



Abbott Analytical



Consulting Scientists to the Disinfectant Industry

Certificate of Analysis

Sample(s) : One sample of Sterizar

Received from: Point Consumables Europe Ltd. 2 Royal Lodge Road, Belfast, BT8 7UL

Date received: 18 February 2010 **Date tested:** 19 February 2010

Certificate no: 10B.117MB.CSS **Certificate date:** 22 February 2010

Sample ref: 10B/117 **Page:** 1 of 3

Analysis required: BS/EN 14348 quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants used in the medical area

Product stored at: Room temperature

Active substance: Not declared

Test conditions:

Product test concentrations: Neat as received
(80% in test suspension) and
20% v/v

Product diluent used during test: Sterile hard water 300mg/l CaCO₃

Contact time: 60 mins

Test temperature: 20°C ± 0.5°C

Interfering substance: 0.3g/l bovine albumin

Neutralising solution: 30g/l polysorbate 80, 3g/l lecithin,
1g/l histidine, 1g/l cysteine

Incubation temperature: 37°C ± 1°C

Identification of mycobacterial strains used: *Mycobacterium avium* ATCC 15769
Mycobacterium terrae ATCC 15755

D C Watson



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Test results: (Neat)

Test Organism	<i>Mycobacterium avium</i>		<i>Mycobacterium terrae</i>	
Validation Suspension	10 ⁻¹	Vc1 514 Vc2 468	Vc1 538 Vc2 474	
		Nv0 4.91 x10 ³	Nv0 5.06 x10 ³	
Experimental Control	10 ⁰	Vc1 458 Vc2 516	Vc1 426 Vc2 484	
		A 4.87 x10 ²	A 4.55 x10 ²	
Neutraliser Control	10 ⁰	Vc1 444 Vc2 424	Vc1 512 Vc2 438	
		B 4.34 x10 ²	B 4.75 x10 ²	
Method Validation	10 ⁰	Vc1 438 Vc2 400	Vc1 466 Vc2 422	
		C 4.19 x10 ²	C 4.44 x10 ²	
Test Suspension	10 ⁻⁶	Vc1 416 Vc2 392	Vc1 388 Vc2 316	
	10 ⁻⁷	Vc1 27 Vc2 36	Vc1 25 Vc2 29	
		N 3.60 x10 ⁸	N 3.11 x10 ⁸	
Results	10 ⁻²	Vc1 0 Vc2 0	Vc1 0 Vc2 0	
		Na < 1.00 x10 ²	Na < 1.00 x10 ²	
		R > 3.60 x10 ⁶	R > 3.11 x10 ⁶	
Log Reduction		> 6.56	> 6.49	

Vc = Viable count
Nv = cfu/ml in the validation suspension

N = cfu/ml in the test suspension
Na = cfu/ml in the test mixture
R = Reduction in viability

Conclusion:

This batch of Sterizar, when used neat, passes the requirements of EN 14348 for mycobactericidal activity in 60 minutes at 20°C against the reference organisms detailed.

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Test results: (20% v/v)

Test Organism	<i>Mycobacterium avium</i>		<i>Mycobacterium terrae</i>	
Validation Suspension	10 ⁻¹	Vc1 514 Vc2 468	Vc1 538 Vc2 474	
		Nv0 4.91 x10 ³	Nv0 5.06 x10 ³	
Experimental Control	10 ⁰	Vc1 458 Vc2 516	Vc1 426 Vc2 484	
		A 4.87 x10 ²	A 4.55 x10 ²	
Neutraliser Control	10 ⁰	Vc1 444 Vc2 424	Vc1 512 Vc2 438	
		B 4.34 x10 ²	B 4.75 x10 ²	
Method Validation	10 ⁰	Vc1 438 Vc2 400	Vc1 466 Vc2 422	
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Test Suspension	10 ⁻⁶	Vc1 416 Vc2 392	Vc1 388 Vc2 316	
	10 ⁻⁷	Vc1 27 Vc2 36	Vc1 25 Vc2 29	
		N 3.60 x10 ⁸	N 3.11 x10 ⁸	
Results	10 ⁻²	Vc1 0 Vc2 0	Vc1 0 Vc2 0	
		Na < 1.00 x10 ²	Na < 1.00 x10 ²	
		R > 3.60 x10 ⁶	R > 3.11 x10 ⁶	
Log Reduction	> 6.56		> 6.49	

Vc = Viable count

Nv = cfu/ml in the validation suspension

N = cfu/ml in the test suspension

Na = cfu/ml in the test mixture

R = Reduction in viability

Conclusion:

This batch of Sterizar, when diluted to 20% v/v, passes the requirements of EN 14348 for mycobactericidal activity in 60 minutes at 20°C against the reference organisms detailed.

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