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ALCOFARM

STUDY REPORT

2021-13105/21 23 00788

ALCOXQUAT

SUSPENSION TEST
ACCORDING TO EN 14348:2005
(Phase 2, step 1)

Chemical Disinfectants and Antiseptics-
Quantitative Suspension Test for The Evaluation of
Mycobactericidal Activity of Chemical Disinfectants Used in The
Medical Area Including Instrument Disinfectants
Test Method and Requirements (Phase 2, Step 1)

DECEMBER 2021

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SUSPENSION TEST ACCORDING TO EN 14348:2005

Chemical Disinfectants and Antiseptics- Quantitative Suspension Test for The Evaluation of Mycobactericidal Activity of Chemical Disinfectants Used in The Medical Area Including Instrument Disinfectants. Test Method and Requirements (Phase 2, Step 1)

TEST PRODUCT IDENTIFICATION

Name of product	:	ALCOXQUAT
Batch no.	:	BH8615
Date of delivery	:	08/09/2021
Storage conditions	:	room temperature and darkness
Appearance of product	:	clear liquid
Odour	:	characteristic
Recommended diluent	:	Product is ready for use
Diluent used	:	distilled water (DW, pH 7.0)
Substances and Their Concentrations	:	73.5% v/v Ethanol 0.4% v/v Benzalkonium Chloride
Method	:	EN 14348:2005
Study Sponsor	:	ALCOFARM
Product manufacturer	:	ALCOFARM
LAB ID	:	2021-13105/21 23 00788
pH value, concentrate:	:	8.1
pH value, 80 % (measured in diluent)	:	8.0
pH value, 50 % (measured in diluent)	:	7.5
pH value, 10 % (measured in diluent)	:	7.0
Identification of Laboratory	:	Subcontractor-External laboratory, accredited under ISO 17025 for the EN 14348:2005

TEST CONDITIONS

Test period	:	09/11/2021 - 30/11/2021
Efficacy claim	:	mycobactericidal activity
Product test concentrations	:	10 + 50 + 80 %
Exposure time	:	5 minutes
Test temperature	:	20°C ± 1°C
Incubation temperature	:	36°C ± 1°C
Organic load	:	clean conditions (0.3 g/L bovine albumin)
Neutraliser	:	filter conditioning pre-rinse 100 ml 1.0 g/L Tween 80 + 0.5 g/L sodium oleate; rinse solution 100 ml 0.5 g/L Tween 80 + 0.1 g/L sodium oleate followed by 100 ml bidest (Membrane filtration)
Test organisms	:	Mycobacterium terrae ATCC 15755 Mycobacterium avium ATCC 15769

METHOD

The tests were carried out according to EN 14348:2005 “Chemical Disinfectants and Antiseptics - Quantitative Suspension Test for the Evaluation of Mycobactericidal Activity of Chemical Disinfectants Used in the Medical Area Including Instrument Disinfectants – Test Methods and Requirements (Phase 2, Step 1)”

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MYCOBACTERICIDAL ACTIVITY

The product shall be deemed to have passed the EN 14348 standard if it demonstrates in a valid test at least a 4 lg reduction within 60 min or less at 20 °C with the chosen interfering substance (clean or dirty conditions) under the conditions defined by this document when the test organisms are Mycobacterium avium and Mycobacterium terrae.

TUBERCULOCIDAL ACTIVITY

If a product passes the test only with Mycobacterium terrae it is characterized as possessing tuberculocidal activity. Tuberculocidal activity is defined as the capability of a product to kill *Mycobacterium tuberculosis*, demonstrated by the capability to produce a reduction in the number of viable cells of *Mycobacterium terrae* under defined conditions

RESULTS

The tested preparation showed **mycobactericidal activity according to EN 14348:2005**, under clean conditions (0.3 g/L bovine albumin) at 20°C ± 1°C, when tested:

Undiluted (80%), for 5 minutes contact time using as tests organisms the reference strains: *Mycobacterium terrae and Mycobacterium avium.*

The tested preparation showed **tuberculocidal activity** according to EN 14348:2005, under clean conditions (0.3 g/L bovine albumin) at 20°C ± 1°C, when tested:

Undiluted (80%), for 5 minutes contact time using as tests organisms the reference strain: Mycobacterium terrae.

The test results based on EN 14348:2005 are summarized in tables 1 & 2

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Table 1

Test Results for Mycobacterium terrae

Test suspension

Test - suspension (N and No)						
N	microbial count of plates				Vc1	Vc2
10^{-7}	>330	>330	>330	>330	>660	>660
10^{-8}	29	20	16	31	49	47
x mean					4.80E+09	
log N					9.68	
No (N/10)					4.80E+08	
log No					8.68	
8,17 < = logNo < = 8,70					Yes	

Validation and controls

Validation suspension (Nvo)				Experimental conditions (A)				Neutralizer control (B)				Method validation (C) Product conc.: 80%			
VC	52	33	x mean	VC 1	49		x mean	VC 1	38		x mean	VC 1	48		x mean
VC	36	50	85.5	VC 2	61		55	VC 2	65		52	VC 2	46		47
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 ?				x mean of C is > 0,5*x mean of Nvo?			
Yes				Yes				Yes				Yes			

Test Results

Product concentration (%)	Contact time	Dilution step	Microbial counts of plates				Vc1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
10%	60sec	10^{0}	> 330		> 330		> 330	> 330	> 6.60E+05	> 6.60E+06	> 6.52	8.68	< 2.16	≥ 4	FAILS TEST
		10^{-1}	> 330		> 330		> 330	> 330							
		10^{-2}	> 330		> 330		> 330	> 330							
		10^{-3}	> 330		> 330		> 330	> 330							
50%	60sec	10^{0}	> 330		> 330		> 330	> 330	1.13E+03	1.13E+04	4.05	8.68	4.63	≥ 4	PASS TEST
		10^{-1}	100		126		100	126							
		10^{-2}	8		22		< 14	22							
		10^{-3}	1		4		< 14	< 14							
80%	60sec	10^{0}	0		0		< 14	< 14	< 14	< 140	< 2.15	8.68	> 6.54	≥ 4	PASS TEST
		10^{-1}	0		0		< 14	< 14							
		10^{-2}	0		0		< 14	< 14							
		10^{-3}	0		0		< 14	< 14							

Table 2

Test Results for Mycobacterium avium

Test suspension

Test - suspension (N and No)						
N	microbial count of plates				Vc1	Vc2
10^{-7}	>330	>330	>330	>330	>660	>660
10^{-8}	28	18	20	18	46	38
x mean					4.20E+09	
log N					9.62	
No (N/10)					4.20E+08	
log No					8.62	
8,17 < = logNo < = 8,70					Yes	

Validation and controls

Validation suspension (Nvo)				Experimental conditions (A)				Neutralizer control (B)				Method validation (C) Product conc.: 80%			
VC	30	39	x mean	VC 1	45		x mean	VC 1	42		x mean	VC 1	56		x mean
VC	31	38	69	VC 2	54		49.5	VC 2	61		52	VC 2	57		56.5
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 ?				x mean of C is > 0,5*x mean of Nvo?			
Yes				Yes				Yes				Yes			

Test Results

Product concentration (%)	Contact time	Dilution step	Microbial counts of plates				Vc1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
10%	60sec	10^{0}	> 330		> 330		> 660	> 660	> 6.60E+05	> 6.60E+06	> 6.52	8.62	< 2.10	≥ 4	FAILS TEST
		10^{-1}	> 330		> 330		> 660	> 660							
		10^{-2}	> 330		> 330		> 660	> 660							
		10^{-3}	> 330		> 330		> 660	> 660							
50%	60sec	10^{0}	0		0		< 14	< 14	< 14	< 1.40E+02	< 2.15	8.62	> 6.48	≥ 4	PASS TEST
		10^{-1}	0		0		< 14	< 14							
		10^{-2}	0		0		< 14	< 14							
		10^{-3}	0		0		< 14	< 14							
80%	60sec	10^{0}	0		0		< 14	< 14	< 14	< 1.40E+02	< 2.15	8.62	> 6.48	≥ 4	PASS TEST
		10^{-1}	0		0		< 14	< 14							
		10^{-2}	0		0		< 14	< 14							
		10^{-3}	0		0		< 14	< 14							

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LIST OF ABBREVIATIONS

A	=	control of test conditions
B	=	control of neutraliser
C	=	validation of method at highest product concentration
N	=	test suspension
N_{V0}	=	suspension for validation
n.t.	=	not tested
N_0	=	microbial count of test suspension N / 10 (microbial count at time index 0)
R	=	germ reduction in log10-steps
red	=	Inactivation issue
V_C	=	viable microbial count per ml
x	=	weighted mean of N

For the QACS Ltd Laboratory

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Date: 07/12/2021

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