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## Test report No. S33/2020

# DETERMINATION OF BACTERICIDAL AND YEASTICIDAL (EN 16615:2015) ACTIVITY OF THE PRODUCT OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments

Sample ID: S33/2020

Page: 1 From pages: 11

Sample name: **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** Client: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY Producer: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY Sampling point: KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI, Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece, Istanbul, TURKEY

Incoming date: 30.1.2020

Delivery date: 16.4.2020

Hodonín, 16.4.2020

Ing. Jana Šlitrová, Head of Laboratory

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<u>Subject of testing:</u> Determination of bactericidal and yeasticidal activity of the product.

<u>Identification of the sample:</u> Name of the product:

Batch number: Date of manufacture: Expiry date: Manufacturer:

Incoming date: Storage conditions: Active ingredients:

#### Experimental conditions:

Period of analysis: Lab temperature: Temperature of media: Test method: Neutralization medium: Product diluent: Appearance of the product: Water control: Test concentration: Contact time: Interfering substances: Test organisms:

Incubation conditions: Test surface:

Wipe:

Test weight: Tampons:

OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes
for Medical Instruments
KAFG35-1200212001
22.01.2020
22.01.2022
KAF GRUP SAGLIK HIZMETLERI INS. SAN VE TIC.LTD.STI,
Atakent Mh. 221. Sk. No:3A Rota Office D.83, Kücükcekmece,
Istanbul, TURKEY
30.1.2020
room temperature
CAS 64-17-5 Ethanol 30%
CAS 67-63-0 2-Propanol 10%
CAS 94667-33-1 Didecyldimethylpoly(oxethyl) Ammonium
Propionate 0.25%

# Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers

SOP-M-19-00 (EN 16615:2015) 17.3. - 18.3.2020 $20 \degree C \pm 2.5 \degree C$  $20 \circ C \pm 1 \circ C$ dilution neutralization method Dey-Engley Neutralizing Broth M 1062 distilled water ready to use wipes (wet white wipes) distilled water + polysorbate 80 100% (wet white wipes) 1 min 0.3 g/l BSA (clean conditions) Pseudomonas aeruginosa ATCC 15442 *Staphylococcus aureus* ATCC 6538 Enterococcus hirae ATCC 10541  $37 \text{ °C} \pm 1 \text{ °C}, 24 \text{ hours}$ 

PVC with PUR coating, width 2.5 mm, 20 cm x 50 cm. The surface is cleaned by 70% n-propanol. After drying draw 4 squares 5 cm x 5 cm 5 cm apart, mark them as test fields 1 to 4. The drying controls  $D_{C0}$  and  $D_{Ct}$  are performed on smaller surface (7 cm x 13 cm, 2 squares 5 cm x 5 cm).

17.5 cm x 28 cm, 55% cellulose, 45% polyethylenterephtalate (PET), the wipe is used only once. 30 minutes before testing put the wipe in Petri dish with 16 ml of the distilled water and polysorbate 80. The wet wipe is weighed before and after testing.

granite, lenght 11.9 cm, width 8.2 cm, height 8.4 cm, weight 2.4 kg sterile, length 150 mm, disposable, tip made of pure cotton without compounds inhibiting or supporting the effect of product solution or growth of microorganisms, producer F.L. Medical

### Parafilm:

Parafilm® M, 10.2 cm x 38 m, producer Brand disposable, protecting the horisontal surface and vertical surfaces before contamination during wiping.

Test procedure:

- 1. Preparation of the test suspension
- 2. Determination of CFU in the test suspension
- 3. Quantitative test on carriers according to EN 16615:2015
- 4. Incubation and calculation
- 5. Expression and interpretation of results

### Note:

Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under defined conditions on nonporous surface in the field 1 by at least a 5 lg reduction (10<sup>5</sup>).  $R = D_{Ct}/N_a$  or lg  $R = lg D_{Ct} - lg N_a$  the reduction in viability, the drying time: 20 – 30 min

### The standard:

EN 16615:2015 Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2) April 2015

EN ISO 4833-1 Microbiology of the food chain – Horizontal method for the enumeration of microorganisms – Part 1: Colony count at 30 degrees C by the pour plate technique, September 2013

The Number of CFU in the tested product (SOP-M-07-00 (EN ISO 4833-1)): 0 CFU/ml (solution)

# 1. Testing the efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces

Tab No	Tab No. 1.1 Verification of methodology, temperature 20°C, clean conditions										
Validation of suspension (Nv0)			Neutralizer toxicity control (B)			Method validation (C), product conc. 100%					
V <sub>c1</sub>	64	đ	- 58 5	V <sub>c1</sub>	62	$\Phi = 51.5$	V <sub>c1</sub>	59	$\Phi_{\rm C} = 56$		
V <sub>c2</sub>	53	4	$N_{\rm Nvo} = 58.5$	V <sub>c2</sub>	41	$\Psi_{\rm B} = 51.5$		V <sub>c2</sub>			53
$30 \le \Phi_{\text{Nvo}} \le 160$		$\Phi_{\mathbf{B}} \ge 0.5 \Phi_{\mathrm{Nvo}}$		$\Phi_{\rm C} \ge 0.5 \; \Phi_{\rm Nyo}$							
х	yes		no	х	yes		no	х	yes		no

Tab No. 1.2 Test suspension

Test suspension N	Dilution	$V_{c1}$	V <sub>c1</sub>		Test suspe	ensior	n N <sub>0</sub>	
$\Phi = 47.5 \text{ x} 10^8 = 199.68$	10-7	> 330	> 330		$N_0 = N/20$ , $lg N_0 = 8.38$			
$9.17 \le \log N \le 9.70$	10-8	46	49	$7.88 \le \lg N_0 \le 8.40$				
				x	ves		no	

Tab No. 1.2.1 Drying in time 0

	Dilution	V <sub>c1</sub>	V <sub>c1</sub>	$l_{\alpha}$ D = $l_{\alpha}$ ( $\Phi$ x 5 x 10 <sup>5</sup> ) = 6.02			
Drying control (D <sub>C0</sub> )	10-4	161	172		$\lim_{x \to 0} \log (\Phi x 5 x 10^{\circ}) = 6.92$		
	10-5	17	14		$0.88 \ge 10^{-1}$	$J_{C0} \ge$	8.40
				х	ves		no

Tab No. 1.2.2 Drying in time t

	Dilution	V <sub>c1</sub>	V <sub>c1</sub>	$1 \alpha D = 1 \alpha (\Phi \times 5 \times 10^5) = 6.99$			
Drying control (D <sub>Ct</sub> )	10-4	140	162		$Ig D_{Ct} = Ig (\Psi X 5 X 10^{\circ}) = 6.88$		
	10-5	15	17		$0.00 \ge 10$	$D_{Ct} \ge$	0.40
				х	ves		no

Tab No. 1.3.1 Test with water  $N_w$  – the effect of water (Wipe with distilled water + polysorbate 80) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions

Field / contact time	Dilution after test	Vc	$N_W =$	N <sub>w</sub> requirement
(min)	procedure		(Φ x 5)	$>10 \text{ cfu}/25 \text{ cm}^2$
2 / 1	100	86	430	yes
3 / 1	100	72	160	yes
4 / 1	$10^{0}$	103	515	yes

Tab No. 1.3.2 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions, field 2-4

			,,	
Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	Vc	$N_a = (\Phi \times 5)$	N <sub>a</sub> requirement <50 cfu/25 cm <sup>2</sup>
/collations / field				
100/1/clean/2	100	0	<14	yes
100/1/clean/3	100	0	<14	yes
100/1/clean/4	$10^{0}$	0	<14	ves

Tab No. 1.3.3 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions, field 1

Test concentration (%)	Dilution after	V <sub>c1</sub>	V <sub>c2</sub>	$lg N_a (\Phi x 5)$	$lg R$ $(lg D_{Cl} = 6.88)$
/conditions / field	test procedure				$(1g D_{Ct} - 0.00)$
100/1/clean/1	$10^{0}$	<14	<14	<1.85	≥ 5.03

Tab No. 1.4 Test - weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
OneSpray Wipes Alcohol-Based Fast	12.3	11.3	1.0
Acting Disinfectant/Wipes for Medical			
Instruments (ready to use wipes)			
Wipe with distilled water + polysorbate 80	19.0	18.0	1.0

# 2. Testing the efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces

## Tab No. 2.1 Verification of methodology, temperature 20°C, clean conditions

Validation of suspension ( $N_{V0}$ )			Neutra	lizer toxicity contr	rol (B)	Method validation (C), product conc. 100%				
V <sub>c1</sub>	35	Φ - 16	V <sub>c1</sub>	36	A 265	V <sub>c1</sub>	34	$\Phi_{\rm C} = 36$		
V <sub>c2</sub>	57	$\Psi_{\rm Nvo} = 40$	V <sub>c2</sub>	37	$\Psi_{\rm B} = 50.5$	V <sub>c2</sub>	38			
$30 \le \Phi_{\text{Nvo}} \le 160$			$\Phi_{\mathbf{B}} \ge 0$	$\Phi_{B} \ge 0.5 \Phi_{Nvo}$			$\Phi_{\rm C} \ge 0.5 \; \Phi_{ m Nvo}$			
х	yes	no	х	yes	no	х	yes	no		

Tab No. 2.2 Test suspension

Test suspension N	Dilution	V <sub>c1</sub>	V <sub>c1</sub>		Test suspe	ension N <sub>0</sub>
$\Phi = 43 \text{ x } 10^8 = \log 9.63$	10-7	> 330	> 330		$N_0 = N/20, 1$	$g N_0 = 8.33$
$9.17 \le \log N \le 9.70$	10-8	34	52	1	7.88 ≤ lg l	$N_0 \le 8.40$
				х	yes	no

#### Tab No. 2.2.1 Drying in time 0

	Dilution	V <sub>c1</sub>	$V_{c1}$	$l_{\alpha} D = l_{\alpha} (\Phi \times 5 \times 10^5) = 7.65$				
Drying control (D <sub>C0</sub> )	10-4	> 330	> 330		$\lim_{t \to 0} \log \left( \frac{1}{2} \exp \left( \frac$			
	10-5	84	96		$0.88 \ge 10^{-1}$	$D_{C0} \ge$	8.40	
				х	yes		no	

#### Tab No. 2.2.2 Drying in time t

	Dilution	V <sub>c1</sub>	Vc1	$\log D_{c_1} = \log (\Phi \mathbf{x} 5 \mathbf{x} 10^5) = 7.65$			(5) - 7.65
Drying control (D <sub>Ct</sub> )	10-4	> 330	> 330		$Ig D_{Ct} = Ig (\Phi x 5 x 10^{\circ}) = 7.65$		
	10-5	89	88		$0.88 \leq 10^{-1}$	$D_{Ct} \ge$	8.40
				x	ves		no

Tab No. 2.3.1 Test with water  $N_w$  – the effect of water (Wipe with distilled water + polysorbate 80) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions

Field / contact time	Dilution after test	$V_{c}$	N <sub>w</sub> =	N <sub>w</sub> requirement
(min)	procedure		(Φ x 5)	$>10 cfu/25 cm^2$
2 / 1	100	92	460	yes
3 / 1	100	5	25	yes
4 / 1	$10^{0}$	4	20	yes

Tab No. 2.3.2 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, field 2-4

Test concentration (%)	Dilution after test	Vc	$N_a =$	N <sub>a</sub> requirement
/contact time (min)	procedure		(Φ x 5)	$<50 \text{ cfu}/25 \text{ cm}^2$
/conditions / field				
100/1/clean/2	$10^{0}$	1	<14	yes
100/1/clean/3	$10^{0}$	2	<14	yes
100/1/clean/4	$10^{0}$	2	<14	yes

Tab No. 2.3.3 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V <sub>e1</sub>	V <sub>c2</sub>	$lg N_a (\Phi x 5)$	lg R ( $lg D_{Ct} = 7.65$ )
100/1/clean/1	$10^{0}$	<14	<14	<1.85	> 5 80

#### Tab No. 2.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
OneSpray Wipes Alcohol-Based Fast	11.1	10.4	0.7
Acting Disinfectant/Wipes for Medical			
Instruments (ready to use wipes)			
Wipe with distilled water + polysorbate 80	18.8	17.8	1.0

#### 3. Testing the efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on *Enterococcus hirae* ATCC 10541 on non-porous surfaces Tab No. 3.1 Verification of methodology, temperature 20°C, clean conditions

Tab No. 5.1 Verification of methodology, temperature 20 °C, clean conditions											
Validation of suspension $(N_{V0})$				Neutralizer toxicity control (B) Method validation (C), product co			onc. 100%				
$V_{c1}$	55	Ф	Ф <u>-545</u>		55	<b>Φ</b> − 52.5	V <sub>c1</sub>	31	$\Phi - 36$		
V <sub>c2</sub>	54	$\Psi_{\text{Nvo}}$	= 54.5	V <sub>c2</sub>	50	$\Psi_{\rm B} = 52.5$	V <sub>c2</sub>	41	$\Psi_{\rm C} = 30$		
$30 \le \Phi_{Nvo} \le 160$		$\Phi_{\mathbf{B}} \ge 0.5 \; \Phi_{\mathrm{Nvo}}$		$\Phi_{ m C} \ge 0.5 \; \Phi_{ m Nvo}$							
х	yes	no	0	х	yes		no	х	yes	n	10

Tab No. 3.2 Test suspension

Test suspension N	Dilution	V <sub>c1</sub>	V <sub>c1</sub>		Test suspe	n N <sub>0</sub>	
$\Phi = 49.5 \text{ x} 10^8 = \lg 9.69$	10-7	> 330	> 330		= 8.39		
$9.17 \le \log N \le 9.70$	10-8	48	51		$7.88 \le \lg N_0 \le 8.40$		
				х	ves		no

Tab No. 3.2.1 Drying in time 0

	Dilution	V <sub>c1</sub>	$V_{cl}$		$\ln D_{1} = \ln (\Phi \times 5 \times 10^{5}) = 7.65$			
Drying control (D <sub>C0</sub> )	10-4	> 330	> 330		$\lim_{x \to 0} \log (\Phi \times 5 \times 10^{\circ}) = 7.65$			
	10-5	98	81		$6.88 \le \log D_{C0} \le 8.40$			
				х	ves		no	

Tab No. 3.2.2 Drying in time t

	Dilution	V <sub>c1</sub>	$V_{c1}$	$\ln D = \ln (\Phi \times 5 \times 10^5) = 7$			(5) - 7.59
Drying control (D <sub>Ct</sub> )	10-4	> 330	> 330		$lg D_{Ct} = lg (\Phi x 5 x 10^3) = 7.58$		
	10-5	86	65		$0.88 \leq 10^{-1}$	$D_{Ct} \ge$	8.40
				x	ves		no

Tab No. 3.3.1 Test with water  $N_w$  – the effect of water (Wipe with distilled water + polysorbate 80) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions

Field / contact time	Dilution after test	$V_{c}$	$N_W =$	N <sub>w</sub> requirement
(min)	procedure		(Φ x 5)	$>10 \text{ cfu}/25 \text{ cm}^2$
2 / 1	100	21	105	yes
3 / 1	100	35	175	yes
4 / 1	$10^{0}$	33	165	yes

Tab No. 3.3.2 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions, field 2-4

Test concentration (%)	Dilution after test	Vc	N <sub>a</sub> =	N <sub>a</sub> requirement
/contact time (min)	procedure		(Φ x 5)	<50 cfu/25 cm <sup>2</sup>
/conditions / field	-			
100/1/clean/2	100	2	<14	yes
100/1/clean/3	100	1	<14	yes
100/1/clean/4	100	1	20	yes

Tab No. 3.3.3 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions, field 1

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	V <sub>cl</sub>	V <sub>c2</sub>	lg N <sub>a</sub> (Φ x 5)	lg R (lg DCt = 7.58)
100/1/clean/1	$10^{0}$	<14	<14	<1.85	> 5.73

Tab No. 3.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
OneSpray Wipes Alcohol-Based Fast	14.2	12.7	1.5
Acting Disinfectant/Wipes for Medical			
Instruments (ready to use wipes)			
Wipe with distilled water + polysorbate 80	19.3	18.4	0.9

# 4. Evaluation of bactericidal activity of the product OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments

Tab No. 4.1 The efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on test strains – bactericidal activity on non-porous surfaces, clean conditions, field 1

Bactericidal activity of the product (EN 16615:2015)									
Strain	Test	Contact	Product test	Interfering	lg R	lg R			
	temperature	time	concentrations	substances -	EN				
	[°C]	[min]	[%]	conditions	16615:2015				
Pseudomonas aeruginosa ATCC 15442	20	1	100	clean	≥ 5	> 5			
Staphylococcus aureus ATCC 6538	20	1	100	clean	≥ 5	> 5			
Enterococcus hirae ATCC 10541	20	1	100	clean	$\geq 5$	> 5			

Note:  $V_c$  = value is the number of cfu per ml,  $\Phi$  = average  $V_{c1}$  a  $V_{c2}$  (1. + 2. duplicate  $V_c$  values), N = the number of cfu/ml in the test suspension,  $N_{v0}$  = the number of cfu/ml in the test suspension for validation,  $N_a$  = the number of bacteria per ml in the test mixture, A, B, C = the number of bacteria per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation R =  $D_{Ct}/N_a$  or lg R = lg  $D_{Ct}$  – lg  $N_a$  the reduction in viability

Prepared by: Mgr. Karolína Světlíková, Lab Technician

Experimental conditions:	Testing of disinfecting efficiency of chemical disinfecting and
	antiseptic agents on carriers
	SOP-M-19-00 (EN 16615:2015)
Period of analysis:	30.3 1.4.2020
Lab temperature:	$20 ^{\circ}\text{C} \pm 2.5 ^{\circ}\text{C}$
Temperature of media:	$20 ^{\circ}\text{C} \pm 1 ^{\circ}\text{C}$
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Product diluent:	distilled water
Appearance of the product:	ready to use wipes (wet white wipes)
Water control:	distilled water + polysorbate 80
Test concentration:	100% (wet white wipes)
Contact time:	1 min
Interfering substances:	0.3 g/l BSA (clean conditions)
Test organisms:	Candida albicans ATCC 10231
Incubation conditions:	30 °C $\pm$ 1 °C, 48 hours and additional period of 24 or 48 hours
Test surface:	PVC with PUR coating, width 2.5 mm, 20 cm x 50 cm. The surface is
	cleaned by 70% n-propanol. After drying draw 4 squares 5 cm x 5 cm
	5 cm apart, mark them as test fields 1 to 4. The drying controls $D_{C0}$
	and $D_{Ct}$ are performed on smaller surface (7 cm x 13 cm, 2 squares 5
	cm x 5 cm).
Wipe:	17.5 cm x 28 cm, 55% cellulose, 45% polyethylenterephtalate (PET),
	the wipe is used only once. 30 minutes before testing put the wipe in
	Petri dish with 16 ml of the distilled water and polysorbate 80. The
	wet wipe is weighed before and after testing.
Test weight:	granite, lenght 11.9 cm, width 8.2 cm, height 8.4 cm, weight 2.4 kg
Tampons:	sterile, length 150 mm, disposable, tip made of pure cotton without
	compounds inhibiting or supporting the effect of product solution or
	growth of microorganisms, producer F.L. Medical
Parafilm:	Parafilm® M, 10.2 cm x 38 m , producer Brand
	disposable, protecting the horisontal surface and vertical surfaces
	before contamination during wiping,

Test procedure:

- 1. Preparation of the test suspension
- 2. Determination of CFU in the test suspension
- 3. Quantitative test on carriers according to EN 16615:2015
- 4. Incubation and calculation
- 5. Expression and interpretation of results

## Note:

Yeasticidal activity – the capability of a product to produce a reduction in the number of viable yeast cells of *Candida albicans* under defined conditions on nonporous surface in the field 1 by at least a 4 lg reduction (10<sup>4</sup>).  $R = D_{Ct'} N_a$  or lg  $R = lg D_{Ct} - lg N_a$  the reduction in viability, the drying time: 20 – 30 min

## The standard:

EN 16615:2015 Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2) April 2015

#### 5. Testing the efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on *Candida albicans* ATCC 10231 on non-porous surfaces Tab No. 5.1 Verification of methodology, temperature 20°C, clean conditions

140 14	Tub T(0. 5.1 Verification of includuology, temperature 20 °; crean conditions										
Validation of suspension (Nv0)		Neutralizer toxicity control (B)			Method validation (C), product conc. 100%						
$V_{c1}$	47		- 41 5	V <sub>c1</sub>	35	م	$\Phi = 41$	V <sub>c1</sub>	44	$\Phi - 38$	
V <sub>c2</sub>	36	$\Psi_{l}$	$N_{VO} = 41.3$	V <sub>c2</sub>	47	$\Psi_{\rm B} = 41$		V <sub>c2</sub>	32		$\Psi_{\rm C} = 38$
$30 \le \Phi_{Nvo} \le 160$		$\Phi_{\mathbf{B}} \ge 0.5 \ \Phi_{\mathrm{Nvo}}$		$\Phi_{\rm C} \ge 0.5 \; \Phi_{\rm Nvo}$							
х	yes		no	х	x yes no			х	yes		no

Tab No. 5.2 Test suspension

Test suspension N	Dilution	V <sub>c1</sub>	Vcl		Test suspe	ension 1	N <sub>0</sub>
$\Phi = 40 \text{ x } 10^7 = \log 8.60$	10-6	> 330	> 330		$N_0 = N/20$ , $lg N_0 = 7.30$		
$8.17 \le lg N \le 8.70$	10-7	44	36	$6.88 \le \lg N_0 \le 7.40$			40
				х	ves		no

Tab No. 5.2.1 Drying in time 0

	Dilution	V <sub>c1</sub>	V <sub>c1</sub>		1- D = 1- (A -	5 1	(4) - (42)
Drying control (D <sub>C0</sub> )	10-3	> 330	> 330		$\log D_{C0} = \log (\Phi \times 5 \times 10^{\circ}) = 6.43$		
	10-4	57	51	$5.88 \le \text{ Ig } D_{C0} \le 7.40$			
				х	ves		no

Tab No. 5.2.2 Drying in time t

	Dilution	V <sub>c1</sub>	$V_{c1}$		1-D -1- (Ф	5 1	$(0^4) = (40)$
Drying control (D <sub>Ct</sub> )	10-3	> 330	> 330		$\log D_{Ct} = \log (\Phi \times 5 \times 10^{\circ}) = 6.40$		
	10-4	53	47		$5.88 \leq 10^{-1}$	$O_{Ct} \ge$	7.40
				x	ves		no

Tab No. 5.3.1 Test with water  $N_w$  – the effect of water (Wipe with distilled water + polysorbate 80) on *Candida albicans* ATCC 10231 on nonporous surfaces, clean conditions

Field / contact time	Dilution after test	$V_{c}$	$N_W =$	N <sub>w</sub> requirement
(min)	procedure		(Φ x 5)	$>10 \text{ cfu}/25 \text{ cm}^2$
2 / 1	$10^{0}$	34	170	yes
3 / 1	100	3	15	yes
4 / 1	$10^{0}$	4	20	yes

Tab No. 5.3.2 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions, field 2-4

Test concentration (%) /contact time (min) /conditions / field	Dilution after test procedure	Vc	$N_a = (\Phi \times 5)$	$N_a$ requirement <50 cfu/25 cm <sup>2</sup>
100/1/clean/2	100	4	20	yes
100/1/clean/3	100	0	<14	yes
100/1/clean/4	$10^{0}$	0	<14	yes

Tab No. 5.3.3 Test – the effect of **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions, field 1

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V <sub>c1</sub>	V <sub>c2</sub>	$lg N_a (\Phi x 5)$	lg R (lg DCt = 6.40)
100/1/clean/1	$10^{0}$	<14	<14	<1.85	≥ 4.55

Tab No. 5.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
OneSpray Wipes Alcohol-Based Fast	14.7	13.6	1.1
Acting Disinfectant/Wipes for Medical			
Instruments (ready to use wipes)			
Wipe with distilled water + polysorbate 80	18.5	17.6	0.9

# 6. Evaluation of yeasticidal activity of the product OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments

Tab No. 6.1 The efficacy of chemical disinfectant **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** on test strains – yeasticidal activity on non-porous surfaces, clean conditions, field 1

Bactericidal and yeasticidal activity of the product (EN 16615:2015)							
Strain	Test	Contact	Product test	Interfering	lg R	lg R	
	temperature	time	concentrations	substances -	EN		
[°C] [min] [%] conditions 16615:2015							
Candida albicans ATCC 10231	20	1	100	clean	≥4	>4	

Note:  $V_c$  = value is the number of cfu per ml,  $\Phi$  = average  $V_{c1}$  a  $V_{c2}$  (1. + 2. duplicate  $V_c$  values), N = the number of cfu/ml in the test suspension,  $N_{v0}$  = the number of cfu/ml in the test suspension for validation,  $N_a$  = the number of bacteria and fungi per ml in the test mixture, A, B, C = the number of bacteria and fungi per ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation R =  $D_{Ct}$ /  $N_a$  or lg R = lg  $D_{Ct}$  – lg  $N_a$  the reduction in viability

Prepared by: Mgr. Karolína Světlíková, Lab Technician

Interpretation:

Results of tests are in Tabs.

According to EN 16615:2015 the tested product **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes), batch No. KAFG35-1200212001, in the contact time 1 min under clean conditions at temperature  $20 \,^{\circ}C \pm 2.5 \,^{\circ}C$  by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of viable bacterial cells of *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538 and *Enterococcus hirae* ATCC 10541 by at least a 5 lg reduction.

According to EN 16615:2015 the tested product **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes), batch No. KAFG35-1200212001, in the contact time 1 min under clean conditions at temperature  $20 \,^{\circ}C \pm 2.5 \,^{\circ}C$  by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of viable vegetative yeast cells of *Candida albicans* ATCC 10231 by at least a 4 lg reduction.

### Conclusion:

The product **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** is capable of reducing the number of viable bacterial cells of the relevant organisms on non-porous surfaces under defined conditions (EN 16615:2015 – **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes), 1 min, clean, 20 °C  $\pm$  2.5 °C) to the declared values and, consequently, can be called bactericidal on non-porous surfaces.

The product **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** is capable of reducing the number of viable vegetative yeast cells of the relevant organism on non-porous surfaces under defined conditions (EN 16615:2015 – **OneSpray Wipes Alcohol-Based Fast Acting Disinfectant/Wipes for Medical Instruments** (ready to use wipes), 1 min, clean, 20 °C  $\pm$  2.5 °C) to the declared values and, consequently, can be called yeasticidal on non-porous surfaces.

16.4.2020, Hodonín

Approved by: Ing. Barbora Stoklásková, Leader of Study