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STUDY REPORT

2020-7622/20 23 00654

Alco X Quat

SUSPENSION TEST
ACCORDING TO EN 13727:2012+A2:2015
(Phase 2 step 1)

Chemical disinfectants and antiseptics
Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)

SEPTEMBER 2020

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SUSPENSION TEST ACCORDING TO EN 13727:2012+A2:2015

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	Alco X Quat
ACTIVE SUBSTANCES	:	Ethyl Alcohol Denat. 59% w/v (73,75% v/v) Benzalkonium Chloride (50%): 0.8%
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room temperature, darkness
TEST CONDITIONS	:	Test conducted at 20ºC ± 1 ºC
LOT	:	Not provided
METHOD	:	EN 13727:2012+A2:2015
CONTACT TIME	:	5 minutes
DILUTIONS	:	Undiluted (80%), 50%, 1%
PRODUCT DILUENT	:	Water
STUDY SPONSOR	:	Σ. ΚΟΥΖΟΥΝΑΣ & ΣΙΑ Ε.Ε. - ALCOFARM MEDICAL
PRODUCT SUPPLIER	:	Σ. ΚΟΥΖΟΥΝΑΣ & ΣΙΑ Ε.Ε. - ALCOFARM MEDICAL
PRODUCT MANUFACTURER	:	Σ. ΚΟΥΖΟΥΝΑΣ & ΣΙΑ Ε.Ε. - ALCOFARM MEDICAL
RECEIPT DATE	:	10/07/2020
STUDY PERIOD	:	07/08/2020-10/08/2020
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SCOPE

This European Standard specifies a test method and the minimum requirements for bactericidal activity of chemical disinfectant and antiseptic products that form a homogeneous, physically stable preparation when diluted with hard water, or - in the case of ready-to-use products - with water. Products can only be tested at a concentration of 80 % or less (97 % with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substance.
This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, surgical handrub, surgical handwash, instrument disinfection by immersion, and surface disinfection by wiping, spraying, flooding or other means.
This European Standard applies to areas and situations where disinfection or antisepsis is medically indicated. Such indications occur in patient care, for example:
— in hospitals, in community medical facilities and in dental institutions;
— in clinics of schools, of kindergartens and of nursing homes;
and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for the patients.

PRINCIPLE

A sample of the product as delivered and/or diluted with hard water (or water for ready-to-use products) is added to a test suspension of bacteria in a solution of an interfering substance. The mixture is maintained at one of the temperatures for the adopted contact time. At the end of this contact time, an aliquot is taken; the bactericidal and/or the bacteriostatic action in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. If a suitable neutralizer cannot be found, membrane filtration is used. The numbers of surviving bacteria in each sample are determined and the reduction is calculated. Handwash products are always prediluted with hard water. The resulting solution is regarded as a ready-to-use product.

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TEST CONDITIONS

1. Product type: Surface Disinfection.
2. The following procedure was performed in water bath at 20 °C.
3. The test product was tested at 5 minutes contact time.
4. Interfering substance: A final concentration of 0.3g/L bovine albumin were used for testing (clean conditions).
5. Neutralization Method used: Dilution neutralization.
6. Neutralizer used: LPT Dilution Broth containing polysorbate 80.
7. According to EN 13727, products shall be tested at a minimum of three different concentrations to include one concentration in the active range and one concentration in the non-active range. In this case the product was tested: Undiluted (80%), 50% 1%.

TEST ORGANISMS

Pseudomonas aeruginosa	NCIMB 10421
Staphylococcus aureus	ATCC 6538
Enterococcus hirae	NCIMB 8192

BACTERICIDAL ACTIVITY FOR SURFACE DISINFECTION PRODUCTS

The product shall be deemed to have passed the EN 13727 standard if it demonstrates in a valid test for surface disinfection products at least a 5 lg reduction within max. 5 min (or between 6 and 60 min for products used on surfaces which do not require an action within 5 min or shorter at) min 4 °C and max 30 °C with the chosen interfering substance (clean or dirty conditions) under the conditions defined by this standard when the test organisms are Pseudomonas aeruginosa, Staphylococcus aureus and Enterococcus hirae.

ASSAY ACCEPTANCE CRITERIA

1. Test Suspension (N) is between 1.5 to 5.0 X 10^8 CFU per mL ($8.17 \leq \log N \leq 8.70$)
2. No (N/10) is between 1.5 to 5.0 X 10^7 CFU per mL ($7.17 \leq \log No \leq 7.70$)
3. Validation Suspension=Nv is between 3.0 x 10^2 and 1.6 x 10^3.
4. Neutralizer control= N_{VB} is between 3.0 x 10^4 and 1.6 x 10^5.
5. N_{VO} (Nv/10) is between 30 and 160.
6. Na is the number of survivors (cells) per ml in the test mixture at the end of contact time.
7. R (log reduction) = No - Na
8. Average recovery values for the experimental conditions control (A) were equal to or greater than 0.5 times the Validation Suspension (Nvo).
9. Average recovery values for the Neutralizer control (B) were equal to or greater than 0.5 times the Validation Suspension (Nvo).
10. Average recovery values for the Method Validation control (C) were equal to or greater than 0.5 times the Validation Suspension (Nvo).
11. Control of weighted mean counts. Quotient is not lower than 5 and not higher than 15.

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TEST RESULTS FOR *Pseudomonas aeruginosa* (BACTERICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	1.89E+08
10^{-6}	192	187		
10^{-7}	20	17	log N	8.28
			No (N/10)	1.89E+07
			log No	7.28
			7,17 < = logNo < = 7,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Product conc.: Undiluted (80%)		
VC 1	34	x mean	VC 1	39	x mean	VC 1	44	x mean	VC 1	36	x mean
VC 2	41	37.5	VC 2	35	37	VC 2	40	42	VC 2	44	40
30<x mean of Nvo < 160?			x mean of A is > 0,5*x mean of Nvo?			x mean of B is > 0,5*x mean of Nvo or Nvb/1000?			x mean of C is > 0,5*x mean of Nvo?		
Yes			Yes			Yes			Yes		

Validation suspension (Nvb)		
VC 1	36	x mean
VC 2	42	39
30<x mean of Nvb < 160?	Yes	

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
Undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.28	> 5.13	≥5	PASS TEST
		10^{-1}	0	0							
50%	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.28	> 5.13	≥5	PASS TEST
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.28	< 2.76	≥5	FAILS TEST
		10^{-1}	> 330	> 330							

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TEST RESULTS FOR *Staphylococcus aureus* (BACTERICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	2.09E+08
10^{-6}	196	221		
10^{-7}	18	24	log N	8.32
			No (N/10)	2.09E+07
			log No	7.32
			7,17 < = logNo < = 7,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Product conc.: ndiluted (80		
VC 1	39	x mean	VC 1	42	x mean	VC 1	47	x mean	VC 1	51	x mean
VC 2	48	43.5	VC 2	49	45.5	VC 2	50	48.5	VC 2	50	50.5
30<x mean of Nvo < 160?			x mean of A is > 0,5*x mean of Nvo?			x mean of B is > 0,5*x mean of Nvo or Nvb/1000?			x mean of C is > 0,5*x mean of Nvo?		
Yes			Yes			Yes			Yes		

Validation suspension (Nvb)		
VC 1	37	x mean
VC 2	40	38.5
30<x mean of Nvb < 160?	Yes	

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
Undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.32	> 5.17	≥5	PASS TEST
		10^{-1}	0	0							
50%	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.32	> 5.17	≥5	PASS TEST
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.32	< 2.80	≥5	FAILS TEST
		10^{-1}	> 330	> 330							

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TEST RESULTS FOR *Enterococcus hirae* (BACTERICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	2.60E+08
10^{-6}	249	276		
10^{-7}	20	28	log N	8.42
			No (N/10)	2.60E+07
			log No	7.42
			7,17 < = logNo < = 7,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Product conc.: ndiluted (80		
VC 1	42	x mean	VC 1	46	x mean	VC 1	50	x mean	VC 1	51	x mean
VC 2	49	45.5	VC 2	52	49	VC 2	54	52	VC 2	59	55
30<x mean of Nvo < 160?			x mean of A is > 0,5*x mean of Nvo?			x mean of B is > 0,5*x mean of Nvo or NVB/1000?			x mean of C is > 0,5*x mean of Nvo?		
Yes			Yes			Yes			Yes		

Validation suspension (NVB)		
VC 1	46	x mean
VC 2	47	46.5
30<x mean of NVB < 160?		Yes

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
Undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.42	> 5.27	≥5	PASS TEST
		10^{-1}	0	0							
50%	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.42	> 5.27	≥5	PASS TEST
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.42	< 2.90	≥5	FAILS TEST
		10^{-1}	> 330	> 330							

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CONCLUSION

SUSPENSION TEST ACCORDING TO EN 13727:2012+A2:2015

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ACTIVE SUBSTANCES	:	Ethyl Alcohol Denat. 59% w/v (73,75% v/v) Benzalkonium Chloride (50%): 0.8%
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room temperature, darkness
TEST CONDITIONS	:	Test conducted at 20ºC ± 1 ºC
LOT	:	Not provided
METHOD	:	EN 13727:2012+A2:2015
CONTACT TIME	:	5 minutes
DILUTIONS	:	Undiluted (80%), 50%, 1%
PRODUCT DILUENT	:	Water
STUDY SPONSOR	:	Σ. ΚΟΥΖΟΥΝΑΣ & ΣΙΑ Ε.Ε. - ALCOFARM MEDICAL
PRODUCT SUPPLIER	:	Σ. ΚΟΥΖΟΥΝΑΣ & ΣΙΑ Ε.Ε. - ALCOFARM MEDICAL
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RECEIPT DATE	:	10/07/2020
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METHODOLOGY ABSTRACT

A sample of the product as delivered and/or diluted with hard water (or water for ready to use products) is added to a test suspension of bacteria in a solution of an interfering substance. The mixture is maintained at temperature θ (°C) and for the chosen contact time t. At the end of this contact time, an aliquot is taken; the bactericidal and/or the bacteriostatic action in this portion is immediately neutralized or suppressed by a validated method. The numbers of surviving bacteria in each sample are determined and the log reduction is calculated.

RESULT

The product under test: "Alco X Quat", demonstrated Bactericidal activity for surface disinfection (> 5 log reduction), according to the EN 13727:2012+A2:2015, at 20±1 °C, under clean conditions for product dilution:

Undiluted (80%) for 5 minutes contact time using as test organisms the reference strains: *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Enterococcus hirae*.

For the QACS Ltd Laboratory,

Signature date: 15/09/2020
Lagiopoulos Giorgos
Agronomist-Food Technologist M.Sc.
Study Manager

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STUDY SUMMARY / ABSTRACT

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PRODUCT DILUENT	:	Water
STUDY SPONSOR	:	Σ. ΚΟΥΖΟΥΝΑΣ & ΣΙΑ Ε.Ε. - ALCOFARM MEDICAL
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A sample of the product as delivered and/or diluted with hard water (or water for ready to use products) is added to a test suspension of bacteria in a solution of an interfering substance. The mixture is maintained at temperature θ (°C) and for the chosen contact time t. At the end of this contact time, an aliquot is taken; the bactericidal and/or the bacteriostatic action in this portion is immediately neutralized or suppressed by a validated method. The numbers of surviving bacteria in each sample are determined and the log reduction is calculated.

RESULT

The product under test: "Alco X Quat", demonstrated Bactericidal activity for surface disinfection (> 5 log reduction), according to the EN 13727:2012+A2:2015, at 20±1 °C, under clean conditions for product dilution:

Undiluted (80%) for 5 minutes contact time using as test organisms the reference strains:
Pseudomonas aeruginosa, *Staphylococcus aureus* and *Enterococcus hirae*.

Results refer to the sample as received and analyzed on the period specified above.
The test report shall not be reproduced except in full, without written approval of the laboratory.
The samples will be stored by the laboratory during 1 month from the end test date.
The study report and raw data will be stored by the laboratory for 5 years.

End of Test report