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INTRADERMA

STUDY REPORT

2022-10294/22 23 00332

NOVASIN

SUSPENSION TEST
ACCORDING TO EN 1276:2019
(Phase 2, step 1)

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

SEPTEMBER 2022

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SUSPENSION TEST ACCORDING TO EN 1276:2019

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal 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 (Sodium hypochlorite 500ppm-pH neutral)
ACTIVE SUBSTANCES	:	Sodium Hypochlorite-NaOCl 20%, Hypochlorite acid-HOCl 80%
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room temperature, darkness
LOT	:	TBD
METHOD	:	EN 1276:2019
COMPANY NAME	:	INTRADERMA
STUDY SPONSOR	:	INTRADERMA
PRODUCT MANUFACTURER	:	INTRADERMA
RECEIPT DATE	:	30/08/2022
STUDY PERIOD	:	30/08/2022-01/09/2022
LAB ID	:	2022-10294/22 23 00332

SCOPE

This document 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, as some dilution is always produced by adding the test organisms and interfering substance.
This document applies to products 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 sample of the product as delivered and/or diluted with hard water (or water for ready-to-use products with the exception of handwash products whose first dilution is done in hard water is added to a test suspension of bacteria in a solution of an interfering substance. The mixture is maintained at the chosen test temperature for the adopted contact time. At the end of this contact time, an aliquot is taken, and the bactericidal and/or the bacteriostatic activity 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.

The test is performed using Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus and Enterococcus hirae as test organisms. For temperatures ≥ 40 °C only Enterococcus faecium shall be used. For testing of hand hygiene products, Pseudomonas aeruginosa, Escherichia coli K12, Staphylococcus aureus and Enterococcus hirae are used as test organisms. Additional test organisms can be used.

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TEST CONDITIONS

1. Test temperature: 20 °C.
2. Contact Time: 1 minute.
3. Interfering substance: Bovine Albumin 0.3g/L final concentration (clean conditions).
4. Test Method: Dilution Neutralization Method - Pour Plate Technique.
5. Neutralizer used: LPT Dilution Broth containing 3% polysorbate 80.
6. Incubation temperature: 37 ± 1°C
7. Appearance of product test solutions: No precipitate during the test procedure (homogeneous solution)
8. According to EN 1276, 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 MICROORGANISMS

Pseudomonas aeruginosa	ATCC 15442
Staphylococcus aureus	ATCC 6538
Escherichia coli K12	NCTC 10538
Enterococcus hirae	NCIMB 8192

BACTERICIDAL ACTIVITY FOR HAND HYGIENE

The bactericidal concentration for hand hygiene is the concentration of the tested product for which at least a 5 lg reduction for hygienic handrub and 3 lg reduction for hygienic handwash (at 50 % in test concentration or less) is demonstrated in a valid test under the conditions defined by this standard when the test organisms are *Escherichia coli K12, Pseudomonas aeruginosa, Staphylococcus aureus and Enterococcus hirae*.

ASSAY ACCEPTANCE CRITERIA AND EXPLANATIONS

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. 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
11. Vc values = Count per ml (one plate or more)
12. If the count on one plate is higher than 330, the number is reported as "> 330".
13. If a Vc value in case of Na is lower than 14, the number is reported "< 14"

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Test Results for Pseudomonas aeruginosa

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	4.18E+08
10^{-7}	43	40	log N	8.62
10^{-8}	4	5	No (N/10)	4.18E+07
			log No	7.62
			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	85	x mean	VC 1	84	x mean	VC 1	86	x mean	VC 1	83	x mean
VC 2	83	84	VC 2	82	83	VC 2	80	83	VC 2	81	82
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%)	1 minute	10^{0}	0	0	< 14	< 140	< 2.15	7.62	> 5.48	≥ 5	PASS TEST
		10^{-1}	0	0							
50%	1 minute	10^{0}	0	0	< 14	< 140	< 2.15	7.62	> 5.48	≥ 5	PASS TEST
		10^{-1}	0	0							
1%	1 minute	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.62	< 3.10	≥ 5	FAILS TEST
		10^{-1}	> 330	> 330							

Test Results for Staphylococcus aureus

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	2.21E+08
10^{-6}	196	244	log N	8.34
10^{-7}	19	27	No (N/10)	2.21E+07
			log No	7.34
			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	42	x mean	VC 1	43	x mean	VC 1	41	x mean	VC 1	42	x mean
VC 2	49	45.5	VC 2	50	46.5	VC 2	50	45.5	VC 2	52	47
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%)	1 minute	10^{0}	0	0	< 14	< 140	< 2.15	7.34	> 5.20	≥ 5	PASS TEST
		10^{-1}	0	0							
50%	1 minute	10^{0}	0	0	< 14	< 140	< 2.15	7.34	> 5.20	≥ 5	PASS TEST
		10^{-1}	0	0							
1%	1 minute	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.34	< 2.83	≥ 5	FAILS TEST
		10^{-1}	> 330	> 330							

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Test Results for Escherichia coli k12

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	2.95E+08
10^{-7}	31	28	log N	8.47
10^{-8}	3	3	No (N/10)	2.95E+07
			log No	7.47
			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	63	x mean	VC 1	64	x mean	VC 1	65	x mean	VC 1	64	x mean
VC 2	60	61.5	VC 2	61	62.5	VC 2	62	63.5	VC 2	61	62.5
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%)	1 minute	10^{0}	0	0	< 14	< 140	< 2.15	7.47	> 5.32	≥ 5	PASS TEST
		10^{-1}	0	0							
50%	1 minute	10^{0}	0	0	< 14	< 140	< 2.15	7.47	> 5.32	≥ 5	PASS TEST
		10^{-1}	0	0							
1%	1 minute	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.47	< 2.95	≥ 5	FAILS TEST
		10^{-1}	> 330	> 330							

Test Results for Enterococcus hirae

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	2.62E+08
10^{-6}	247	279	log N	8.42
10^{-7}	23	28	No (N/10)	2.62E+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.: undiluted (80%)		
VC 1	53	x mean	VC 1	54	x mean	VC 1	57	x mean	VC 1	58	x mean
VC 2	59	56	VC 2	62	58	VC 2	61	59	VC 2	60	59
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%)	1 minute	10^{0}	0	0	< 14	< 140	< 2.15	7.42	> 5.27	≥ 5	PASS TEST
		10^{-1}	0	0							
50%	1 minute	10^{0}	0	0	< 14	< 140	< 2.15	7.42	> 5.27	≥ 5	PASS TEST
		10^{-1}	0	0							
1%	1 minute	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.42	< 2.90	≥ 5	FAILS TEST
		10^{-1}	> 330	> 330							

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LOT	:	TBD
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LAB ID	:	2022-10294/22 23 00332

METHODOLOGY ABSTRACT

A test suspension of bacteria is tested against a product test solution at three different concentrations with the presence of interfering substance. The mixture is maintained at 20°C ±1°C for 1 minute. At the end of this contact time, an aliquot is taken, and the bactericidal activity in this portion is immediately neutralized or suppressed. The numbers of surviving flora are determined and the log reduction is calculated.

CONCLUSION

The product under test: "NOVASIN " demonstrated bactericidal activity according to EN 1276:2019 (≥ 5 log reduction), under clean conditions, at 20 ± 1 °C, when tested at product concentration:

Undiluted (80%) for 1 minute contact time using as test organisms the reference strains:
Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli K12 and *Enterococcus hirae*.

50 % for 1 minute contact time using as test organisms the reference strains:
Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli K12 and *Enterococcus hirae*.

The method is accredited according to EN ISO/IEC 17025:2017 (Cert. No 195).

For the QACS Ltd Laboratory

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Testing
Cert. No 195

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STUDY SUMMARY / ABSTRACT

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TEST MICROORGANISMS

Pseudomonas aeruginosa	ATCC 15442
Staphylococcus aureus	ATCC 6538
Escherichia coli K12	NCTC 10538
Enterococcus hirae	NCIMB 8192

CONCLUSION

The product under test: "NOVASIN " demonstrated bactericidal activity according to EN 1276:2019 (≥ 5 log reduction), under clean conditions, at 20 ± 1 °C, when tested at product concentration:

Undiluted (80%) for 1 minute contact time using as test organisms the reference strains:
Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli K12 and *Enterococcus hirae*.

50 % for 1 minute contact time using as test organisms the reference strains:
Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli K12 and *Enterococcus hirae*.

RESULTS AUTHENTICITY

The study concerned by this report was carried out according to the experimental protocol, under responsibility and quality plan of the QACS Ltd laboratory. All the observations and data recorded during this trial are reported in this study report.

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