



Toulouse, October 30th 2017

TEST REPORT N°17-1233

STUDY 17-2198

NF EN 13624 (November 2013)

**QUANTITATIVE SUSPENSION TEST FOR THE EVALUATION OF
FUNGICIDAL ACTIVITY IN THE MEDICAL AREA (Phase2, step1)**

DISINFECTION OF SURFACE

OBLIGATORY CONDITIONS

Clean conditions

Promotor

OXY'PHARM
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Assay Laboratory

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I - IDENTIFICATION OF ASSAY LABORATORY

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Faculté des Sciences Pharmaceutiques
35 Chemin des Maraîchers
31062 Toulouse Cedex 9

II - IDENTIFICATION OF TEST PRODUCT

Product : NOCOLYSE®
Batch : 041017N
Expiry date: 10/2019
Packaging: Flask 1L
Date of receipt : Oct/05/2017
Internal code : 17-2198-1

Active substances : Hydrogen peroxide
Period of testing : October 2017

Storage conditions during the period of testing : Room temperature

III - TEST

Method : Dilution - neutralization

Neutralizer : Tween 80 (3%), Sodium Pyruvate (3%), qsp distilled water (Batch 7509)

Count(s) per ml : 1 or 2 for $N/10^{-5}$ or $N/10^{-6}$ (modified method) for *C. albicans*
1 or 2 for $N/10^{-5}$ or $N/10^{-6}$ (modified method) for *A. brasiliensis*

Appearance of the product : liquid, clear

IV - EXPERIMENTAL CONDITIONS

Product diluent : Water for injectables preparations

Interfering substance: 0,3 g/L bovine albumin (clean conditions)

Obligatory conditions : Tests-organisms : *Candida albicans* DSM 1386
Aspergillus brasiliensis CBS 733.88

Concentrations of the product: **97%, 70% and 0,5% (V/V)**

Test temperature : $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$

Contact time : 60 minutes $\pm$ 10 secondes

Incubation temperature: $30^{\circ}\text{C} \pm 1^{\circ}\text{C}$

No precipitate during the test procedure (test mixtures were homogeneous).

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V - RESULTS

CANDIDA ALBICANS DSM 1386 - NOCOLYSE Batch 041017N

VALIDATION AND CONTROLS				TEST SUSPENSION		TEST			
Validation suspension Nvo NvB	Experimental conditions control A	Neutralizer control B	Method validation Product conc. 50% C	N			Concentration of product % (V/V)		
				10 ⁻⁵	10 ⁻⁶		Contact time	70%	0.5%
Vc1-Vc2	Nvo 72-77 NvB 56-59	64-67	76-78	68-71	238-237 20-21	Vc1 - Vc2	60 minutes	10 ⁰ >330-1-2 10 ⁻¹ 0-1	10 ⁰ >330->330 10 ⁻¹ >330->330
$\bar{x}$	Nvo 75 NvB 58	66	77	70	$\bar{x}$ $x_{mp} = 234,55.10^5$ $lg N = 7,37$	$\bar{x}$	60 minutes	< 14	> 3.3.10 ³
$\bar{x}$ of Nvo and NvB between 30 and 160	$\bar{x}$ of A $\geq 0,5$ $\bar{x}$ of Nvo	$\bar{x}$ of B $\geq 0,5$ $\bar{x}$ of Nvo and NvB	$\bar{x}$ of C $\geq 0,5$ $\bar{x}$ of Nvo	N/10= 234,55.10 ⁴ $lg N/10 = 6,37$		$\bar{Na} = \bar{x} \times 10$	60 minutes	< 140	> 3.3.10 ⁴
				6,17 ≤lg N/10 ≤ 6,70		lg Na	60 minutes	< 2,15	> 4,52
						lg R	60 minutes	>4,22	<1,85

Date of the test: Oct/ 18/2017

Vc = Count per ml (1 or 2 plates for N/10⁻⁵)

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}_{wm}$ = weighted mean of $\bar{x}$

R = Reduction ($\lg R = \lg N_0 - \lg N_d$)

CANDIDA ALBICANS DSM 1386 - Modified Method - NOCOLYSE Batch 041017N

VALIDATION AND CONTROLS				TEST SUSPENSION		TEST			
Validation suspension Nvo NVB	Experimental conditions control A	Neutralizer control B	Method validation Product conc. 97% C	N			Concentration of product % (V/V)		
				10 ⁻⁶	10 ⁻⁷				
Vc1-Vc2	Nvo 72-77 NVB 56-59	70-75	76-78	79-83	238-237	20-21	Vc1 - Vc2	60 minutes	10 ⁰ 0 - 0 10 ⁻¹ 0 - 0
$\bar{x}$	Nvo 75 NVB 58	73	77	81	$\bar{x}$ mp = 234,55.10 ⁶ lg N = 8,37		$\bar{x}$	60 minutes	< 14
$\bar{x}$ of Nvo and NVB between 30 and 160	$\bar{x}$ of A ≥ 0,5 $\bar{x}$ of Nvo	$\bar{x}$ of B ≥ 0,5 $\bar{x}$ of Nvo and NVB	$\bar{x}$ of C ≥ 0,5 $\bar{x}$ of Nvo	N/100= 234,55.10 ⁴ lg N/100 = 6,37		$\bar{Na}$ = $\bar{x}$ x10	60 minutes	< 140	
						lg Na	60 minutes	< 2,15	
				6,17 ≤lg N/100 ≤ 6,70					
						lg R	60 minutes	>4,22	

Date of the test: Oct/ 18/2017

Vc = Count per ml (1 or 2 plates for N/10⁻⁶)

x = average of Vc1 and Vc2

x wm = weighted mean of x

R = Reduction (lg R = lg N₀ - lg N_g)

ASPERGILLUS BRASILIENSIS CBS 733.88 - NOCOLYSE Batch 041017N

VALIDATION AND CONTROLS				TEST SUSPENSION		TEST					
Validation suspension Nvo NVB	Experimental conditions control A	Neutralizer control B	Method validation Product conc. 50% C	N			Concentration of product % (V/V)				
				10 ⁻⁵	10 ⁻⁶		Contact time	70%	0.5%		
Vc1-Vc2	Nvo 75-80 NVB 95-96	91-100	125-127	92-105	312-303	43-33	Vc1 - Vc2	60 minutes	10 ⁰ >165->165 10 ⁻¹ 52-55	10 ⁰ >165->165 10 ⁻¹ >165->165	
x	Nvo 78 NVB 96	96	126	99	x mp = 314,09.10 ⁵ lg N = 7,50		x	60 minutes	535	> 1,65.10 ³	
					N/10= 314,09.10 ⁴ lg N/10 = 6,50			Na= x x10	60 minutes	5350	> 1,65.10 ⁴
								lg Na	60 minutes	3,73	> 4,22
				6,17 ≤lg N/10 ≤ 6,70			lg R	60 minutes	2,77	<2,28	

Date of the test: Oct/23/2017

Vc = Count per ml (1 or 3 plates for N/10⁻⁵)

x = average of Vc1 and Vc2

x wm = weighted mean of x

R = Reduction (lg R = lg N₀ - lg N_a)

ASPERGILLUS BRASILIENSIS CBS 733.88 - Modified Method - NOCOLYSE Batch 041017N

VALIDATION AND CONTROLS				TEST SUSPENSION		TEST	
	Validation suspension N _{vo} N _{VB}	Experimental conditions control A	Neutralizer control B	Method validation Product conc. 97% C	N		Concentration of product % (V/V)
					10 ⁻⁶	10 ⁻⁷	
Vc1-Vc2	N _{vo} 75-80 N _{VB} 95-96	83-91	125-127	95-116	312-303	43-33	Vc1 - Vc2 60 minutes 10 ⁰ 0 - 1 10 ⁻¹ 0 - 0
$\bar{x}$	N _{vo} 78 N _{VB} 96	87	126	106	$\bar{x}_{mp} = 314,09.10^6$ $\lg N = 8,50$		$\bar{x}$ 60 minutes < 14
	$\bar{x}$ of N _{vo} and N _{VB} between 30 and 160	$\bar{x}$ of A $\geq 0,5 \bar{x}$ of N _{vo}	$\bar{x}$ of B $\geq 0,5 \bar{x}$ of N _{vo} and N _{VB}	$\bar{x}$ of C $\geq 0,5 \bar{x}$ of N _{vo}	N/100= 314,09.10 ⁴ $\lg N/100 = 6,50$		$\bar{N}_d = \bar{x} \times 10$ 60 minutes < 140
							$\lg N_d$ 60 minutes < 2,15
					6,17 $\leq \lg N/100 \leq 6,70$		$\lg R$ 60 minutes > 4,35

Date of the test: Oct/23/2017

Vc = Count per ml (1 or 3 plates for N/10⁻⁶)

$\bar{x}$ = average of Vc1 and Vc2

$\bar{x}_{wm}$ = weighted mean of $\bar{x}$

R = Reduction ($\lg R = \lg N_b - \lg N_d$)

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VI - CONCLUSION

For the product **NOCOLYSE®** (batch 041017N) - Packaging Flask 1L, the fungicidal concentration for **disinfection of surfaces** according to the NF EN 13624 (November 2013), obligatory conditions, after a 60 minutes contact time at 20°C under clean conditions, against *C. albicans* DSM 1386 and *Aspergillus brasiliensis* CBS 733.88, is 97% (V/V).

The limiting microorganism is *Aspergillus brasiliensis* CBS 733.88.

The results hold only for the product under assay.