



FONDation pour le  
DEveloppement de la  
REcherche  
PHARmaceutique

Système de management de la qualité  
Certifié ISO 9001

Toulouse, May 13<sup>th</sup> 2015

## STUDY 15-1780/2

Determination of bactericidal, fungicidal, sporicidal, mycobactericidal and virucidal  
activity for aerial surface disinfection processes  
According to the method described  
in the standard NF T 72-281 (November 2014)

Medical area

Additional Conditions : *Bacillus subtilis* (spores)

Promotor

OXY'PHARM  
917 rue Marcel Paul  
94500 CHAMPIGNY SUR MARNE

Test laboratory

FONDÉREPHAR  
Faculté des Sciences Pharmaceutiques  
35 Chemin des Maraîchers  
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## 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

Appartus : NOCOSPRAY  
Serial number : 37S347

Disinfectant : NOCOLYSE ONE SHOT  
Batches : 160315N+F (Expiry date: 03/2017)

Concentration of product in the room : 5 ml/m<sup>3</sup>  
One treatment with one hour of wait (carriers recovery after waiting)  
Amount of disinfectant diffusion  $\approx$  260 mL/treatment of 5mL/m<sup>3</sup>.

Promotor : OXY'PHARM

Storage conditions: Room temperature  
Period of testing: April - May 2015  
Actives Substances: Hydrogen peroxide

## 3. Experimental Conditions

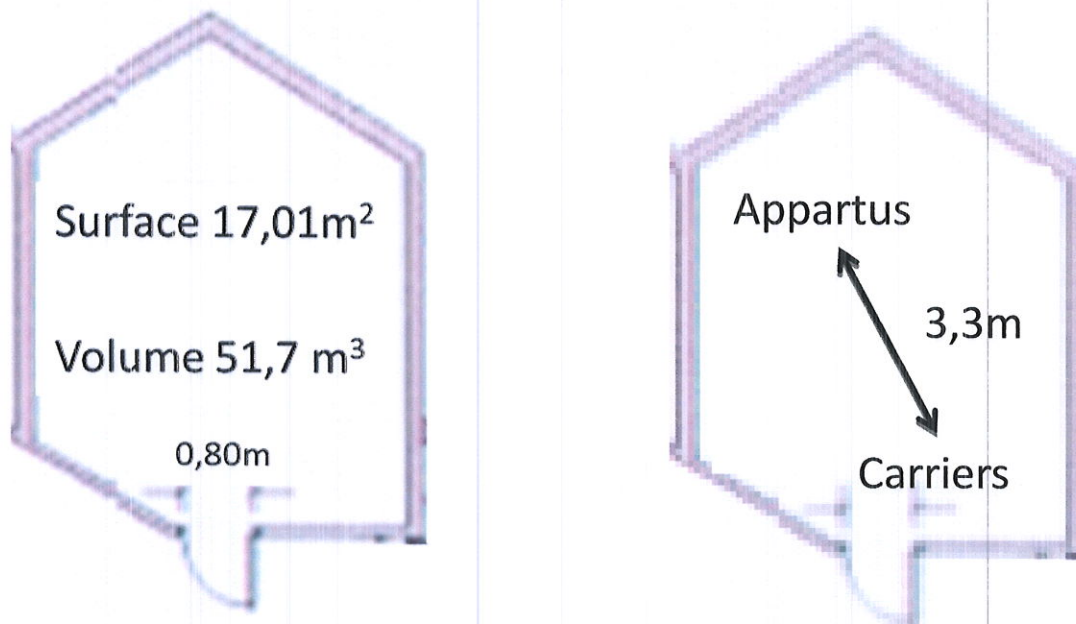
### a. Tests micro-organisms

- Sporicidal activity :
  - o *Bacillus subtilis* (spore) CIP 52.62

The selected tests surfaces are stainless steel discs, flats, corresponding to the requirements of paragraph 5.2.3.1 of the standard. The supplier is CONTIGIANI (Toulouse).

**b. Conditions of aerial disinfection system use**

- Room :



Relative humidity ranging from 40% to 55%.

Initial temperatures ranging from 20°C to 21°C.

Test room volume : 51,7m³.

Distance between the appartus and the carriers : 3,3m (tableau B.1).

**Diluants and culture media**

**Interfering substances**

1/20 reconstituted milk (Internal preparation - Batch 5866 Exp. May/13/2015)

**Diluants**

Suspension preparation : EPPI (Cooper, Batch 19HD03GA Exp. March 2017)

Recovery solution (Internal preparation - Batch 5905)

**Filtration membranes**

Nitrocellulos emembranes 0,45µm (Millipore, batch F4SA32924 Exp. December 2016)

**Culture media**

GGL Medium (Internal preparation - Batches 5902 Exp. May/23/2015 and 5910 Exp. May/28/2015)



## 4. Assays

• Treatment 5 mL / m<sup>3</sup> - waiting 2H

Tests microorganisms	N Test suspension (CFU/mL)	Preliminary assay			T Control (CFU/spot - 50µL)  ≈ 10 <sup>4</sup>	n'1 + n'2 UFC/ spot 50µL (dilution/filtration - disc in agar)	Log reduction  -  Mean
		n1/N1	n2/N2	n3/N1			
<i>B. subtilis</i>	2.10 <sup>5</sup> - 5.10 <sup>5</sup>	n1 > 0.5 N1	n2 > 0.5 N2	n3 > 0.5 N1			
Date Apr/29/2015		d1 : 26/24	d1 : 24/24	d1 : 33/24	d1 : 1,37.10 <sup>4</sup>	d1 : 0 + 0	R1 : 4,11
B : 20,3°C/RH 43%	2,4.10 <sup>5</sup>	d2 : 24/24	d2 : 15/24	d2 : 18/24	d2 : 1,22.10 <sup>4</sup>	d2 : 0 + 0	R2 : 4,11
E : 20,6°C/RH 51%					T = 1,30.10 <sup>4</sup>	d3 : 0 + 0	R3 : 4,11
							<b>R = 4,11</b>

T : counting of micro-organisms on the discs.

N<sub>1</sub> : counting of test suspension by pour plate technique - N<sub>2</sub> : counting of test suspension by filtration method

n<sub>1</sub> : counting to search inhibitor effect in agar medium - n<sub>2</sub> : counting to search inhibitor effect on membrane filtration - n<sub>3</sub> : counting to search inhibitor effect after inclusion of disc in agar medium

n'<sub>1</sub> : number of survival micro-organisms in 100mL of tryptone-salt - n'<sub>2</sub> : number of micro-organisms after inclusion of the disc in agar medium.

n'<sub>1</sub> + n'<sub>2</sub> : total number of survival micro-organisms on the carrier surface.

d1 : disc N°1 / d2 : disc N°2 / d3 : disc N°3

## 5. Conclusion

According to the conditions of test, the couple apparatus/product led to:

- A sporicidal activity (log reduction  $\geq 3$ )
  - After 5 mL/m<sup>3</sup> treatment - 2 hours of wait on the following strain :
    - *Bacillus subtilis* (spore) CIP 52.62