

Report: CIB.20D103.MB

Issued: 15 May 2020

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Test Report:

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)

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:

20D/103

Name of the product:

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 13727:2012+A2:2015 (5.5.2)

Experimental conditions:

Period of analysis: 12 May 2020 to 14 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: 36°C ± 1°C

Identification of the bacterial strain(s) used: *Pseudomonas aeruginosa* (NCIMB 10421)
Staphylococcus aureus (NCTC 10788)
Enterococcus hirae (NCIMB 8192)

Deviations: None

Remarks:

- 1) All test conditions are as requested by the client, irrespective of whether these are in accordance with EN 13727:2012+A2:2015 (5.4.2) or EN 13727:2012+A2:2015 (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 5 decimal log (lg) reduction against every test organism.

Conclusion:

According to EN 13727:2012+A2:2015, this sample of VitaCoat possesses bactericidal activity against all of the referenced strains of *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Enterococcus hirae*, 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:

15 May 2020

Approved by:

Signed:



Name:

Tony Watson

Position:

General Manager

Date:

15 May 2020

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Results: EN 13727:2012+A2:2015

RST 004 (Issue 3)

Test organism:	<i>Pseudomonas aeruginosa</i>	(NCIMB 10421)
Date of test:	12 May 2020	
Test temperature:	20°C ± 1°C	Incubation temperature: 36°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	82	\bar{x} =	Vc1	80	\bar{x} =	Vc1	82	\bar{x} =	Vc1	80	\bar{x} =
Vc2	82	82	Vc2	79	79.5	Vc2	80	81	Vc2	80	80
30 ≤ \bar{x} of N_{V_0} ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			\bar{x} of A ≥ 0.5 x \bar{x} of N_{V_0} ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			\bar{x} of B ≥ 0.5 x \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 x \bar{x} of N_{V_0} ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		
Validation suspension (N_{V_B})											
Vc1	80	\bar{x} =									
Vc2	79	79.5									
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} wm = 2.59 x 10 ⁸ ;	lg N = 8.41
10 ⁻⁶	264	248	$N_0 = N / 10$;	lg N_0 = 7.41
10 ⁻⁷	28	30	7.17 ≤ lg N_0 ≤ 7.70 ?	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	Na (\bar{x} x 10 or \bar{x} wm x 10)	lg Na	lg R (lg N_0 - lg Na)
<i>Neat</i>	5 min	10 ⁰	0	0	<140	<2.15	>5.26
		10 ⁻¹	0	0			

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Results: EN 13727:2012+A2:2015

RST 004 (Issue 3)

Test organism:	<i>Staphylococcus aureus</i>	(NCTC 10788)
Date of test:	12 May 2020	
Test temperature:	20°C ± 1°C	Incubation temperature: 36°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	68	$\bar{x} =$ 65	Vc1	65	$\bar{x} =$ 66	Vc1	69	$\bar{x} =$ 67	Vc1	62	$\bar{x} =$ 61
Vc2	62		Vc2	67		Vc2	65		Vc2	60	
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	65	$\bar{x} =$ 67									
Vc2	69										
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} wm = 2.73 × 10 ⁸ ; $N_0 = N / 10$; 7.17 ≤ lg N_0 ≤ 7.70 ?
10 ⁻⁶	256	288	lg N = 8.44 lg N_0 = 7.44
10 ⁻⁷	28	28	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	Na ($\bar{x} \times 10$ or \bar{x} wm × 10)	lg Na	lg R (lg N_0 - lg Na)
<i>Neat</i>	5 min	10 ⁰	0	0	<140	<2.15	>5.29
		10 ⁻¹	0	0			

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Results: EN 13727:2012+A2:2015

RST 004 (Issue 3)

Test organism:	<i>Enterococcus hirae</i>	(NCIMB 8192)
Date of test:	12 May 2020	
Test temperature:	20°C ± 1°C	Incubation temperature: 36°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	60	$\bar{x} =$ 62	Vc1	61	$\bar{x} =$ 62	Vc1	64	$\bar{x} =$ 63	Vc1	58	$\bar{x} =$ 57
Vc2	64		Vc2	63		Vc2	62		Vc2	56	
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	60	$\bar{x} =$ 60									
Vc2	60										
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} wm = 2.96 × 10 ⁸ ;	lg N = 8.47
10 ⁻⁶	312	288	$N_0 = N / 10$;	lg N_0 = 7.47
10 ⁻⁷	24	27	7.17 ≤ lg N_0 ≤ 7.70 ?	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	Na (\bar{x} × 10 or \bar{x} wm × 10)	lg Na	lg R (lg N_0 - lg Na)
<i>Neat</i>	5 min	10 ⁰	0	0	<140	<2.15	>5.32
		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