Test Report: EN 13727 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1)

Test Laboratory

BluTest Laboratories Ltd
Robertson Incubator (Level 4)
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Identification of sample

Name of the product	Clinell Universal Wipes
Batch number	Not Provided
Client	GAMA Healthcare Ltd
Project Code	BT- GAM-13FT(2)(1)
Date of Delivery	18 August 2015
Storage conditions	Ambient
Active substances	Not Provided

Test Method and its validation

Method	Chemical neutralization
Neutralizer	Lecithin 11.7g/l, Polysorbate 80 100g/l, sodium thiosulphate 5.0g/l, sodium dodecyl sulphate 10.0g/l, sodium chloride 8.5g/l, tryptone 1.0g/l sterilized by autoclave.

Experimental Conditions

Period of analysis	18 August 2015 to 10 September 2015
Product test concentrations	100% v/v
Appearance product dilutions	Clear
Contact time	1 min; 2 min; 5 min ± 10s
Test temperature	20ºC ± 1ºC
Interfering substance	3.0 g/l bovine albumin + 3.0ml sheep erythrocytes
Stability of mixture	Stable
Temperature of incubation	37ºC ± 1ºC
Identification of strains	*Vancomycin resistant enterococci* (VRE) ATCC 12201 *Methicillin-resistant Staphylococcus aureus* (MRSA) UK16

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EN 13727:2012. Results for the efficacy of Clinell Universal Wipes from GAMA Healthcare Ltd under DIRTY conditions

Test organisms	Validation test					Bacterial test suspension (N)		Contact time at 100.0% V/V		
	Bacterial Suspension (Nv)	Experimental conditions (A)	Bacterial suspension validation (NvB)	Neutralizer toxicity Control or filtration control (B)	Dilution-neutralization control or filtration test control (C)			1 min	2 mins	5 mins
VRE	*V* c: 58 ; 70	Vc: 72 ; 74	Vc 61 ; 66	Vc 63 ; 67	Vc: 69 ; 75	10^{-7}:	253 ; 265	Vc	0 ; 0	1 ; 1	0 ; 0
								-1	0 ; 3	2 ; 2	0 ; 0
						10^{-8}:	26 ; 32	Na	<1.40E+02	<1.40E+02	<1.40E+02
						N:	2.59E+09	R	>10(6)	>10(6)	>10(6)
	N v: 6.40E+02	A: 7.30E+01	Nv 6.35E+03	B: 6.50E+01	C: 7.20E+01						
Validation	30 ≤ Nv_0 ≤ 160 ?	A ≥ 0.5 x Nv_0 ?	30 ≤ Nv_0 ≤ 160 ?	B ≥ 0.5 x NvB ?	C ≥ 0.5 x Nv_0?	8.17≤ log N_0 ≤8.70?		Test is valid			
	yes	yes	yes	yes	yes	yes					
MRSA UK16	*V* c: 36 ; 48	Vc: 40 ; 41	Vc 34 ; 41	Vc 50 ; 64	Vc: 32 ; 44	10^{-7}:	142 ; 179	Vc	0 ; 0	0 ; 0	0 ; 0
								-1	0 0	0 0	0 ; 0
						10^{-8}:	10 ; 24	Na	<1.40E+02	<1.40E+02	<1.40E+02
						N:	1.61E+09	R	>10(6)	>10(6)	>10(6)
	N v: 6.40E+02	A: 7.30E+01	Nv 6.35E+03	B: 6.50E+01	C: 7.20E+01						
Validation	30 ≤ Nv_0 ≤ 160 ?	A ≥ 0.5 x Nv_0 ?	30 ≤ Nv_0 ≤ 160 ?	B ≥ 0.5 x NvB ?	C ≥ 0.5 x Nv_0?	8.17≤ log N_0 ≤8.70?		Test is valid			
	yes	yes	yes	yes	yes	yes					

V c = viable count

N = number of cfu/ml of the bacterial test suspension

N v = number of cfu/ml in the bacterial suspension

R = reduction in viability

N a = number of cfu/ml in the test mixture

A = number of cfu/ml of the experimental conditions validation

B = number of cfu/ml of the neutralizer toxicity validation or of the filtration validation

C = the number of cfu/ml of the dilution-neutralization validation or the membrane filtration test validation

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Conclusion

According to EN 13727:2012, Clinell Universal Wipes **possesses** bactericidal activity at a minimum of > 6 log reduction at a concentration of **100% V/V** of the working concentration as tested after **1 minute** at 20°C under **DIRTY** conditions (3.0g/L bovine albumin + sheep erythrocytes) for *Vancomycin resistant enterococci* (VRE) ATCC 12201 and *Methicillin-resistant Staphylococcus aureus* (MRSA) UK16.

Signed

Dr Chris Woodall, Director
BluTest Laboratories Ltd
Glasgow, UK,
Date: 10 September 2015

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