mgsLABORATORIES Microbiological Services and Consultancy						Doc No.	TRA-2012-080-02	UKAS TESTING 4393
Title	**Microbiological Analysis Based on EN 14561 (2006) Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area. (Phase 2 / Step 2)**							
Product	**Clinell Universal Sanitising Wipes**	**MGS No**	**02645**	**SO No**	**3269**			

a) **Identification of test laboratory:**

Test laboratory	MGS Laboratories Ltd Unit 14, Newlands Drive Poyle 14 Horton Road Poyle Berkshire SL3 0DX

b) **Identification of the Customer:**

Customer Name	Gama Healthcare Ltd
Customer Address	Unit 2 , Brent Cross Gardens , Brent Cross , London , NW4 3RJ

c) **Identification of the sample:**

Name of product	Clinell Universal Sanitising Wipes
Batch number (and expiry date if available)	UB1205 Exp Feb 17
Manufacturer	Gama Healthcare Ltd
Date of delivery	23 Mar 12
Storage conditions	Room temperature and darkness
Product diluent recommended by the manufacturer for use	N/A
Active substance(s) and their concentration(s) (optional)	Not stated
Appearance of the product	Wet wipe

d) **Test method and its validation:**

MGS procedure reference	WIN-1000.060-05
Method	Dilution neutralisation
Neutraliser	Tryptone soya broth 30g/l, lecithin 30g/l, polysorbate 20 100g/l, Catalase 0.25g/l
Details of validation of the neutraliser	Neutraliser validation performed according to 5.5.2 in EN 14561:2006

NOTE 1: The results relate only to the sample which was tested and cannot be guaranteed to represent the batch from which it was taken.

e) **Experimental conditions:**

Period of analysis	29 Mar 12 – 13 Apr 12
Product diluent used during the test	N/A
Product test concentrations	Ready to Use (RTU)
Product preparation	Solution was squeezed out of the wipes and used for testing
Appearance of product dilutions	N/A
Contact time	60 seconds ± 10s
Test temperature range	20°C ± 2°C
Interfering substance	3.0ml/l sheep erythrocytes and 3.0g/l Bovine albumin
Stability and appearance of the mixture	Precipitate absent throughout test
Temperature of incubation	36°C ± 2°C
Identification of the bacterial strains used	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* NCIMB 8192

f) **Results:**

Test results	1) Controls and validation 2) Evaluation of bactericidal activity
g) **Conclusion:**	Based on EN 14561 (2006), the batch UB1205 of the product Clinell Universal Sanitising Wipes, when tested at RTU,possesses bactericidal activity in 60 seconds at 20°C under dirty conditions for the referenced strains of *P. aeruginosa, S. aureus* and *E. hirae*.
h) **Deviations:**	None

Re-issued By:

Name: Mrs Emma Newton BSc (Hons)

Position: Quality Manager

Date: 19 Apr 12

Approved by:

Name: Mrs Kim Morwood BSc (Hons) CBiol MiBiol

Position: Technical Director

Date: 19 APR 12

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The MGS procedure WIN-1000.060 is a laboratory method based on the EN 14561 (2006) standard; the minor deviations from the standard, which do not affect the overall results, are detailed below:

- The carriers are sterilised in an autoclave rather than by dry heat.
- EN 14561 states an allowed tolerance of 36°C ±1°C or 37°C±1°C, MGS laboratories equipment is validated to ±2°C therefore MGS procedures state ±2°C.
- Organisms are prepared by swabbing plates and adding to 9ml diluent to form a suspension, rather than adding loopfuls of organism to 10ml diluent with beads, shaking for 3 minutes, aspirating and adding to a new container. Swabbing forms a smooth suspension removing the need to shake with beads.
- The laboratory is regulated at 20°C; therefore for testing at 20°C a temperature controlled chamber is not used.
- Hard water is prepared as stated in EN 1276:2009, solution A is autoclaved, Solution B is filter sterilised so SHW does not require sterilisation.
- Sterilisation of BSA is performed as stated in EN 1276:2009 0.22µm filters are used to filter sterilize BSA and hard water, not 0.45µm filters.
- Once inoculated surfaces are dried in a validated manner rather than at 36°C±1°C.
- Neutraliser is prepared at 8ml, 9ml and 10ml taking into account required concentrations so that water does not have to be added to 8ml/9ml for Test, Nw and NTV aliquots.
- Neutralisation is not proved prior to the test, but is validated in the test.
- Dilutions of controls plated differ, if the plated dilutions were not correct and the plates had <1cfu or >300cfu the test would be invalid.
- Plates are incubated for the full time rather than performing an interim read; in addition the incubation period may be extended to a maximum of 4 days due to business hours.
- Any part of the method may be altered to meet customer requirements; MGS does not insist on testing the standard conditions or three concentrations of product with replicates of the limiting organism

Product batch number: UB1205
Appearance of product: Clear colourless solution
Number of plates: 1/ml Pour plate [X] Spread plate [ ]
Neutraliser: Tryptone soya broth 30g/l, lecithin 30g/l, polysorbate 20 100g/l, catalase 0.25g/l
Actual test temperature: 20°C
Interfering substances: 3.0g/l Bovine albumin and 3ml/l sheep erythrocytes
Test organism: *P. aeruginosa* ATCC 15442
Drying time on carrier: 15 minutes (not >60 minutes)
Incubation temperature: 36°C ± 2°C
Date of Test: 11 Apr 12
Person responsible: Janice Wong Signature:

Validation and Controls

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)** Prod conc: 1 wipe in 75ml water		
Vc1	38	χ =40	Vc1	59	χ =56	Vc1	61	χ =70	Vc1	91	χ =75
Vc2	42		Vc2	52		Vc2	78		Vc2	59	
30 ≤ χ of Nv_0 ≤ 160? Yes [X] No [ ]			χ of A is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of B is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of C is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]		

Test suspension, water control and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	χ wm = 202 x 10^7; lg N = 9.31 N_0 = N/10; lg N_0 = 8.31 8.17 ≤ lg N_0 ≤ 8.70? Yes [X] No [ ]
	10^{-7}	178	223	
	10^{-8}	25	19	

Water Control (Nw)	**Nw**	**Vc1**	**Vc2**	χ x10 = 157 x 10^5; lg Nw = 7.20 7.15 ≤ lg Nw = 7.20 ≤ (lgN-1.3)? Yes [X] No [ ]
	10^{-4}	163	150	
	10^{-5}	12	16	

Conc of the product	**Dilution Step**	**Vc1**	**Vc2**	**Na = χ x10**	**lg Na** Lg(χ)	**lg R** (lgNw = 7.20)	**Contact time**
RTU	10^0	<14	<14	<140	<2.15	>5.05	60 sec
	10^{-1}	<14	<14				
	10^{-2}	<14	<14				
	10^{-3}	<14	<14				

Product batch number: UB1205
Appearance of product: Clear colourless solution
Number of plates: 1/ml Pour plate [X] Spread plate [ ]
Neutraliser: Tryptone soya broth 30g/l, lecithin 30g/l, polysorbate 20 100g/l, catalase 0.25g/l
Actual test temperature: 20°C
Interfering substances: 3.0g/l Bovine albumin and 3ml/l sheep erythrocytes
Test organism: *S. aureus* ATCC 6538
Drying time on carrier: 15 minutes (not >60 minutes)
Incubation temperature: 36°C ± 2°C
Date of Test: 11 Apr 12
Person responsible: Janice Wong Signature:

Validation and Controls

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)** Prod conc: RTU		
Vc1	105	χ = 96	Vc1	123	χ = 109	Vc1	101	χ =98	Vc1	114	χ =107
Vc2	86		Vc2	94		Vc2	95		Vc2	99	
$30 \le \chi$ of $Nv_0 \le 160$? Yes [X] No [ ]			χ of A is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of B is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of C is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]		

Test suspension, water control and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	$\chi = 50 \times 10^8$; lg N = 9.70; N_0 = N/10; lg N_0 = 8.70; $8.17 \le \lg N_0 \le 8.70$? Yes [X] No [ ]
	10^{-7}	>330	>330	
	10^{-8}	50	50	

Water Control (Nw)	**Nw**	**Vc1**	**Vc2**	χ x10 = 123 x 10^6; lg Nw = 8.09; $7.15 \le \lg Nw = 8.09 \le (\lg N-1.3)$? Yes [X] No [ ]
	10^{-4}	>330	>330	
	10^{-5}	125	121	

Conc of the product	**Dilution Step**	**Vc1**	**Vc2**	**Na = χ x10**	**lg Na** Lg(χ)	**lg R** (lgNw = 8.09)	**Contact time**
RTU	10^0	25	29	270	2.43	5.66	60 sec
	10^{-1}	<14	<14				
	10^{-2}	<14	<14				
	10^{-3}	<14	<14				

NOTE 1: The results relate only to the sample which was tested and cannot be guaranteed to represent the batch from which it was taken.

Product batch number: UB1205
Appearance of product: Clear colourless solution
Number of plates: 1/ml Pour plate [X] Spread plate [ ]
Neutraliser: Tryptone soya broth 30g/l, lecithin 30g/l, polysorbate 20 100g/l, catalase 0.25g/l
Actual test temperature: 20°C
Interfering substances: 3.0g/l Bovine albumin and 3ml/l sheep erythrocytes
Test organism: *E. hirae* NCIMB 8192
Drying time on carrier: 15 minutes (not >60 minutes)
Incubation temperature: 36°C ± 2°C
Date of Test: 11 Apr 12
Person responsible: Janice Wong Signature:

Validation and Controls

Validation suspension (Nv_0)			**Experimental Conditions Control (A)**			**Neutraliser Control (B)**			**Method Validation (C)** Prod conc: RTU		
Vc1	93	χ =79	Vc1	83	χ =83	Vc1	79	χ =73	Vc1	60	χ =69
Vc2	65		Vc2	83		Vc2	66		Vc2	77	
30 ≤ χ of Nv_0 ≤ 160? Yes [X] No [ ]			χ of A is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of B is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]			χ of C is ≥ 0.5 x χ of Nv_0? Yes [X] No [ ]		

Test suspension, water control and test

Test suspension (N and N_0):	**N**	**Vc1**	**Vc2**	χ = 38 x 10^8; lg N = 9.58 N_0 = N/10; lg N_0 = 8.58 8.17 ≤ lg N_0 ≤ 8.70? Yes [X] No [ ]
	10^{-7}	>330	>330	
	10^{-8}	39	37	

Water Control (Nw)	**Nw**	**Vc1**	**Vc2**	χ x10 = 46 x 10^6; lg Nw = 7.66 7.15 ≤ lg Nw = 7.66 ≤ (lgN-1.3)? Yes [X] No [ ]
	10^{-4}	>330	>330	
	10^{-5}	45	47	

Conc of the product	**Dilution Step**	**Vc1**	**Vc2**	**Na = χ x10**	**lg Na** Lg(χ)	**lg R** (lgNw = 7.66)	**Contact time**
RTU	10^0	<14	<14	<140	<2.15	>5.51	60 sec
	10^{-1}	<14	<14				
	10^{-2}	<14	<14				
	10^{-3}	<14	<14				

Explanations:
Vc = count per ml
χ = average of Vc1 and Vc2 (1. + 2. duplicate)
χ wm = weighed mean of χ
Na = number of survivors in the test mixture
Nv = number of cells in the validation suspension
Nv_0 = Nv/10
R = reduction (lg R = lgN_w – lgNa)
If Na<140, lgR = > [lgNw – 2.15]
If Na > X x 10, lgR = < [lgN_w – lg X] (X = upper limit for Vc)

All test results have an associated uncertainty of measurement; for this test the expanded uncertainty is based on the estimated uncertainty multiplied by a coverage factor K=2 providing a level of confidence of approximately 95%. The uncertainty evaluation has been assessed in accordance with MGS laboratories' UKAS Accreditation and is available on request.