TUBERCULOCIDAL EFFICACY TESTS

EN 14348 (PHASE 2, STEP 1)

VIRUSOLVE +

AMITY LTD

HOSPITAL INFECTION RESEARCH LABORATORY

QUEEN ELIZABETH HOSPITAL

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MANUFACTURER Amity Ltd

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TEST PRODUCT

Virusolve +

Blend of Alkyl-triamine, 2-aminoethanol and Potassium carbonate

Batch Number: Not stated **Expiry Date:** Not stated

TEST METHOD AND VALIDATION

EN 14348 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the medical area including instrument disinfectants (Phase 2, step 1).

REQUIREMENT

The test product when tested in accordance with the test methodology described under simulated clean and dirty conditions shall demonstrate at least a 4 $\log_{10}$ reduction in 60 min.

Product diluent used during the test	Sterile hard water 300mg/kg $CaCO_3$
Product test concentration	2.5, 5 and 10%
Contact time	1**,** 5, 10 and 60 minutes
Test temperature	20^0C
Interfering substance	**clean conditions:-**0.03% Bovine albumin **dirty conditions:-** 0.3% Bovine albumin plus 0.3 % washed sheep erythrocytes
Inhibition method	Dilution/neutralization
Neutralizer	Tween 80 30g/l, Sodium lauryl sulphate 4g/l, Lecithin 3g/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 METHODS

The EN 14348 test method involves mixing 1 ml of the test bacteria with 1 ml of soil (0.3% or 3% albumin) and then adding 8 ml of test disinfectant. After the required contact time, 1 ml is removed to 9 ml of recovery broth (8ml neutralizer and 1ml diluent), which is then plated to detect surviving test bacteria.

RESULTS

MYCOBACTERICIDAL ACTIVITY OF VIRUSOLVE+ USING PHASE 2 STEP 1 SUSPENSION TEST EN 14348

Log_{10} counts/reductions achieved in, 1, 5, 10, 20, 30 and 60 minutes

(Tests carried out in duplicate)

Contact time	2.5%		5%		10%	
	Clean conditions	Dirty conditions	Clean conditions	Dirty conditions	Clean conditions	Dirty conditions
Pre count	8.86	8.86	8.86	8.86	8.86	8.86
1 min	0.96	0.88	2.58	3.11	**5.12**	**5.24**
5 mins	2.83	2.11	**4.97**	**4.88**	**>7.86**	**>7.86**
10 mins	**4.58**	**4.18**	**6.13**	**6.08**	**>7.86**	**>7.86**
60 mins	**>7.86**	**>7.86**	**>7.86**	**>7.86**	**>7.86**	**>7.86**

A contact time of 60 mins is stated in EN 14348. However Amity UK commissioned shorter contact times as more relevant for a hard surface disinfectant for use in health care premises. The tests carried out, were therefore more stringent.

The requirements of EN 14348 are that the test product when tested in accordance with the test methodology described under simulated clean and dirty conditions shall demonstrate at least a 4 log_{10} reduction in 60 min.

It can be seen from the log reductions shown that Virusolve+ passes when tested under clean conditions and dirty conditions. Contact times of 10 mins are required for a 2.5% solution, 5 mins for a 5% solution and 1 min for a 10% solution

CONCLUSION

When tested in accordance with EN 14348, Virusolve+ at 5 and 10% possesses tuberculocidal activity when tested under clean conditions (0.03% albumin) and dirty conditions (0.3% albumin and 0.3% erythrocytes). Under clean and dirty conditions Virusolve+ at 2.5% achieves a 4 $\log_{10}$ reduction in 10 mins, 5% solution in 5 mins and a 10% solution in 1 min.

Virusolve+ at 2.5, 5 and 10%, therefore, complies with the requirements of EN 14348 for tuberculocidal activity.

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

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