

Report: CIB.20D103.MY

Issued: 13 May 2020

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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 VitaCoat
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.

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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:	<i>Candida albicans</i> (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.

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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 VitaCoat 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:

Signed:



Name:

Karl Cumings

Position:

Microbiologist

Date:

13 May 2020

Approved by:

Signed:



Name:

Tony Watson

Position:

General Manager

Date:

13 May 2020

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Results: EN 13624:2013

RST 019 (Issue 2)

Test organism:	<i>Candida albicans</i>	(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 (N_{V_0})			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: <i>Neat</i>		
Vc1	52	$\bar{x} =$ 51	Vc1	48	$\bar{x} =$ 47	Vc1	46	$\bar{x} =$ 47	Vc1	48	$\bar{x} =$ 48
Vc2	50		Vc2	46		Vc2	48		Vc2	48	
30 ≤ \bar{x} of N_{V_0} ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			\bar{x} of A ≥ 0.5 × \bar{x} of N_{V_0} ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			\bar{x} of B ≥ 0.5 × \bar{x} of N_{V_0} (or $N_{V_B} / 1000$) ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			\bar{x} of C ≥ 0.5 × \bar{x} of N_{V_0} ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		
Validation suspension (N_{V_B})											
Vc1	57	$\bar{x} =$ 54.5									
Vc2	52										
30 ≤ \bar{x} of $N_{V_B} / 1000$ ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no											

Test suspension (N and N_0):

N	Vc1	Vc2	\bar{x} $w_m = 2.36 \times 10^7$;	$\lg N = 7.37$
10^{-5}	232	248	$N_0 = N / 10$;	$\lg N_0 = 6.37$
10^{-6}	20	19	6.17 ≤ $\lg N_0$ ≤ 6.70 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	

Test:

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	N_a ($\bar{x} \times 10$ or \bar{x} $w_m \times 10$)	$\lg N_a$	$\lg R$ ($\lg N_0 - \lg N_a$)
<i>Neat</i>	5 min	10^0	0	0	<140	<2.15	>4.22
		10^{-1}	0	0			

Explanations:

V_c	count per ml (one plate or more)
\bar{x}	average of V_{c1} and V_{c2} (1 + 2 duplicate)
\bar{x}_{wm}	weighted mean of \bar{x}
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 ($N_o = N / 10$)
N_a	number of survivors per ml in the test mixture at the end of the contact time (before neutralisation or filtration)
R	reduction ($\lg R = \lg N_o - \lg N_a$)
N_v	number of cells per ml in the validation suspension
N_{v_o}	number of cells in the validation mixtures at the beginning of the contact time ($N_{v_o} = N_v / 10$)
N_{v_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