QACS LAB
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INTRADERMA

STUDY REPORT

2022-10294/22 23 00333

NOVASIN

SUSPENSION TEST
ACCORDING TO EN 1650:2019
(Phase 2, step 1)

Chemical disinfectants and antiseptics
Quantitative suspension test for the evaluation of yeasticidal 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 1650:2019

Chemical disinfectants and antiseptics – evaluation of yeasticidal 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 1650:2019
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 00333

SCOPE

This document specifies a test method and the minimum requirements for yeasticidal or fungicidal 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) is added to a test suspension of fungi (yeast cells or mould spores) 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 yeasticidal and/or fungicidal 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 fungi in each sample are determined and the reduction is calculated.

The test is performed using the vegetative cells of Candida albicans and the spores of Aspergillus brasiliensis (fungicidal activity) or only the vegetative cells of Candida albicans (yeasticidal activity) 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: 30 ± 1°C
7. Appearance of product test solutions: No precipitate during the test procedure (homogeneous solution)
8. According to EN 1650, 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

Candida albicans ATCC 10231

YEASTICIDAL ACTIVITY FOR GENERAL PURPOSES

The product shall be deemed to have passed the EN 1650 standard (yeasticidal activity) if it demonstrates in a valid test a reduction of at least a 4 lg within the adopted test conditions with the chosen interfering substance simulating clean or dirty conditions defined by this European Standard when the test organism is Candida albicans.

YEASTICIDAL ACTIVITY FOR HAND HYGIENE

The yeasticidal concentration for a hand hygiene is the concentration of the tested product for which a reduction of at least:
• lgR ≥ 4 for handrubs
or
• lgR ≥ 2 for handwashes at 50 % in test concentration or less.
is demonstrated in a valid test under the chosen test conditions in terms of interfering substance.

In this test was used as additional test organism the Aspergillus brasiliensis for fungicidal activity. Fungicidal activity for hand hygiene products is an optional claim.

ASSAY ACCEPTANCE CRITERIA AND EXPLANATIONS

1. Test Suspension (N) is between 1.5 to 5.0 X 10^7 CFU per mL (7.17≤ log No ≤7.70).
2. No (N/10) is between 1.5 to 5.0 X 10^6 CFU per mL (6.17 ≤ log No ≤ 6.70).
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 for yeasts 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 Candida albicans

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	3.18E+07
10^{-6}	33	31	log N	7.50
10^{-7}	3	3	No (N/10)	3.18E+06
			log No	6.50
			6,17 < = logNo < = 6,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Product conc.: undiluted (80%)		
Vc 1	70	x mean	Vc 1	69	x mean	Vc 1	69	x mean	Vc 1	70	x mean
Vc 2	64	67	Vc 2	65	67	Vc 2	68	68.5	Vc 2	66	68
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	6.50	> 4.36	≥ 4	PASS TEST
		10^{-1}	0	0							
50%	1 minute	10^{0}	0	0	< 14	< 140	< 2.15	6.50	> 4.36	≥ 4	PASS TEST
		10^{-1}	0	0							
1%	1 minute	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	6.50	< 1.98	≥ 4	FAILS TEST
		10^{-1}	> 330	> 330							

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LOT	:	TBD
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METHODOLOGY ABSTRACT

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

CONCLUSION

The product under test: "NOVASIN" demonstrated yeasticidal activity according to EN 1650:2019 (≥ 4 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 strain: *Candida albicans.*

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

For the QACS Ltd Laboratory

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ESYD
Testing
Cert. No 195

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Technical Manager of Microbiological Dpt
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Date: 01/09/2022

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STUDY SUMMARY / ABSTRACT

SUSPENSION TEST ACCORDING TO EN 1650:2019

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Candida albicans	ATCC 10231

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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 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