FONdation pour le
DEveloppement de la
REcherche
PHARmaceutique

Système de management de la qualité
Certifié ISO 9001

Toulouse, December 2nd 2016

STUDY 16-2074

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)

Human Health

Additional Conditions : *Clostridium difficile* (spore)

Promotor	**OXY'PHARM** **917 rue Marcel Paul** **94500 CHAMPIGNY SUR MARNE**
Test laboratory	**FONDEREPHAR** **Faculté des Sciences Pharmaceutiques** **35 Chemin des Maraîchers** **31062 TOULOUSE cedex 9**

Dr **Catherine FEUILLOLAY** Study Manager	Dr **Jocelyne BACARIA** Quality Manager

FONDEREPHAR - Faculté des Sciences Pharmaceutiques – 35, chemin des Maraîchers – 31062 TOULOUSE cedex 9 - Email : contact@fonderephar.com - www.fonderephar.com
Tél. +33 (0)5 62 25 68 60 - Fax. +33 (0)5 61 25 95 72 - Siret 328 649 538 000 27 - APE 7211Z - N° TVA : FR 80328649538 - Association Loi 1901 n° 8219

1. Test Laboratory

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® 6% Neutral
Batch : 031116N (Expiry date: 11/2018)

Concentration of product in the room : 5 ml/m^3
One treatment with one hour of wait (carriers recovery after waiting)
Amount of disinfectant diffusion ≈ 160 mL/treatment

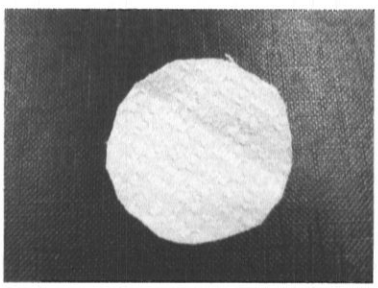
Promotor :	OXY'PHARM
Storage conditions:	Ambiant temperature
Period of testing:	November 2016
Actives Substances:	Hydrogen peroxide

3. Experimental Conditions

a. Tests micro-organisms

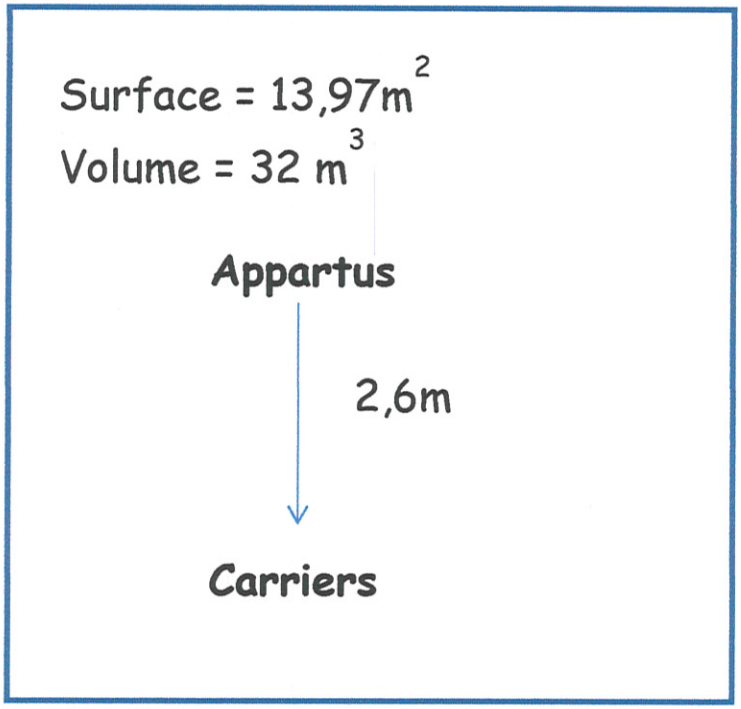
- Sporicidal activity :
  - *Clostridium difficile* (spore) NCTC 13366

The test surface is a cloth material (photo below). The color is unbleached. Some circles (diameter 3,5 cm) were cut, then sterilized in the autoclave (121°C - 15 to 20 minutes).
The cloth material was transferred by OXY'PHARM.



b. Conditions of aerial disinfection system use

- Room :



Relative humidity ranging from 52% to 65%.
Initial temperatures ranging from 20,1°C to 20,5°C.
Test room volume : 32m³.
Distance between the appartus and the carriers : 2,6m (tableau B.1).
Samples were placed for a height between 1m and 1,5m, in a vertical position, with facing away from the source

Diluants and culture media

Interfering substances
1/20 reconstituted milk (Internal preparation - Batch 6927 Exp. Dec/21/2016)

Diluants
Suspension preparation : EPPI (Cooper, Batch 19KB14GA Exp. January 2019)
Recovery solution (Internal preparation - Batch 6915 Exp. Dec/14/2016)

Filtration membranes
Nitrocellulos emembranes 0,45µm (Millipore, batch F6JA76997 Exp. July 2018)

Culture media
Medium for Clostridium difficile (Internal preparation - Batch 6916 Exp. Dec/14/2016)

4. Assays

- **Treatment 5 mL / m^3 – waiting 1H**

Tests microorganisms	N Test suspension (CFU/mL)	Preliminary assay			T Control (CFU/spot - 50µL)	n'1 + n'2 UFC/ 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		
C. difficile Date Nov/22/2016 B: 20,1°C/RH 52% E: 20,5°C/RH 65%	$2,9.10^5$	d1 : 125/137 d2 : 127/137	d1 : 90/102 d2 : 83/102	d1 : 105/137 d2 : 92/137	d1 : $9,8.10^3$ d2 : $1,18.10^4$ T = $1,07.10^4$	d1 : 0 + 0 d2 : 0 + 0 d3 : 0 + 0	R1 : 4,03 R2 : 4,03 R3 : 4,03 R = 4,03

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 carrier surface 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

According to standard NF T 72-281 (November 2014) and for the test conditions, the couple NOCOSPRAY (serial number 37S347) / NOCOLYSE® 6% Neutral (Batch 031116N Expiry date: November 2018), in use of human health, on the cloth material transfer by client, led to:

- **A sporicidal activity (log reduction ≥ 3)**
  - **After 5 mL/m^3 treatment - 1 hour of wait on the following strain :**
    - *Clostridium difficile (spore)* NCTC 13366