BACTERICIDAL EFFICACY TESTS

EN 13727 (PHASE 2, STEP 1)

STERI-7

SENTINEL

HOSPITAL INFECTION RESEARCH LABORATORY

CITY HOSPITAL

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MANUFACTURER	Sentinel Unit 1 Batsworth Road Mitcham Surrey CR4 3BX
TEST PRODUCT	**Steri-7**
LOT NUMBER	Not stated
EXPIRY DATE	Not stated

TEST ORGANISMS

Staphylococcus aureus	NCTC 10788
Pseudomonas aeruginosa	NCTC 6749
Enterococcus hirae	NCTC 12367

TEST METHOD AND VALIDATION

EN 13727:(2003) Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants used in the medical area. (Phase 2, step 1).

Copies available from BSI, 389 Chiswick High Road, London W4 4AL.

REQUIREMENT

The test product when tested in accordance with the test methodology described under simulated clean and dirty conditions shall demonstrate at least a 5 $\log_{10}$ reduction.

Product diluent used during the test	Sterile hard water 300mg/kg $CaCO_3$
Product test concentration	Undiluted as supplied (stated to be 1 in 10). Tests were also carried out on a 1 in 20 dilution
Contact time	1, 2, 5 and 10 mins
Test temperature	20^0C
Interfering substance	0.03% Bovine albumin - clean conditions 0.3% Bovine albumin plus 0.3% sheep erythrocytes - dirty conditions
Inhibition method	Dilution/neutralization
Neutralizer	Lecithin 3g/l, Tween 80 30g/l, Sodium lauryl sulphate 10g/l Tests were performed to establish the suitability of this neutralizer in neutralizing the activity of the disinfectant without being inhibitory to the test organisms.

SUMMARY OF TEST METHOD

EN 13727: - This test method involves mixing 1 ml of the test bacteria with 1 ml of soil (0.3% albumin – clean conditions or 3% albumin with 3% freshly triple washed and spun sheep erythrocytes – dirty conditions), and then adding 8 ml of the test disinfectant. After the required contact time, 1 ml is removed to 9 ml of recovery/neutralizer, which is then plated to detect surviving test bacteria.

RESULTS

BACTERICIDAL ACTIVITY OF STERI-7
USING PHASE 2 STEP 1 SUSPENSION TEST EN 13727

Log_{10} counts/reductions achieved in 1, 2, 5 and 10 minutes at 20°C

(Tests carried out in duplicate – figures expressed are the mean of two test results)

Table 1 Undiluted ie 1 in 10

Log_{10} reduction									
Test organism	Log_{10} initial count (challenge)	Clean conditions (0.03% albumin)				Dirty conditions (0.3% albumin/0.3% sheep erythrocytes)			
		1min	2min	5min	10min	1min	2min	5min	10min
Ps. aeruginosa	7.42	6.12	>6.42	>6.42	>6.42	5.32	>6.42	>6.42	>6.42
Ent. hirae	6.28	>6.28	>6.28	>6.28	>6.28	>6.28	>6.28	>6.28	>6.28
Staph. aureus	6.53	>6.53	>6.53	>6.53	>6.53	>6.53	>6.53	>6.53	>6.53

Table 2 1 in 20 dilution

Log_{10} reduction									
Test organism	Log_{10} initial count (challenge)	Clean conditions (0.03% albumin)				Dirty conditions (0.3% albumin/0.3% sheep erythrocytes)			
		1min	2min	5min	10min	1min	2min	5min	10min
Ps. aeruginosa	7.42	5.43	>6.42	>6.42	>6.42	4.86	>6.42	>6.42	>6.42
Ent. hirae	6.28	>6.28	>6.28	>6.28	>6.28	>6.28	>6.28	>6.28	>6.28
Staph. aureus	6.53	>6.53	>6.53	>6.53	>6.53	>6.53	>6.53	>6.53	>6.53

CONCLUSION

When tested in accordance with EN 13727 (1997), Steri-7 disinfectant solution possesses bactericidal activity at 20°C when tested under clean conditions (0.03% albumin) and dirty (0.3% albumin and 0.3% sheep erythrocytes) conditions. A >5 $\log_{10}$ (99.999%) reduction was achieved with all test organisms i.e. *Ps. aeruginosa*, *Staph. aureus* and *Ent. hirae* in 1 min when tested undiluted and in 2 mins when tested at 1 in 20.

Steri-7, therefore, complies with the requirements described in EN 13727

Testing by the Hospital Infection Research Laboratory does not imply approval or endorsement.

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