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INTRADERMA

STUDY REPORT

2021-12648/21 23 00763

NOVASIN

SUSPENSION TEST
ACCORDING TO EN 13704:2018
(Phase 2 step 1)

Chemical disinfectants and antiseptics
Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1)

JULY 2021

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SUSPENSION TEST ACCORDING TO EN 13704:2018
Chemical disinfectants and antiseptics Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1)

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	NOVASIN
ACTIVE SUBSTANCES	:	HOCl 80% NaClO 20%
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room temperature, darkness
TEST CONDITIONS	:	Test conducted at 20ºC ± 1 ºC
LOT	:	Not Provided
METHOD	:	EN 13704:2018
STUDY SPONSOR	:	INTRADERMA
PRODUCT SUPPLIER	:	INTRADERMA
PRODUCT MANUFACTURER	:	INTRADERMA
RECEIPT DATE	:	05/07/2021
STUDY PERIOD	:	13/07/2021-16/07/2021
LAB ID	:	2021-12648/21 23 00763

SCOPE

This document specifies a test method (phase 2/step 1) and the minimum requirements for sporicidal activity of chemical disinfectant products that form a homogeneous, physically stable preparation in hard water and that are used in food, industrial, domestic and institutional areas, excluding areas and situations where disinfection is medically indicated and excluding products used on living tissues except those for hand hygiene in the above considered areas.

PRINCIPLE

A test suspension of bacterial spores in a solution of interfering substance, simulating clean and/or dirty conditions, is added to a prepared sample of the product under test diluted in hard water (in water for ready-to-use products). The mixture is maintained at specific test temperature ± 1 °C for the specific test contact (time ± 10) s (required test conditions). In case the contact time is 60 minutes, the tolerance allowed shall be ± 5 s.
At this contact time, an aliquot is taken; the sporicidal 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 number of surviving bacterial spores in each sample are determined and the reduction in viable counts is calculated.

This protocol for sporicidal activity is performed with minimum one test microorganism: Bacillus subtilis in order to substantiate minimum spectrum of sporicidal activity. Additional sporicidal activity vs anaerobes for specific use is performed with further use of reference strain: Clostridium sporogenes. Additional sporicidal activity vs aerobes for specific use is performed with further use of reference strain: Bacillus cereus. The disinfectant has to achieve a log 3 kill against each of the test strains within contact time: t (t: according to the manufacturer's recommendation, but between 1min and 60 min)

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TEST CONDITIONS

1. Product application area: medical use
2. The following procedure was performed at 20 °C
3. The test product was tested at 15 minutes and 60 minutes contact time
4. A final concentration of 0.3g/L bovine albumin was used for testing (clean conditions)
5. Neutralization Method used: Dilution neutralization.
6. Neutralizer used: LPT Dilution Broth containing polysorbate 80.

TEST ORGANISMS (Minimum spectrum of test organisms)

Bacillus subtilis	ATCC 6633

SPORICIDAL ACTIVITY FOR GENERAL PURPOSES

Sporicidal activity for general purposes is characterized by the concentration of the tested product in a valid test for which a 3 lg or more reduction in viability is demonstrated under the suitable test conditions for general purpose defined by this standard, and when the test organisms are spores of Bacillus subtilis (Minimum spectrum of test organisms).

ASSAY ACCEPTANCE CRITERIA

1. Test Suspension (N) is between 1.5 to 5.0 X 10^6 CFU per mL ($6.17 \leq \log N \leq 6.70$)
2. No (N/10) is between 1.5 to 5.0 X 10^5 CFU per mL ($5.17 \leq \log No \leq 5.70$)
3. Validation Suspension=Nv is between 3.0 x 10^2 and 1.6 x 10^3.
4. Nvo (Nv/10) is between 30 and 160
5. Na is the number of survivors (cells) per ml in the test mixture at the end of contact time.
6. R (log reduction) = No - Na
7. Average recovery values for the experimental conditions control (A) were equal to or greater than 0.5 times the Validation Suspension (Nvo)
8. Average recovery values for the Neutralizer control (B) were equal to or greater than 0.5 times the Validation Suspension (Nvo)
9. Average recovery values for the Method Validation control (C) were equal to or greater than 0.5 times the Validation Suspension (Nvo)
10. Control of weighted mean counts. Quotient is not lower than 5 and not higher than 15

ARCHIVING

The laboratory book which contains all the information (raw data and results) regarding the study and the study reports are kept in the laboratory archives for 5 years.

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Test Results for Bacillus subtilis

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	3.00E+06
10^{-5}	34	27	log N	6.48
10^{-6}	2	3	No (N/10)	3.00E+05
			log No	5.48
			5,17 < = logNo < = 5,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Product conc.: undiluted (80%)		
VC 1	69	x mean	VC 1	60	x mean	VC 1	50		VC 1	60	x mean
VC 2	56	62.5	VC 2	64	62	VC 2	53	51.5	VC 2	51	55.5
30<x mean of Nvo < 160? Yes			x mean of A is > 0,5*x mean of Nvo? Yes			x mean of B is > 0,5*x mean of Nvo ? Yes			x mean of C is > 0,5*x mean of Nvo? 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%)	15 minutes	10^{0}	26	31	28.5	285	2.45	5.48	3.02	≥ 3	PASS TEST
		10^{-1}	4	5							
50%	15 minutes	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	5.48	< 0.96	≥ 3	FAILS TEST
		10^{-1}	> 330	> 330							
1%	15 minutes	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	5.48	< 0.96	≥ 3	FAILS TEST
		10^{-1}	> 330	> 330							

Test Results for Bacillus subtilis

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	2.41E+06
10^{-5}	23	25	log N	6.38
10^{-6}	2	3	No (N/10)	2.41E+05
			log No	5.38
			5,17 < = logNo < = 5,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Product conc.: undiluted (80%)		
VC 1	48	x mean	VC 1	56	x mean	VC 1	42		VC 1	40	x mean
VC 2	51	49.5	VC 2	50	53	VC 2	49	45.5	VC 2	45	42.5
30<x mean of Nvo < 160? Yes			x mean of A is > 0,5*x mean of Nvo? Yes			x mean of B is > 0,5*x mean of Nvo ? Yes			x mean of C is > 0,5*x mean of Nvo? 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%)	60 minutes	10^{0}	13	9	< 14	< 140	< 2.15	5.38	3.24	≥ 3	PASS TEST
		10^{-1}	1	1							
50%	60 minutes	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	5.38	< 0.86	≥ 3	FAILS TEST
		10^{-1}	> 330	> 330							
1%	60 minutes	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	5.38	< 0.86	≥ 3	FAILS TEST
		10^{-1}	> 330	> 330							

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CONCLUSION

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METHODOLOGY ABSTRACT

A test suspension of bacterial spores (*Bacillus subtilis*) in a solution of interfering substance, simulating clean and/or dirty conditions, is added to a prepared sample of the product under test diluted in hard water (in water for ready-to-use products). The mixture is maintained at specific test temperature ± 1 °C for the specific test contact (time ± 10) s (required test conditions). In case the contact time is 60 minutes, the tolerance allowed shall be ± 5 s.
At this contact time, an aliquot is taken; the sporicidal action in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. The number of surviving bacterial spores in each sample are determined and the log reduction is calculated.

RESULT

The product under test: "NOVASIN" demonstrated sporicidal activity according to EN13704:2018 (≥ 3 log reduction), when tested at 20 ± 1 °C under clean conditions at product concentration:

Undiluted (80%) for 15 minutes contact time using as test organisms the reference strain: *Bacillus subtilis*.
Undiluted (80%) for 60 minutes contact time using as test organisms the reference strain: *Bacillus subtilis*.

For the QACS Ltd Laboratory,

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TEST ORGANISMS (Minimum spectrum of test organisms)

Bacillus subtilis ATCC 6633

RESULT

The product under test: "NOVASIN" demonstrated sporicidal activity according to EN13704:2018 (≥ 3 log reduction), when tested at 20 ± 1 °C under clean conditions at product concentration:

Undiluted (80%) for 15 minutes contact time using as test organisms the reference strain: *Bacillus subtilis*.
Undiluted (80%) for 60 minutes contact time using as test organisms the reference strain: *Bacillus subtilis*.

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