

EFFICACY TESTS (EN 1276)

Clinell Sporicidal Wipes

GAMMA Healthcare Ltd

HOSPITAL INFECTION RESEARCH LABORATORY

CITY HOSPITAL

DUDLEY ROAD

BIRMINGHAM B18 7QH

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MANUFACTURER

GAMMA Healthcare Ltd
Hampstead House,
173 Finchley Road,
London.
NW3 6BT

TEST PRODUCTS

Clinell Sporidal Wipes A57

Ingredients – sodium percarbonate and tetra acetyl ethylene diamine.

Clinell sporicidal wipes comprise of a dry cellulose based non-woven Airtex, laminated together with EVA adhesive and the powdered particles of the active ingredients stated above.

Batch number: Not Stated

Lot number: Not Stated

STORAGE CONDITIONS

Room temperature, in a dry place out of direct sunlight.

TEST ORGANISMS

<i>Staphylococcus aureus</i>	NCTC 10788
<i>Pseudomonas aeruginosa</i>	NCTC 6749
<i>Escherichia coli</i>	NCTC 10538
<i>Enterococcus hirae</i>	NCTC 12367

TEST METHOD AND VALIDATION

EN 1276 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (Phase 2, step 1). Tests for disinfectants for medical establishments not yet ratified.

PRODUCT TEST CONCENTRATION

Not Applicable

APPEARANCE PRODUCT

Clear solution

CONTACT TIMES

30 seconds, 1, 2 and 5 minutes

TEST TEMPERATURE

20 °C

INTERFERING SUBSTANCE

Bovine albumin:-

Clean conditions - 0.03 % albumin (final concentration)

Dirty conditions - 0.3 % albumin (final concentration)

INHIBITION METHOD

Dilution/neutralization

NEUTRALIZER

Tween 80 (30g/L); Sodium Lauryl Sulphate (4g/L); Lecithin (3g/ L); Saponin (30g/L); Histidine (1g/L) and Sodium thio-sulphate (5g/L).

Tests were performed to establish the suitability of this neutralizer in inhibiting the activity of the disinfectant without being toxic to the test organisms (method described in EN 1276).

SUMMARY OF TEST METHOD

No standard test method exists for wipes therefore the following test was carried out on the disinfectant impregnated into the wipes. The test method is described in EN 1276 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity

of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (Phase 2, step 1). Tests for disinfectants for medical establishments are not yet ratified. Copies of EN 1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The disinfectant was extracted from the wipes in accordance to manufacturers' instruction, immediately prior to testing.

The disinfectant was extracted by soaking a wipe of approx 30cm by 20 cm with 75ml of standard hard water, prepared in accordance to EN2176. Wearing gloves, the wipe was squeezed to release the solution. The solution was allowed to be reabsorbed on to the wipe and the process repeated three more times. This solution was then used for testing.

The test method involves mixing 1 ml of the test bacteria with 1 ml of interfering substance (0.3 or 3g/L albumin) and then adding 8 ml of test product. After the required contact time, 1 ml is removed and added to 9 ml of neutralizer fluid. After a period of 5 minutes neutralization, 1 ml is removed and plated onto tryptone soya agar plates. The plates are incubated for 18 hours at 37°C, and examined for surviving test organisms.

RESULTS

**Bactericidal Activity Of ‘Clinell Sporicidal Wipes A57’
Using Phase 2 Step 1 Suspension Test
EN 1276**

(All tests carried out in duplicate)

Test Organism	Log ₁₀ Initial Count (Challenge)	Contact Time	Log ₁₀ Reduction Achieved					
			Clean Conditions (0.3 % Albumin)			Dirty Conditions (3 % Albumin)		
			Test 1	Test 2	Mean	Test 1	Test 2	Mean
<i>Pseudomonas aeruginosa</i>	8.31	30 secs	>7.31	>7.31	> 7.31	>7.31	>7.31	> 7.31
		1 min	>7.31	>7.31	> 7.31	>7.31	>7.31	> 7.31
		2 mins	>7.31	>7.31	> 7.31	>7.31	>7.31	> 7.31
		5 mins	>7.31	>7.31	> 7.31	>7.31	>7.31	> 7.31
<i>Staphylococcus aureus</i>	8.29	30 secs	>7.29	>7.29	> 7.29	>7.29	>7.29	> 7.29
		1 min	>7.29	>7.29	> 7.29	>7.29	>7.29	> 7.29
		2 mins	>7.29	>7.29	> 7.29	>7.29	>7.29	> 7.29
		5 mins	>7.29	>7.29	> 7.29	>7.29	>7.29	> 7.29
<i>Escherichia coli</i>	7.91	30 secs	>6.91	>6.91	> 6.91	>6.91	>6.91	> 6.91
		1 min	>6.91	>6.91	> 6.91	>6.91	>6.91	> 6.91
		2 mins	>6.91	>6.91	> 6.91	>6.91	>6.91	> 6.91
		5 mins	>6.91	>6.91	> 6.91	>6.91	>6.92	> 6.91
<i>Enterococcus hirae</i>	6.52	30 secs	>5.52	>5.52	> 5.52	>5.52	>5.52	> 5.52
		1 min	>5.52	>5.52	> 5.52	>5.52	>5.52	> 5.52
		2 mins	>5.52	>5.52	> 5.52	>5.52	>5.52	> 5.52
		5 mins	>5.52	>5.52	> 5.52	>5.52	>5.52	> 5.52

To meet the requirements of this test a >5 Log₁₀ reduction in test bacteria within 5 minutes is required.

CONCLUSION

In accordance with EN 1276 (1997), the disinfectant contained within the ‘Clinell Sporicidal Wipes A57’ successfully satisfies the requirements of the test, i.e. at least a $> 5 \text{ Log}_{10}$ reduction in specified test organisms is required within 5 minutes when the disinfectant is tested at its intended use dilution.

This was successfully achieved with all test organisms, under all test times, under both clean and dirty conditions and therefore the disinfectant contained within the ‘Clinell Sporicidal Wipes A57’ passes EN1276.

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

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CR Bradley
Laboratory Manager

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K Chana
Biomedical Scientist

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Dr AP Fraise
Director