Test Report: EN 13624:2013

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)

Identification of the test laboratory:
Abbott Analytical Ltd
Unit 2, Hickmans Road, Birkenhead, CH41 1JH, United Kingdom

Identification of the client:
NanoTech Solutions Norway AS
Hofslundveien 6, N-3090 Hof
Norway

Identification of the sample:

Name of the product:	20D/103 NanoSanis
Batch number/reference and expiry date (if available):	N/A
Date of delivery:	22 April 2020
Storage conditions:	Room temperature in darkness
Product diluent recommended by the manufacturer for use:	Not disclosed
Active substance(s) and their concentrations (s) (optional):	Not disclosed
Appearance of the product:	Clear colourless liquid

Notes:

1) The test results in this report relate only to the sample(s) tested.
2) This test report may not be reproduced except in full, adapted, altered or used to create a derivative work, without written approval from Abbott Analytical Ltd.

Test method and its validation:

Method:	Dilution-neutralisation
Neutraliser:	100.0 g/l Polysorbate 80 + 30.0 g/l Lecithin + 30.0 g/l Tryptone Soya Broth + 5.0 g/l Sodium thiosulphate + 1.0 g/l L-histidine (Neutraliser B)
Neutraliser validation:	Validated in accordance with EN 13624:2013 (5.5.2)

Experimental conditions:

Period of analysis:	11 May 2020 to 13 May 2020
Product test concentration(s):	Neat
Diluent used for product test solution(s):	N/A
Contact time(s):	5 min ± 10 s
Test temperature(s):	20°C ± 1°C
Interfering substance:	0.3 g/l bovine albumin (clean conditions)
Temperature of incubation:	30°C ± 1°C
Identification of the bacterial strain(s) used:	*Candida albicans* (DSM 1386)

Deviations: None

Remarks:

1) All test conditions are as requested by the client, irrespective of whether these are in accordance with EN 13624:2013 (5.4.2) or EN 13624:2013 (5.5.1.1).
2) 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.

Requirements:

The product shall demonstrate at least a 4 decimal log (lg) reduction against every test organism.

Conclusion:

According to EN 13624:2013, this sample of NanoSanis possesses yeasticidal activity against the referenced strain of *Candida albicans*, when tested neat with a contact time of 5 minutes at 20°C under clean conditions.

Report prepared by:		**Approved by:**	
Signed:		Signed:	
Name:	Karl Cumings	Name:	Tony Watson
Position:	Microbiologist	Position:	General Manager
Date:	13 May 2020	Date:	13 May 2020

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A company registered in England and Wales
Company number: 10031406

Results: EN 13624:2013

RST 019 (Issue 2)

Test organism:	*Candida albicans*		(DSM 1386)
Date of test:	11 May 2020		
Test temperature:	20°C ± 1°C	Incubation temperature:	30°C ± 1°C
Dilution-neutralisation method:	Pour plate	Number of plates:	1 / ml
Neutraliser:	B	Test conditions:	Clean conditions

Validation and controls:

Validation suspension (Nv_o)			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: *Neat*		
*Vc*1	*52*	$\bar{n}$ =	*Vc*1	*48*	$\bar{n}$ =	*Vc*1	*46*	$\bar{n}$ =	*Vc*1	*48*	$\bar{n}$ =
*Vc*2	*50*	51	*Vc*2	*46*	47	*Vc*2	*48*	47	*Vc*2	*48*	48
$30 \le \bar{n}$ of $Nv_o \le 160$? ☒ yes ☐ no			$\bar{n}$ of $A \ge 0.5 \times \bar{n}$ of Nv_o ? ☒ yes ☐ no			$\bar{n}$ of $B \ge 0.5 \times \bar{n}$ of Nv_o (or Nv_B / 1000) ? ☒ yes ☐ no			$\bar{n}$ of $C \ge 0.5 \times \bar{n}$ of Nv_o ? ☒ yes ☐ no		

Validation suspension (Nv_B)		
*Vc*1	*57*	$\bar{n}$ =
*Vc*2	*52*	54.5
$30 \le \bar{n}$ of Nv_B / 1000 ≤ 160 ? ☒ yes ☐ no		

Test suspension (N and N_o):

N	*Vc*1	*Vc*2			
10^{-5}	*232*	*248*	$\bar{n}$ wm = 2.36×10^7 ;	lg N =	7.37
10^{-6}	*20*	*19*	$N_o = N / 10$;	lg N_o =	6.37
			$6.17 \le \lg N_o \le 6.70$?	☒ yes	☐ no

Test:

Conc. of the product	Contact time	Dilution step	*Vc*1	*Vc*2	*Na* ($\bar{n}$ x 10 or $\bar{n}$ wm x 10)	lg *Na*	lg *R* (lg N_o - lg *Na*)
Neat	*5 min*	10^0	*0*	*0*	<140	<2.15	>4.22
		10^{-1}	*0*	*0*			

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Explanations:

Vc	count per ml (one plate or more)
$\overline{\nu}$	average of *Vc*1 and *Vc*2 (1 + 2 duplicate)
$\overline{\nu}$ wm	weighted mean of $\overline{\nu}$
N	number of cells per ml in the test suspension
N_o	number of cells in the test mixture at the beginning of the contact time ($N_o = N / 10$)
Na	number of survivors per ml in the test mixture at the end of the contact time (before neutralisation or filtration)
R	reduction ($\lg R = \lg N_o - \lg Na$)
Nv	number of cells per ml in the validation suspension
Nv_o	number of cells in the validation mixtures at the beginning of the contact time ($Nv_o = Nv / 10$)
Nv_B	number of cells per ml in the neutraliser control validation suspension
A	number of survivors per ml in the experimental conditions control mixture
B	number of survivors per ml in the neutraliser or filtration control mixture
C	number of survivors per ml in the method validation mixture