FONdation pour le
DEveloppement de la
REcherche
PHARmaceutique

Système de management de la qualité
Certifié ISO 9001

Toulouse, December 7th 2017

STUDY 17-2217

Determination of sporicidal 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)

Client

OXY'PHARM
917 rue Marcel Paul
94500 CHAMPIGNY SUR MARNE

Test laboratory

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1. Test Laboratory

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2. Identification of the aerial disinfection system

Device : NOCOSPRAY
Serial number: 37S347

Disinfectant : NOCOLYSE®
Batch : 041017N (Expiry date: 10/2019)
Internal Code. 17-2217-1

Concentration of product in the room : 3 mL/m^3
One treatment with one hour of wait (carriers recovery after waiting)
Amount of disinfectant diffusion ≈ 96 mL/treatment (exactly 103,5g)

Promotor :	OXY'PHARM
Storage conditions:	Ambiant temperature
Period of testing:	November - December 2017
Actives Substances:	Hydrogen peroxide (6%)

3. Experimental Conditions

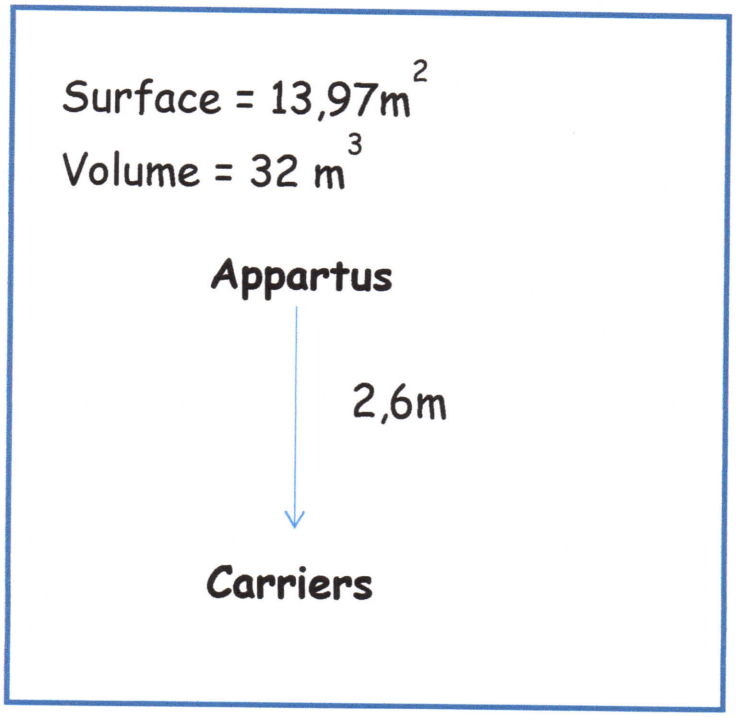
a. Tests micro-organisms

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

The test surface is a blue curtain which was transferred by OXY'PHARM.
Reference : "Polypropylène incorporé à un agent antimicrobien à base d'argent"
Batch 036111 - AMG MEDICAL INC

b. Conditions of aerial disinfection system use

- Room :



Relative humidity ranging from 42% to 38%.
Initial temperatures ranging from 19,6°C to 19,2°C.
Test room volume : 32m³.
Distance between the appartus and the carriers : 2,6m (tableau B.1).
Squares (3 cm) have been drawn on the surface (rough side) at a height between 1,3m and 1,5m, in a vertical position (the curtain has been set up in the room), with facing away from the source

Diluants and culture media

Interfering substances
1/20 reconstituted milk (Internal preparation - Batch 6279 Exp. Dec/29/2017)

Diluants
Suspension preparation : EPPI (Cooper, Batch 19KL09GA Exp. October 2019)
Recovery solution (Internal preparation - Batch 7594 Exp. Dec/28/2017)

Filtration membranes
Nitrocellulos membranes 0,45µm (Millipore, batch F7JA35599 Exp. July 2019)

Culture media
Medium for Clostridium difficile (Internal preparation - Batch 7589 Exp. Dec/12/2017)

4. Assays

- **Treatment 3 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/30/2017 B: 19,6°C/RH 42% E: 19,2°C/RH 38%	$2,3.10^5$	d1 : 56/110 d2 : 55/110	d1 : 82/137 d2 : 89/137	d1 : 118/110 d2 : 101/110	d1 : $9,5.10^2$ d2 : $1,6.10^3$ T = $1,3.10^{3*}$	d1 : 0 + 0 d2 : 0 + 0	R1 : 3,11 R2 : 3,11 R = 3,11

* A 1 log decrease after the step of drying has been observed

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

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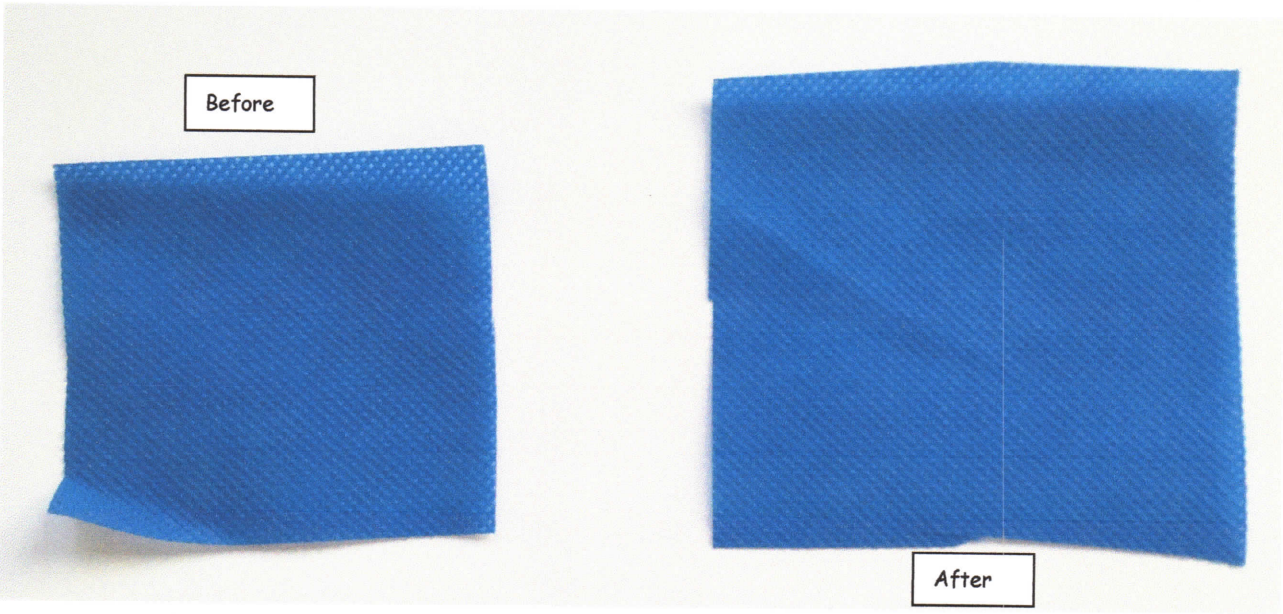
No modification of blue color have been observed after the treatment



5. Conclusion

According to standard NF T 72-281 (November 2014) and for the test conditions, the couple NOCOSPRAY (serial number 37S347) / NOCOLYSE® (Batch 041017N Expiry date: December 2019), in use of human health, on the blue curtain transfer by client, led to:

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