 Microbiological Services and Consultancy		<b>Report</b>			
		Doc No.	TRA-2009-074-02		
Title	<b>EN 1040 (2005)</b> <b>Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics (Phase 1 / Step 1)</b>				
Product	<b>Medspek</b>	MGS No	17144	SO No	<b>1914</b>

**a) Identification of test laboratory:**

Test laboratory MGS Laboratories Ltd  
Science Centre  
Coopers Hill Lane  
Egham  
Surrey TW20 0LB  
United Kingdom

**b) Identification of the Customer:**

Customer Name Astor and Windsor International  
Customer Address 1 Cross End  
Pebmarsh  
Essex  
CO9 2NT

**c) Identification of the sample:**

Name of product Medspek  
Batch number (and expiry date if available) Not stated  
Manufacturer Not stated  
Date of delivery 15 Jul 09  
Storage conditions Room temperature and darkness  
Product diluent recommended by the manufacturer for use Not stated  
Active substance(s) and their concentration(s) (optional) Not stated  
Appearance of the product Clear colourless gel

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

MGS procedure reference WIN-1000.048-01  
Method Dilution neutralisation  
Neutraliser Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l  
Details of validation of the neutraliser Neutraliser validation performed according to 5.5.2.

**e) Experimental conditions:**

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Product	<b>Medspek</b>	MGS No	17144	SO No	<b>1914</b>

Period of analysis	20 Jul 09 – 24 Jul 09
Product diluent used during the test	Ready to Use (RTU) product
Product test concentrations	RTU
Appearance of product dilutions	Clear colourless gel
Contact time	5 minutes ± 10s
Test temperature	20°C ± 2°C
Stability and appearance of the mixture	Precipitate absent throughout test
Temperature of incubation	37°C ± 2°C
Identification of the bacterial strains used	<i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Staphylococcus aureus</i> ATCC 6538 MRSA NCTC 12493

**f) Results:**


Test results	1) Controls and validation 2) Evaluation of bactericidal activity
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**g) Conclusion:**

Based on EN 1040 (2005), the batch of the product Medspek, supplied by Astor and Windsor, when tested at RTU, possesses bactericidal activity in 5 minutes at 20 °C for the referenced strains of *P. aeruginosa*, *S. aureus* and MRSA.

**h) Deviations:**

None

**Prepared By:** 

**Name:** Miss Emma Crane BSc (Hons)

**Position:** Laboratory Manager

**Date:** 31 Jul 09

**Approved by:** 


**Name:** Mrs Kim Morwood BSc (Hons) CBiol MiBiol

**Position:** Technical Director

**Date:** 31 JUL 09

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Product	Medspek	MGS No	17144	SO No	1914

Product batch number: Not stated

Dilution-neutralisation method      Pour plate       Spread plate

Number of plates: 1/ml

Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l

Test temperature: 20°C ± 2°C

Test organism: *P. aeruginosa* ATCC 15442

Incubation temperature: 37°C ± 2°C

Date of Test: 20 Jul 09

Person responsible: Emilia Brzosko

Signature: *Emilia Brzosko*

Diluent used for product test solutions: RTU product

Appearance of product test solutions: Clear colourless gel

#### Validation and Controls

Validation suspension (N <sub>v0</sub> )			Neutraliser Control (B)			Method Validation (C)		
						Prod conc: RTU		
Vc1	84	χ = 82	Vc1	87	χ = 80	Vc1	81	χ = 82
Vc2	80		Vc2	73		Vc2	83	
30 ≤ χ of N <sub>v0</sub> ≤ 160?			χ of B is ≥ 0.5 x χ of N <sub>v0</sub> ?			χ of C is ≥ 0.5 x χ of N <sub>v0</sub> ?		
Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>


#### Test suspension and test

Test suspension (N and N <sub>0</sub> ):	N	Vc1	Vc2			
	10 <sup>-6</sup>	>330	>330	χ = 34 x 10 <sup>7</sup> ; lgN = 8.53		
	10 <sup>-7</sup>	36	31	N <sub>0</sub> = N/10; lgN <sub>0</sub> = 7.53		
				7.17 ≤ lg N <sub>0</sub> ≤ 7.70?      Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		

Conc of the product	Vc1	Vc2	Na = χ x 10	lgNa	lgR	Contact time (min)
RTU	<14	<14	<140	<2.15	>5.38	5 min

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Product	<b>Medspek</b>	MGS No	17144	SO No	<b>1914</b>

Product batch number: Not stated

Dilution-neutralisation method      Pour plate       Spread plate

Number of plates: 1/ml

Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l

Test temperature: 20°C ± 2°C

Test organism: *S. aureus* ATCC 6538

Incubation temperature: 37°C ± 2°C

Date of Test: 20 Jul 09

Person responsible: Emilia Brzosko

Signature: *Emilia Brzosko*

Diluent used for product test solutions: RTU product

Appearance of product test solutions: Clear colourless gel

**Validation and Controls**

Validation suspension (Nv <sub>0</sub> )			Neutraliser Control (B)			Method Validation (C)		
						Prod conc: RTU		
Vc1	36	χ = 37	Vc1	33	χ = 32	Vc1	23	χ = 27
Vc2	68		Vc2	30		Vc2	31	
30 ≤ χ of Nv <sub>0</sub> ≤ 160?			χ of B is ≥ 0.5 x χ of Nv <sub>0</sub> ?			χ of C is ≥ 0.5 x χ of Nv <sub>0</sub> ?		
Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>

**Test suspension and test**

Test suspension (N and N <sub>0</sub> ):	N	Vc1	Vc2			
	10 <sup>-6</sup>	154	152	χ <sub>wm</sub> = 155 x 10 <sup>6</sup> ; lgN = 8.19		
	10 <sup>-7</sup>	20	10	N <sub>0</sub> = N/10; lgN <sub>0</sub> = 7.19		
				7.17 ≤ lg N <sub>0</sub> ≤ 7.70?      Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		

Conc of the product	Vc1	Vc2	Na = χ x 10	lgNa	lgR	Contact time (min)
RTU	<14	<14	<140	<2.15	>5.04	5 min

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	<b>Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics (Phase 1 / Step 1)</b>				
Product	<b>Medspek</b>	MGS No	17144	SO No	<b>1914</b>

Product batch number: Not stated

Dilution-neutralisation method      Pour plate       Spread plate

Number of plates: 1/ml

Neutraliser: Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l

Test temperature: 20°C ± 2°C

Test organism: MRSA NCTC 12493

Incubation temperature: 37°C ± 2°C

Date of Test: 22 Jul 09

Person responsible: Emilia Brzosko

Signature: *Emilia Brzosko*

Diluent used for product test solutions: RTU product

Appearance of product test solutions: Clear colourless gel

### Validation and Controls

Validation suspension (Nv <sub>0</sub> )			Neutraliser Control (B)			Method Validation (C)		
						<b>Prod conc: RTU</b>		
Vc1	78	χ = 81	Vc1	97	χ = 99	Vc1	53	χ = 61
Vc2	84		Vc2	100		Vc2	68	
30 ≤ χ of Nv <sub>0</sub> ≤ 160?			χ of B is ≥ 0.5 x χ of Nv <sub>0</sub> ?			χ of C is ≥ 0.5 x χ of Nv <sub>0</sub> ?		
Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>

### Test suspension and test

Test suspension (N and N <sub>0</sub> ):	N	Vc1	Vc2		
	10 <sup>-6</sup>	>330	>330	χ = 36 x 10 <sup>7</sup> ; lgN = 8.56	
	10 <sup>-7</sup>	38	34	N <sub>0</sub> = N/10; lgN <sub>0</sub> = 7.56	
				7.17 ≤ lg N <sub>0</sub> ≤ 7.70?      Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	

Conc of the product	Vc1	Vc2	Na = χ x 10	lgNa	lgR	Contact time (min)
RTU	<14	<14	<140	<2.15	>5.43	5 min

### Explanations:

- Vc = count per plate (one plate or more)
- χ = average of Vc1 and Vc2 (1. + 2. duplicate)
- χ<sub>wm</sub> = weighed mean of χ
- R = reduction (lgR = lgN<sub>0</sub> - lgNa)
- Na = number of survivors in the test mixture
- Nv = number of cells in the validation suspension
- Nv<sub>0</sub> = Nv/10

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