INTRADERMA

STUDY REPORT

2023-19543/23 23 00358

NOVASIN GEL

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)

DECEMBER 2023

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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	:	Novasin Gel
ACTIVE SUBSTANCES	:	Hypochlorite acid-HOCl 80%, Sodium Hypochlorite-NaOCl 20%
APPEARANCE OF THE PRODUCT	:	Gel
STORAGE CONDITIONS	:	Cool dry place, protected from light
LOT	:	Not listed
METHOD	:	EN 13727:2012+A2:2015
COMPANY NAME	:	INTRADERMA
STUDY SPONSOR	:	INTRADERMA
PRODUCT MANUFACTURER	:	INTRADERMA
RECEIPT DATE	:	20/11/2023
LAB ID	:	2023-19543/23 23 00358

EXPERIMENTAL CONDITIONS

STUDY PERIOD	:	05/12/2023-07/12/2023
PRODUCT TEST CONCENTRATIONS	:	Undiluted (80%), 50%, 1%
PRODUCT DILUENT	:	Water
CONTACT TIME	:	1 minute
TEST TEMPERATURE	:	20°C ± 1°C
INCUBATION TEMPERATURE	:	37°C ± 1°C
INTERFERING SUBSTANCE	:	Clean conditions – 0.3g/L bovine Albumin
TEST METHOD	:	Dilution Neutralization Method
NEUTRALIZER	:	LPT Dilution Broth with 3% polysorbate 80
APPEARANCE OF PRODUCT TEST SOLUTIONS	:	No precipitate during the test procedure (homogeneous solution)

TEST MICROORGANISMS

Pseudomonas aeruginosa	ATCC 15442
Staphylococcus aureus	ATCC 6538
Escherichia coli K12	NCTC 10538
Enterococcus hirae	ATCC 10541

BACTERICIDAL ACTIVITY FOR HANDRUB AND HANDWASH PRODUCTS

The product shall be deemed to have passed the EN 13727 standard if it demonstrates in a valid test for handrub and handwash products at 20 °C under the conditions defined by this standard when the test organisms are: *Escherichia coli K12, Pseudomonas aeruginosa, Staphylococcus aureus* and *Enterococcus hirae* at least a:

- 5 lg reduction within max. 1 min under clean conditions (hygienic handrub);
- 5 lg reduction within max. 5 min under clean conditions (surgical handrub);
- 3 lg reduction within max. 1 min under dirty conditions (hygienic handwash);
- 5 lg reduction within max. 5 min under dirty conditions (surgical handwash).

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.

PRINCIBLE

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. This solution simulates the addition of tap water in practice (1:1 in order to simulate real use conditions). Such a product is nevertheless regarded as a "ready-to-use product".
The test is performed using *Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae* and for certain product types (hand hygiene) *Escherichia coli* K12 as test-organisms. Other contact times and temperatures within the limits may be used. Additional interfering substances and test organisms may be used.

BASIC LIMITS 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. 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.
12. Vc values = Count per ml (one plate or more)
13. If the count on one plate is higher than 330, the number is reported as "> 330".
14. If a Vc value in case of Na is lower than 14, the number is reported "< 14"
15. At least one concentration per test shall demonstrate a 5 log or more reduction and at least one concentration shall demonstrate a log reduction of less than 5.

RESULTS

Test microorganisms	Log reduction (R) / Criteria ≥ 5 log			Contact time
	Product Concentrations			
	Undiluted (80%)	50%	1%	
Pseudomonas aeruginosa	> 5.44	> 5.44	< 3.07	1 min
Staphylococcus aureus	> 5.25	> 5.25	< 2.88	1 min
Escherichia coli K12	> 5.48	> 5.48	< 3.10	1 min
Enterococcus hirae	> 5.11	> 5.11	< 2.74	1 min

CONCLUSION

The product under test: "Novasin Gel" demonstrated bactericidal activity according to EN 13727:2012+A2:2015 (≥5 log reduction), under clean conditions, at 20 ± 1 °C, when tested at product concentrations:

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

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

The test results based on EN 13727:2012+A2:2015 are summarized in Appendices 1 and 2.

For the QACS Ltd Laboratory:

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The method is accredited according to EN ISO/IEC 17025:2017.

ESYD

Testing Cert. No 195

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.

APPENDIX No 1: RESULTS-COMPILED RAW

Test Results for Pseudomonas aeruginosa

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	3.86E+08
10^{-7}	37	39	log N	8.59
10^{-8}	3	6	No (N/10)	3.86E+07
			log No	7.59
			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	86	x mean	VC 1	85	x mean	VC 1	91	x mean	VC 1	82	x mean
VC 2	91	88.5	VC 2	82	83.5	VC 2	80	85.5	VC 2	80	81
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 or NVB/1000?		Yes	x mean of C is > 0,5*x mean of Nvo?		Yes

Validation suspension (NVB)			
	VC 1	80	x mean
	VC 2	87	83.5
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%)	1 min	10^{0}	0	0	< 14	< 140	< 2.15	7.59	> 5.44	≥ 5	PASS TEST
		10^{-1}	0	0							
50.0%	1 min	10^{0}	0	0	< 14	< 140	< 2.15	7.59	> 5.44	≥ 5	PASS TEST
		10^{-1}	0	0							
1.0%	1 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.59	< 3.07	≥ 5	FAILS TEST
		10^{-1}	> 330	> 330							

Test Results for Staphylococcus aureus

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	2.49E+08
10^{-6}	235	264	log N	8.40
10^{-7}	23	26	No (N/10)	2.49E+07
			log No	7.40
			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	51	x mean	VC 1	48	x mean	VC 1	50	x mean	VC 1	47	x mean
VC 2	57	54	VC 2	53	50.5	VC 2	51	50.5	VC 2	46	46.5
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 or NVB/1000?		Yes	x mean of C is > 0,5*x mean of Nvo?		Yes

Validation suspension (NVB)			
	VC 1	50	x mean
	VC 2	56	53
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%)	1 min	10^{0}	0	0	< 14	< 140	< 2.15	7.40	> 5.25	≥ 5	PASS TEST
		10^{-1}	0	0							
50.0%	1 min	10^{0}	0	0	< 14	< 140	< 2.15	7.40	> 5.25	≥ 5	PASS TEST
		10^{-1}	0	0							
1.0%	1 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.40	< 2.88	≥ 5	FAILS TEST
		10^{-1}	> 330	> 330							

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APPENDIX No 2: RESULTS-COMPILED RAW

Test Results for Escherichia coli K12

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	4.18E+08
10^{-7}	41	43	log N	8.62
10^{-8}	4	4	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	86	x mean	VC 1	79	x mean	VC 1	82	x mean	VC 1	79	x mean
VC 2	93	89.5	VC 2	86	82.5	VC 2	84	83	VC 2	83	81
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 or NVB/1000?		Yes	x mean of C is > 0,5*x mean of Nvo?		Yes
Validation suspension (NVB)			VC 1	85	x mean						
			VC 2	80	82.5						
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%)	1 min	10^{0}	0	0	< 14	< 140	< 2.15	7.62	> 5.48	≥ 5	PASS TEST
		10^{-1}	0	0							
50.0%	1 min	10^{0}	0	0	< 14	< 140	< 2.15	7.62	> 5.48	≥ 5	PASS TEST
		10^{-1}	0	0							
1.0%	1 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.62	< 3.10	≥ 5	FAILS TEST
		10^{-1}	> 330	> 330							

Test Results for Enterococcus hirae

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	1.80E+08
10^{-6}	174	186	log N	8.26
10^{-7}	18	19	No (N/10)	1.80E+07
			log No	7.26
			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	36	x mean	VC 1	35	x mean	VC 1	29	x mean	VC 1	35	x mean
VC 2	32	34	VC 2	33	34	VC 2	38	33.5	VC 2	30	32.5
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 or NVB/1000?		Yes	x mean of C is > 0,5*x mean of Nvo?		Yes
Validation suspension (NVB)			VC 1	30	x mean						
			VC 2	37	33.5						
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%)	1 min	10^{0}	0	0	< 14	< 140	< 2.15	7.26	> 5.11	≥ 5	PASS TEST
		10^{-1}	0	0							
50.0%	1 min	10^{0}	0	0	< 14	< 140	< 2.15	7.26	> 5.11	≥ 5	PASS TEST
		10^{-1}	0	0							
1.0%	1 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.26	< 2.74	≥ 5	FAILS TEST
		10^{-1}	> 330	> 330							

Results refer to the sample as received and analyzed during 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 for 1 month from the end of the test date.
The study report and raw data will be stored by the laboratory for 5 years.

End of Test Report