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Saga ApS

STUDY REPORT

2020-9159/20 23 00921

Hand Sanitizer Formula 73% Gel

SUSPENSION TEST
ACCORDING TO EN 13624:2013
(Phase 2 step 1)

Chemical disinfectants and antiseptics
Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)

NOVEMBER 2020

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Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of yeasticidal activity in the medical area – Test method and requirements
(Phase 2 step 1)

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	HAND SANITIZER FORMULA 73% GEL
ACTIVE SUBSTANCES	:	Ethanol 73% w/w
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room temperature, darkness
LOT	:	Not provided
METHOD	:	EN 13624:2013
CONTACT TIME	:	30 seconds
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
STUDY SPONSOR	:	Saga ApS
PRODUCT SUPPLIER	:	Saga ApS
PRODUCT MANUFACTURER	:	Saga ApS
RECEIPT DATE	:	21/09/2020
STUDY PERIOD	:	13/10/2020-15/10/2020
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SCOPE

This European Standard specifies a test method and the minimum requirements for fungicidal or yeasticidal 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 yeasts in a solution of an interfering substance. The mixture is maintained at the temperature (θ) and and for the chosen contact time (*t*). At the end of this contact time, an aliquot is taken; the yeasticidal 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 yeasts in each sample are determined and the reduction is calculated. Handwash products are always prediluted with hard water. The resulting solution is regarded as a ready-to-use product.

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TEST CONDITIONS

1. Product type: Hygienic handrub.
2. The following procedure was performed in water bath at 20 °C.
3. The test product was tested at 30 seconds contact time.
4. Interfering substance: 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.
7. According to EN 13624, 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, 50%, 1%.

TEST MICROORGANISMS

Candida albicans ATCC 10231

YEASTICIDAL ACTIVITY FOR HANDRUB AND HANDWASH PRODUCTS

The product shall be deemed to have passed the EN 13624 Standard (yeasticidal activity) 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 organism is Candida albicans at least a:

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

ASSAY ACCEPTANCE CRITERIA

1. Test Suspension (N) is between 1.5 to 5.0 X 10^7 CFU per mL ($7.17 \leq \log No \leq 7.70$)
2. No (N/10) is between 1.5 to 5.0 X 10^6 CFU per mL ($6.17 \leq \log No \leq 6.70$)
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. Nvo (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) or N_{VB}/1000.
10. Average recovery values for the Method Validation control (C) were equal to or greater than 0.5 times the Validation Suspension (Nvo)

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TEST RESULTS FOR *Candida albicans* (YEASTICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	3.00E+07
10^{-6}	31	29		
10^{-7}	3	3	log N	7.48
			No (N/10)	3.00E+06
			log No	6.48
			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	67	x mean	VC 1	69	x mean	VC 1	68	x mean	VC 1	65	x mean
VC 2	63	65	VC 2	64	66.5	VC 2	62	65	VC 2	64	64.5
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	67	x mean
VC 2	68	67.5
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%)	30 seconds	10^{0}	0	0	< 14	< 140	< 2.15	6.48	> 4.33	≥4	PASS TEST
		10^{-1}	0	0							
50%	30 seconds	10^{0}	0	0	< 14	< 140	< 2.15	6.48	> 4.33	≥4	PASS TEST
		10^{-1}	0	0							
1%	30 seconds	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	6.48	< 1.96	≥4	FAILS TEST
		10^{-1}	> 330	> 330							

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CONCLUSION
SUSPENSION TEST ACCORDING TO EN 13624:2013

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METHODOLOGY ABSTRACT

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 yeasts in a solution of an interfering substance. The mixture is maintained at 20 °C for 30 seconds. 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.

RESULT

The product under test: "HAND SANITIZER FORMULA 73% GEL" demonstrated yeasticidal activity (≥ 4 log reduction) according to EN 13624:2013, at 20±1 °C, under clean conditions when tested at concentration:

Undiluted (80%) for 30 seconds contact time using as test organism the reference strain: *Candida albicans*.

For the QACS Ltd Laboratory,

Signature date: 09/11/2020
Lagiopoulos Giorgos
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Study Manager

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TEST MICROORGANISMS

Candida albicans	ATCC 10231

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Undiluted (80%) for 30 seconds contact time using as test organism the reference strain: *Candida albicans*.

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