

BACTERICIDAL EFICACY TEST

PrEN 12054

(PHASE 2 STEP 1)

**V2 HANDWASH AND HANDRUB
FORMULATIONS**

EBIOX LTD

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MANUFACTURER Ebiox Ltd
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TEST PRODUCTS **Ebiox Handwash**
Ebiox Handrub V2

Lot numbers Not stated

Expiry Dates Not stated

TEST METHOD

PrEN 12054 Quantitative suspension test for the evaluation of bactericidal activity of products for hygienic and surgical handrub and handwash used in human medicine (phase 2/step 1).

This test has not yet been ratified by the European Committee and was in final draft form in July 1998.

TEST ORGANISMS

<i>Staphylococcus aureus</i>	NCTC 10788
<i>Pseudomonas aeruginosa</i>	NCTC 6749
<i>Escherichia coli</i>	NCTC 10418
<i>Enterococcus hirae</i>	NCTC 12367
MRSA	NCTC12493

TEST REQUIREMENTS

Hygienic Handrub

The product shall demonstrate a 10^5 reduction in viable count at 1 minute. At the manufacturers request 30 seconds may also be tested. The product is tested undiluted.

Hygienic Handwash

The product shall demonstrate a 10^3 reduction in viable count at 1 minute. A 55% dilution of the product is tested. At the manufacturers request 30 seconds may also be tested.

Contact time	30 seconds and 1 minute.
Test temperature	20°C
Inhibition method	Dilution/neutralization
Neutralizer	Tween 80 40g/1, Sodium Lauryl Sulphate 10g/1, Lecithin 4g/1, Sodium thiosulphate 5g/1, Saponin 30g/litre.

Tests were performed to establish the suitability of this neutralizer in neutralizing the activity of the disinfectant without being inhibitory to the test organisms. Initial tests were carried out with the standard neutralizer described in EN 1276 but this proved unsatisfactory as a neutralizer. An increase in the Tween 80 and Lecithin concentration and the addition of Sodium Lauryl Sulphate was required.

SUMMARY OF TEST METHOD

The test method involves mixing 1 ml of the test bacteria with 9 ml of disinfectant. After the required contact time, 1 ml is removed to 9 ml of recovery/neutralizer, which is then diluted/plated to detect surviving test bacteria.

RESULTS

BACTERICIDAL ACTIVITY OF EBIOX HANDWASH FORMULATION

USING SUSPENSION TEST prEN 12054

Log₁₀ reductions achieved in 30 sec and 1 minute

(Tests carried out in duplicate)

Test organism	Log ₁₀ initial count (challenge)	Contact time	
		30 sec	1 minute
<i>Ps. aeruginosa</i>	6.92	4.86	5.74
<i>Esch. coli</i>	6.92	>5.92	>5.92
<i>Staph. aureus</i>	6.81	>5.81	>5.81
<i>Ent. hirae</i>	7.08	>6.08	>6.08
MRSA	6.95	>6.95	>6.95

BACTERICIDAL ACTIVITY OF EBIOX HANDRUB FORMULATION

USING SUSPENSION TEST prEN 12054

Log₁₀ reductions achieved in 30 sec and 1 minute

(Tests carried out in duplicate)

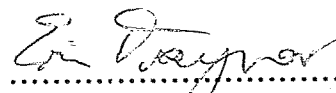
Test organism	Log ₁₀ initial count (challenge)	Contact time	
		30 sec	1 minute
<i>Ps. aeruginosa</i>	6.23	>5.23	>5.23
<i>Esch. coli</i>	6.95	>5.95	>5.95
<i>Staph. aureus</i>	7.04	>6.04	>6.04
<i>Ent. hirae</i>	6.41	>5.41	>5.41
MRSA	7.11	>6.11	>6.11

CONCLUSION

When tested in accordance with PrEN 12054, Ebiox Handwash and Handrub formulations possess bactericidal activity at 20°C. A $>5 \log_{10}$ (99.999%) reduction was achieved with all test organisms i.e. *Ps. aeruginosa*, *Staph. aureus*, *Esch. coli*, *Ent. hirae* and MRSA in 1 min. To satisfy the requirements for the test, at least a $5 \log_{10}$ reduction in specified test organisms is required within 1 minute for the hygienic handrub formulation and at least a $3 \log_{10}$ reduction in 1 minute for the hygienic handwash formulation. Both products also passed the test at 30 seconds.



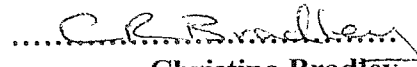
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