



Portion 5, Corporate Park South, Midrand
Postnet Suite 125, Private bag X3, The Reeds
Tel: +27 12 685 0800
E-mail: Microlab@aspirata.co.za
Web address: www.aspirata.co.za

**EN 1276: BACTERICIDAL EFFICACY
EN 13727: BACTERICIDAL EFFICACY**

FINAL TEST REPORT

Contact Person: **CHRIS VORSTER**
Company: **PHEND PHARMA PTY LTD**
17 WESTMINSTER AVE
BRYANSTON
SANDTON
2192

Lab Number : **M20-5561**
Order reference : **PEROXASIL Ag+**
Sample Date : **25/05/2020**
Submit Date : **25/05/2020**
Report Date : **29/06/2020**

Disclaimer:

The results reported relate only to the samples tested and is expressed on an 'as received' basis unless specified otherwise. The test report shall not be reproduced except in full, without written approval of the Laboratory.

SANS 51276:2011 - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

SANS 53727:2011 - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area.

Product Identification:	PEROXASIL Ag+
Active Substances:	HYDROGEN PEROXIDE AND SILVER IONS

Batch Number:	202005-1
Expiry Date:	MAY 2022
Storage Conditions:	AMBIENT OUT OF DIRECT SUNLIGHT
Recommended Diluent:	NONE

Appearance of Product:	SUITABLE FOR TESTING
Diluent Used in Test:	STERILE HARD WATER
Product Concentrations:	3%
Appearance of Dilutions:	HOMOGENOUS SUSPENSION
Interfering Substances:	0,3g/L BOVINE SERUM ALBUMIN
Appearance during Test:	HOMOGENOUS SUSPENSION
Method:	MEMBRANE FILTRATION
Neutralizer / Rinsing Liquid:	TRYPTONE SOY + 30g/L POLYSORBATE 80

Analysis performed by:	J JACOBS
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Conclusion:

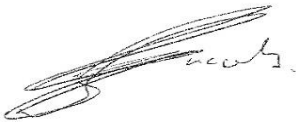
Validations and Controls:

All validations and controls were within specification during the test

Testing was performed using the membrane filtration method as no suitable neutraliser could be found to inactivate the effect of the silver ions in the culture media.

PEROXSiL Ag+ eliminated >99,999% of viable *E.coli*, *S.aureus*, *E.hirae* and *P.aeruginosa* when allowed a contact period of 5 minutes under simulated clean conditions with bovine serum albumin at a concentration of 0,3g/L.

Additionally, Peroxsil Ag+ was able to reach the required killing efficacy of a 5-Log reduction in viable organisms as required by SANS53727 for application in medical areas. The test was performed at an adjusted 5 minute contact period under clean conditions.



Johan Jacobs
Technical Advisor

Organism:	Escherichia coli ATCC10536
Replicate:	1 of 2

Test Date:	04/06/2020
Test Temperature:	20°C
Incubation Temperature:	37°C

Validation and Controls:

Validation suspension (N _{v0})		Experimental condition control (A)		Filtration control (B)		Method Validation (C)	
V _c 1a	36	V _c 1a	51	V _c 1a	43	V _c 1a	36
V _c 1b	28						
V _c 2a	24	V _c 2a	47	V _c 2a	49	V _c 2a	31
V _c 2b	29						
$\bar{X} =$	58,5	$\bar{X} =$	49	$\bar{X} =$	46	$\bar{X} =$	33,5
Spec	30 ≤ \bar{X} ≤ 160	Spec	$\bar{X} \geq 0.5XN_{v0}$	Spec	$\bar{X} \geq 0.5XN_{v0}$	Spec	$\bar{X} \geq 0.5XN_{v0}$
Complies	Yes	Complies	Yes	Complies	Yes	Complies	Yes

Test Suspension and Test:

Test Suspension (N and N ₀):	N	V_c1	V_c2	\bar{X} wm = 2,53E+08	log10N = 8,40
	10 ⁻⁶	247	255	N ₀ = N/10	log10N ₀ = 7,40
	10 ⁻⁷	26	29	7.17 ≤ LgN ₀ ≤ 7.70?	Yes

Product Conc.	Vc1	Vc2	Na = \bar{X} x 10	Log Na	Log R	Contact time
6%	0	0	<10	<1	>5	5 MINUTES
3%	0	0	<10	<1	>5	5 MINUTES
0,3%	>150	>150	>1500	>3,18	<4,22	5 MINUTES

Summary:

Lowest effective concentration	3%
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Organism:	Escherichia coli ATCC10536
Replicate:	2 of 2

Test Date:	04/06/2020
Test Temperature:	20°C
Incubation Temperature:	37°C

Validation and Controls:

Validation suspension (N _{v0})		Experimental condition control (A)		Filtration control (B)		Method Validation (C)	
V _c 1a	36	V _c 1a	51	V _c 1a	43	V _c 1a	37
V _c 1b	28						
V _c 2a	24	V _c 2a	47	V _c 2a	49	V _c 2a	34
V _c 2b	29						
$\bar{X} =$	58,5	$\bar{X} =$	49	$\bar{X} =$	46	$\bar{X} =$	35,5
Spec	30 ≤ \bar{X} ≤ 160	Spec	$\bar{X} \geq 0.5XN_{v0}$	Spec	$\bar{X} \geq 0.5XN_{v0}$	Spec	$\bar{X} \geq 0.5XN_{v0}$
Complies	Yes	Complies	Yes	Complies	Yes	Complies	Yes

Test Suspension and Test:

Test Suspension (N and N ₀):	N	V_c1	V_c2	\bar{X} wm = 2,53E+08	log10N = 8,40
	10 ⁻⁶	247	255	N ₀ = N/10	log10N ₀ = 7,40
	10 ⁻⁷	26	29	7.17 ≤ LgN ₀ ≤ 7.70?	Yes

Product Conc.	Vc1	Vc2	Na = \bar{X} x 10	Log Na	Log R	Contact time
6%	0	0	<10	<1	>5	5 MINUTES
3%	0	0	<10	<1	>5	5 MINUTES
0,3%	>150	>150	>1500	>3,18	<4,22	5 MINUTES

Summary:

Lowest effective concentration	3%
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Organism:	Pseudomonas aeruginosa ATCC15442
Replicate:	1 of 2

Test Date:	04/06/2020
Test Temperature:	20°C
Incubation Temperature:	37°C

Validation and Controls:

Validation suspension (N _{v0})		Experimental condition control (A)		Filtration control (B)		Method Validation (C)	
V _c 1a	27	V _c 1a	43	V _c 1a	39	V _c 1a	28
V _c 1b	24						
V _c 2a	26	V _c 2a	47	V _c 2a	45	V _c 2a	32
V _c 2b	21						
$\bar{X} =$	49	$\bar{X} =$	45	$\bar{X} =$	42	$\bar{X} =$	30
Spec	30 ≤ \bar{X} ≤ 160	Spec	$\bar{X} \geq 0.5 \times N_{v0}$	Spec	$\bar{X} \geq 0.5 \times N_{v0}$	Spec	$\bar{X} \geq 0.5 \times N_{v0}$
Complies	Yes	Complies	Yes	Complies	Yes	Complies	Yes

Test Suspension and Test:

Test Suspension (N and N ₀):	N	V_c1	V_c2	\bar{X} wm = 2,58E+08	log10N = 8,41
	10 ⁻⁶	255	263	N ₀ = N/10	log10N ₀ = 7,41
	10 ⁻⁷	27	23	7.17 ≤ LgN ₀ ≤ 7.70?	Yes

Product Conc.	Vc1	Vc2	Na = \bar{X} x 10	Log Na	Log R	Contact time
6%	0	0	<10	<1	>5	5 MINUTES
3%	0	0	<10	<1	>5	5 MINUTES
0,3%	>150	>150	>1500	>3,18	<4,23	5 MINUTES

Summary:

Lowest effective concentration	3%
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Organism:	Pseudomonas aeruginosa ATCC15442
Replicate:	2 of 2

Test Date:	04/06/2020
Test Temperature:	20°C
Incubation Temperature:	37°C

Validation and Controls:

Validation suspension (N _{v0})		Experimental condition control (A)		Filtration control (B)		Method Validation (C)	
V _c 1a	27	V _c 1a	43	V _c 1a	39	V _c 1a	34
V _c 1b	24						
V _c 2a	26	V _c 2a	47	V _c 2a	45	V _c 2a	31
V _c 2b	21						
$\bar{X} =$	49	$\bar{X} =$	45	$\bar{X} =$	42	$\bar{X} =$	32,5
Spec	30 ≤ \bar{X} ≤ 160	Spec	$\bar{X} \geq 0.5 \times N_{v0}$	Spec	$\bar{X} \geq 0.5 \times N_{v0}$	Spec	$\bar{X} \geq 0.5 \times N_{v0}$
Complies	Yes	Complies	Yes	Complies	Yes	Complies	Yes

Test Suspension and Test:

Test Suspension (N and N ₀):	N	V_c1	V_c2	\bar{X} wm = 2,58E+08	log10N= 8,41
	10 ⁻⁶	255	263	N ₀ = N/10	log10N ₀ = 7,41
	10 ⁻⁷	27	23	7.17 ≤ LgN ₀ ≤ 7.70?	Yes

Product Conc.	Vc1	Vc2	Na = \bar{X} x 10	Log Na	Log R	Contact time
6%	0	0	<10	<1	>5	5 MINUTES
3%	0	0	<10	<1	>5	5 MINUTES
0,3%	>150	>150	>1500	>3,18	<4,23	5 MINUTES

Summary:

Lowest effective concentration	3%
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Organism:	Staphylococcus aureus ATCC6538
Replicate:	1 of 2

Test Date:	5/06/2020
Test Temperature:	20°C
Incubation Temperature:	37°C

Validation and Controls:

Validation suspension (N _{v0})		Experimental condition control (A)		Filtration control (B)		Method Validation (C)	
V _c 1a	47	V _c 1a	86	V _c 1a	76	V _c 1a	57
V _c 1b	43						
V _c 2a	50	V _c 2a	81	V _c 2a	86	V _c 2a	48
V _c 2b	46						
$\bar{X} =$	93	$\bar{X} =$	83,5	$\bar{X} =$	81	$\bar{X} =$	52,5
Spec	30 ≤ \bar{X} ≤ 160	Spec	$\bar{X} \geq 0.5 \times N_{v0}$	Spec	$\bar{X} \geq 0.5 \times N_{v0}$	Spec	$\bar{X} \geq 0.5 \times N_{v0}$
Complies	Yes	Complies	Yes	Complies	Yes	Complies	Yes

Test Suspension and Test:

Test Suspension (N and N ₀):	N	V_c1	V_c2	\bar{X} wm = 4,10E+08	log10N= 8,61
	10 ⁻⁶	>300	>300	N ₀ = N/10	log10N ₀ = 7,61
	10 ⁻⁷	37	45	7.17 ≤ LgN ₀ ≤ 7.70?	Yes

Product Conc.	Vc1	Vc2	Na = \bar{X} x 10	Log Na	Log R	Contact time
6%	0	0	<10	<1	>5	5 MINUTES
3%	0	0	<10	<1	>5	5 MINUTES
0,3%	>150	>150	>1500	>3,18	<4,43	5 MINUTES

Summary:

Lowest effective concentration	3%
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Organism:	Staphylococcus aureus ATCC6538
Replicate:	2 of 2

Test Date:	5/06/2020
Test Temperature:	20°C
Incubation Temperature:	37°C

Validation and Controls:

Validation suspension (N _{v0})		Experimental condition control (A)		Filtration control (B)		Method Validation (C)	
V _c 1a	47	V _c 1a	86	V _c 1a	76	V _c 1a	51
V _c 1b	43						
V _c 2a	50	V _c 2a	81	V _c 2a	86	V _c 2a	57
V _c 2b	46						
$\bar{X} =$	93	$\bar{X} =$	83,5	$\bar{X} =$	81	$\bar{X} =$	54
Spec	30 ≤ \bar{X} ≤ 160	Spec	$\bar{X} \geq 0.5 \times N_{v0}$	Spec	$\bar{X} \geq 0.5 \times N_{v0}$	Spec	$\bar{X} \geq 0.5 \times N_{v0}$
Complies	Yes	Complies	Yes	Complies	Yes	Complies	Yes

Test Suspension and Test:

Test Suspension (N and N ₀):	N	V_c1	V_c2	\bar{X} wm = 4,10E+08	log10N= 8,61
	10 ⁻⁶	>300	>300	N ₀ = N/10	log10N ₀ = 7,61
	10 ⁻⁷	37	45	7.17 ≤ LgN ₀ ≤ 7.70?	Yes

Product Conc.	Vc1	Vc2	Na = \bar{X} x 10	Log Na	Log R	Contact time
6%	0	0	<10	<1	>5	5 MINUTES
3%	0	0	<10	<1	>5	5 MINUTES
0,3%	>150	>150	>1500	>3,18	<4,43	5 MINUTES

Summary:

Lowest effective concentration	3%
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Organism:	Enterococcus hirae ATCC10541
Replicate:	1 of 2

Test Date:	5/06/2020
Test Temperature:	20°C
Incubation Temperature:	37°C

Validation and Controls:

Validation suspension (N _{v0})		Experimental condition control (A)		Filtration control (B)		Method Validation (C)	
V _c 1a	49	V _c 1a	83	V _c 1a	76	V _c 1a	51
V _c 1b	55						
V _c 2a	46	V _c 2a	88	V _c 2a	71	V _c 2a	58
V _c 2b	47						
$\bar{X} =$	98,5	$\bar{X} =$	85,5	$\bar{X} =$	73,5	$\bar{X} =$	54,5
Spec	30 ≤ \bar{X} ≤ 160	Spec	$\bar{X} \geq 0.5 \times N_{v0}$	Spec	$\bar{X} \geq 0.5 \times N_{v0}$	Spec	$\bar{X} \geq 0.5 \times N_{v0}$
Complies	Yes	Complies	Yes	Complies	Yes	Complies	Yes

Test Suspension and Test:

Test Suspension (N and N ₀):	N	V_c1	V_c2	\bar{X} wm = 4,30E+08	log10N = 8,63
	10 ⁻⁶	>300	>300	N ₀ = N/10	log10N ₀ = 7,63
	10 ⁻⁷	39	47	7.17 ≤ LgN ₀ ≤ 7.70?	Yes

Product Conc.	Vc1	Vc2	Na = \bar{X} x 10	Log Na	Log R	Contact time
6%	0	0	<10	<1	>5	5 MINUTES
3%	0	0	<10	<1	>5	5 MINUTES
0,3%	>150	>150	>1500	>3,18	<4,43	5 MINUTES

Summary:

Lowest effective concentration	3%
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Organism:	Enterococcus hirae ATCC10541
Replicate:	2 of 2

Test Date:	5/06/2020
Test Temperature:	20°C
Incubation Temperature:	37°C

Validation and Controls:

Validation suspension (N _{v0})		Experimental condition control (A)		Filtration control (B)		Method Validation (C)	
V _c 1a	49	V _c 1a	83	V _c 1a	76	V _c 1a	45
V _c 1b	55						
V _c 2a	46	V _c 2a	88	V _c 2a	71	V _c 2a	57
V _c 2b	47						
$\bar{X} =$	98,5	$\bar{X} =$	85,5	$\bar{X} =$	73,5	$\bar{X} =$	51
Spec	30 ≤ \bar{X} ≤ 160	Spec	$\bar{X} \geq 0.5XN_{v0}$	Spec	$\bar{X} \geq 0.5XN_{v0}$	Spec	$\bar{X} \geq 0.5XN_{v0}$
Complies	Yes	Complies	Yes	Complies	Yes	Complies	Yes

Test Suspension and Test:

Test Suspension (N and N ₀):	N	V_c1	V_c2	\bar{X} wm = 4,30E+08	log10N= 8,63
	10 ⁻⁶	>300	>300	N ₀ = N/10	log10N ₀ = 7,63
	10 ⁻⁷	39	47	7.17 ≤ LgN ₀ ≤ 7.70?	Yes

Product Conc.	Vc1	Vc2	Na = \bar{X} x 10	Log Na	Log R	Contact time
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3%	0	0	<10	<1	>5	5 MINUTES
0,3%	>150	>150	>1500	>3,18	<4,43	5 MINUTES

Summary:

Lowest effective concentration	3%
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