

Study Title:

Quantitative suspension test for evaluation of virucidal activity in the medical area (Phase 2 Step1)

BS EN 14476:2013+A1:2015

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Job reference – J000712

Lab Ref/Report No.	J000712
Testing Laboratory Site	Microbiological Solutions Limited Gollinrod, Walmersley, Bury , BL9 5NB
Company owner	Angela Davies, Managing Director
Report Date	05/03/2018
Period of Analysis	23/02/2018-26/02/2018

Customer	Goldshield
Contact Name	Andrew Payne
Address	Unit C, Lincoln Lodge Farm, Castlethorpe, MK19 7HJ
Email	andrew.payne@goldshieldtech.co.uk
PO Number/Quote Ref	Q001066

Name of product	GS86
Batch number	L529/88/TD
Manufacturer / Supplier	Goldshield
Storage Conditions	Ambient
Appearance of the Product	Clear liquid
Preservatives/Actives & Conc.%	N/S
Standard Method	BS EN 14476:2013+A1:2015
Product diluent	Deionised water (ready to use product)
Test Concentrations *	Neat, 70%,50%
Experimental Conditions	Clean
Interfering substances	Clean 0.3g/l Bovine Albumin
Test Temperature	20°C ± 1°C
Identification of the viral strains:	Vaccinia Ankara (MVA), ATCC VR-1508
Contact times	5 minutes ± 5 seconds

* Products supplied as “neat” can only be tested at a concentration of 80% or less, as some dilution is always produced by adding test organisms and interfering substance.

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Introduction

The standard method BS EN 14476 describes a test method and the minimum requirements for virucidal activity of a chemical disinfectant and antiseptic products that form a homogenous physically stable preparation when diluted with hard water – or in the case of ready to use products that are not diluted when applied, - with water. Products can only be tested at a concentration of 80% (97% with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substances.

This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection.

This European standard applies to areas and situations where disinfection is medically indicated. Such indication occur in patient care, for example:

- In hospitals, in community medical facilities and in dental institutions;
- In clinics of schools, of kindergartens and of nursing homes.

and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for patients.

Outline of Test Method (Obligatory test conditions)

A sample of the test product is diluted in synthetic hard water in products diluted at point of use or water in the case of ready to use products is added to a test suspension of viruses in a solution of interfering substance. The mixture is maintained at one of the temperatures and contact times specified in the standard. At the end of this contact time, an aliquot is taken; the virucidal action in this portion is immediately suppressed by a validated method (dilutions of the sample in ice-cold cell maintenance medium). The dilutions are transferred into cell culture units either using monolayer or cell suspension. Infectivity tests are done either by plaque test or quantal tests. After incubation, the titres of infectivity are calculated according to Spearman and Käber or by plaque counting. Reduction of virus infectivity is calculated from differences of lg virus titres before (virus control) and after treatment with the product. The standard minimum spectrum of test organisms is *Poliovirus*, *Adenovirus* and *Murine Norovirus*. Virucidal activity against enveloped viruses only will be assessed against *Vacciniavirus*.

Deviations from Standard Method

This product was tested for virucidal activity against enveloped viruses only.

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Acceptance CriteriaThe product when tested as above shall demonstrate at least a 4 log₁₀ reduction in the infectivity titre.**Conclusion**

The product GS86 has **Passed** the test according to the acceptance criteria as outlined in the standard against when tested under **clean** conditions at a concentration of **Neat**, with a **5 minute** contact time for **enveloped viruses only**.

See raw data tables below for test results.

The sample will be retained for 1 month unless otherwise requested.



Laboratory Manager
Daniel Crane

Technical Project Manager
Carolyn Burney

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Summary

Vaccinia virus

Controls					
					
Conditions	Concentration	Contact time	log TCID50	log reduction	Control validation
Virus control (water)	N/A	5 minutes	6.83	N/A	Validated
Cytotoxicity (product)	Neat	N/A	< 1.92	N/A	Validated
Product suppression control	Neat	Neat	6.79	0.04	Validated
Reference virus inactivation (formaldehyde)	1.4%	30 minutes	3.21	3.63	Validated
Reference virus inactivation (formaldehyde)	1.4%	60 minutes	< 2.42	> 4.42	Validated
Cytotoxicity (formaldehyde)	1.4%	N/A	2.67	N/A	Validated

Interference controls					
					
Condition	Concentration	Contact time	log TCID50	Log difference	Control validation
Interference control (untreated)	Neat	N/A	7.92	N/A	N/A
Interference control (treated)	Neat	N/A	7.75	0.17	Validated

Test Results					
					
Condition	Concentration	Contact time	log TCID50	log reduction	Pass/Fail
Test product	Neat		< 2.25	>4	Pass
Test product	70%		3.25	3.58	Fail
Test product	Neat		4.00	2.83	Fail

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**Quantitative suspension test for evaluation of virucidal
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Raw Data

Raw data Vaccinia

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Virus control (water)				Contact time				1 min	
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	3	3	2	3	3	0.75	0.1875	
-7	2	2	1	2	2	1	0.41666667	0.243056	
-8	1	1	1	0	1	0	0.16666667	0.138889	
-9	0	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> ATCC VR-5	
d	1
sum px	2.33
n	8
SD50	-6.83
SE	0.29
xp	-5

Cytotoxicity (product)				Product concentration				Neat	
Dilution	Counts						% CPE	p(1-p)	
-2	2	2	1	1	1	1	0.33333333	0.222222	
-3	1	1	0	0	0	0	0.08333333	0.076389	
-4	0	0	0	0	0	0	0	0	
-5	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	

Organism <i>Adenovirus type 5</i> ATCC VR-5	
d	1
sum px	1.42
n	8
SD50	< -1.92
SE	0.21
xp	-1

Product supression control				Product concentration				Neat	
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	3	3	2	2	0.75	0.1875	
-7	2	2	2	1	1	1	0.375	0.234375	
-8	1	1	1	0	0	1	0.16666667	0.138889	
-9	0	0	0	0	0	0	0	0	

Organism <i>Adenovirus type 5</i> ATCC VR-5	
d	1
sum px	2.29
n	8
SD50	-6.79
SE	0.28
xp	-5

Interference control (untreated)				Product concentration				Neat	
Dilution	Counts						% CPE	p(1-p)	
-1	4	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	4	3	4	3	4	4	0.91666667	0.076389	
-8	2	1	3	2	2	2	0.5	0.25	
-9	0	0	0	0	0	0	0	0	
-10	0	0	0	0	0	0	0	0	

Organism <i>Adenovirus type 5</i> ATCC VR-5	
d	1
sum px	2.4167
n	10
SD50	-7.917
SE	0.1904
xp	-6

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Interference control (treated)				Product concentration				Neat	
Dilution	Counts						% CPE	p(1-p)	
-1	4	4	4	4	4	4	4	1	0
-2	4	4	4	4	4	4	4	1	0
-3	4	4	4	4	4	4	4	1	0
-4	4	4	4	4	4	4	4	1	0
-5	4	4	4	4	4	4	4	1	0
-6	4	4	4	4	4	4	4	1	0
-7	4	2	3	4	2	3	0.75	0.1875	
-8	1	1	3	2	3	2	0.5	0.25	
-9	0	0	0	0	0	0	0	0	0
-10	0	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> ATCC VR-5	
d	1
sum px	2.25
n	10
SD50	-7.75
SE	0.2205
xp	-6

Reference virus inactivation (formaldehyde)				Contact time			30 minutes	
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	4	3	2	2	3	2	0.66666667	0.222222
-4	0	0	0	0	0	0	0	0
-5	1	0	0	0	0	0	0.04166667	0.039931
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> ATCC VR-5	
d	1
sum px	1.71
n	8
SD50	-3.21
SE	0.19
xp	-2

Reference virus inactivation (formaldehyde)				Contact time			60 minutes	
Dilution	Counts						% CPE	p(1-p)
-2	3	4	3	4	3	3	0.83333333	0.138889
-3	1	1	0	0	0	0	0.08333333	0.076389
-4	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> ATCC VR-5	
d	1
sum px	1.92
n	8
SD50	< -2.42
SE	0.18
xp	-1

Cytotoxicity (formaldehyde)								
Dilution	Counts						% CPE	p(1-p)
-2	4	4	4	4	4	4	1	0
-3	2	2	0	0	0	0	0.16666667	0.138889
-4	0	0	0	0	0	0	0	0
-5	0	0	0	0	0	0	0	0
-6	0	0	0	0	0	0	0	0
-7	0	0	0	0	0	0	0	0
-8	0	0	0	0	0	0	0	0
-9	0	0	0	0	0	0	0	0

Organism <i>Adenovirus type 5</i> ATCC VR-5	
d	1
sum px	1.17
n	8
SD50	-2.67
SE	0.14
xp	-2

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Raw data Vaccinia (cont)

Test product		Product concentration					1 Contact time		
Dilution	Counts						% CPE	p(1-p)	
-2	3	2	3	3	3	3	0.70833333	0.206597	
-3	1	0	0	0	0	0	0.04166667	0.039931	
-4	0	0	0	0	0	0	0	0	
-5	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	

Organism <i>Adenovirus type 5</i>	
ATCC VR-5	
d	1
sum px	1.75
n	8
SD50	< -2.25
SE	0.19
xp	-1

Test product		Product concentration					0.7 Contact time		
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	
-3	2	2	3	3	2	2	0.58333333	0.243056	
-4	1	0	0	1	0	2	0.16666667	0.138889	
-5	0	0	0	0	0	0	0	0	
-6	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	

Organism <i>Adenovirus type 5</i>	
ATCC VR-5	
d	1
sum px	1.75
n	8
SD50	-3.25
SE	0.23
xp	-2

Test product		Product concentration					0.5 Contact time		
Dilution	Counts						% CPE	p(1-p)	
-2	4	4	4	4	4	4	4	1	
-3	4	4	4	4	4	4	4	1	
-4	2	2	2	1	1	2	0.41666667	0.243056	
-5	1	1	0	0	0	0	0.08333333	0.076389	
-6	0	0	0	0	0	0	0	0	
-7	0	0	0	0	0	0	0	0	
-8	0	0	0	0	0	0	0	0	
-9	0	0	0	0	0	0	0	0	

Organism <i>Adenovirus type 5</i>	
ATCC VR-5	
d	1
sum px	1.50
n	8
SD50	-4.00
SE	0.21
xp	-3

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KEY

CPE	Cytopathic effect	
Counts	0-4 indicating degree of cytopathic effect 0 = No effect, 1 = 25% CPE, 2 = 50% CPE, 3 = 75% CPE, 4 = 100% CPE	
d	Dilution factor (log)	
Sum px	Sum of % CPE from the highest dilution showing 100% CPE to the lowest dilution assessed.	
n	Number of dilutions	
SD50	Dilution showing 50% of the end point according to Spearman-Kärber method	
SE	Standard error	
xp	Lowest dilution showing 100% CPE	
TCID50	Titre causing 50% of the end point according to Spearman-Kärber	
PASS	= lg R greater than or equal to 4	
FAIL	= lg R less than 4	
>	greater than	≥ equal to or greater than
<	less than	≤ equal to or less than

Calculation notes

In cases where the highest dilution assessed has not shown 100% CPE, the value has been calculated assuming the dilution above this would give 100% CPE and the corresponding value has been assigned as <x.

The standard requires the product suppression control to show a <0.5 log reduction in viral titre. In cases where the product has failed to achieve the required 4 log reduction, but the product suppression control shows a >0.5 log reduction the result has been deemed as valid for fail as the consequence of inadequate suppression would be a partially extended contact time which would generate false positives, but not false negatives.

A similar approach has been taken in regard to the cytotoxicity controls. The standard requires a 4 log difference between the cytotoxicity level and the viral titre. In cases where this is not obtained, but the log reduction observed by the product is within the difference between the cytotoxicity levels and the viral titre the result is deemed acceptable for a fail as there will be no impact on the determination of efficacy.

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