / Formula N-5 (batches A071220FD/1 Exp. Dec/2022 and A160222FD/1 Exp. Feb/2024), for use in clean conditions, in in food industrial, industry and collectivity areas, meets the criteria of standard NF EN 17272 (April 2020) for bactericidal, fungicidal, sporicidal, mycobactericidal, phagocidal and virucidal efficacy tests and for distribution test (*S. aureus* CIP 4.83) after treatment at 6 mL/m^3 - waiting time 120 minutes.

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