

Test Report

Number: GZHH00377820

Applicant: Orbel Health Limited
82 St John Street, London, England, EC1M 4JN

Date: Sep 14, 2020

Sample Description:

One (1) style of submitted sample said to be :
Item Name : **Orbel hand rub.**
Item Quantity : 10 pcs 60mL units.
Item Batch : **PHA-O 04282020.**
Item Description : Alcohol hand sanitizer.
Manufacturer : Bath Concept Cosmetics (Dongguan) Co.,Ltd.
Country of Origin : China.
Date Sample Received : Aug 28, 2020



Tests conducted:

As requested by the applicant, refer to attached page(s) for details.

Conclusion:

<u>Tested Sample</u>	<u>Standard</u>	<u>Result</u>
Submitted sample(s)	BS EN 13727:2012+A2:2015 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)	Pass

Intertek GM Testing Service Zhuhai Co. Ltd.

Sarah Xu

Sarah Xu
Asst. Manager
Healthcare and Beauty Products



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Tests Conducted

1 Quantitative suspension test for evaluation of bactericidal activity in medical area of chemical disinfectants and antiseptics

With reference to BS EN 13727:2012+A2:2015

Dilution recommended for use:	No dilution
Product test concentration:	80% v/v
Active ingredient in product:	Alcohol
Appearance:	Light blue gel
Contact time:	60s±5s
Test temperature:	(20±1)°C
Interfering substance:	0.3g/L bovine albumin solution(clean condition)
Inhibition method:	Dilution-neutralization
Neutralizing solution:	D/E neutralizing broth
Incubation:	(37±1)°C, 48 hours
Agar medium:	Trypticase Soy Agar(TSA)
Test culture:	Escherichia coli K12 (NCTC 10538) Pseudomonas aeruginosa (ATCC 15442) Staphylococcus aureus (ATCC 6538) Enterococcus hirae (ATCC 10541)

Controls & validation:

Test microorganism	Validation suspension (cfu/ml) N_v $N_{v_0}=1/10N_v$ Criteria: $300 \leq N_v \leq 1600$	Experimental conditions control (cfu/ml) A Criteria: $A \geq 0.5 N_{v_0}$	Neutralizer control (cfu/ml) B Criteria: $B \geq 0.5 N_{v_0}$	Method validation (cfu/ml) C Criteria: $C \geq 0.5 N_{v_0}$	Validity
Escherichia coli K12 (NCTC 10538)	980	98	86	110	Valid
Pseudomonas aeruginosa (ATCC 15442)	990	95	100	110	Valid
Staphylococcus aureus (ATCC 6538)	1200	130	120	130	Valid
Enterococcus hirae (ATCC 10541)	590	68	61	62	Valid



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Result:

Test microorganism	Initial suspension(N) (cfu/ml) $N_0=1/10N$ Criteria: $1.5 \times 10^8 \leq N \leq 5.0 \times 10^8$	Final count (cfu/ml) N_a	$R(\text{Log}_{10} \text{Reduction}) = \text{Log } N_0 - \text{Log } N_a$ Criteria: $R \geq 5.0$	%Reduction Criteria: ≥ 99.999	Assessment
Escherichia coli K12 (NCTC 10538)	3.8×10^8	<140	>5.0	>99.999	Meet
Pseudomonas aeruginosa (ATCC 15442)	4.3×10^8	<140	>5.0	>99.999	Meet
Staphylococcus aureus (ATCC 6538)	4.5×10^8	<140	>5.0	>99.999	Meet
Enterococcus hirae (ATCC 10541)	2.7×10^8	<140	>5.0	>99.999	Meet

Remark:

- N = Test suspension, Number of cells per ml in bacterial suspensions.
- N_0 = ($N_0=1/10N$), Number of cells per ml in the test mixtures at the beginning of the contact time (time 0).
- N_a = Number of survivors per ml in the test mixtures at the end of the contact time.
- N_v = Validation suspension, Number of cells per ml in bacterial suspensions.
- N_{v0} = ($N_{v0} = 1/10N_v$), Number of cells per ml in the test mixtures at the beginning of the contact time (time 0).
- A,B,C = Represent the different control test mixtures, A(experimental conditions control), B(Neutralizer control), C(Method validation).

Criteria: According BS EN 13727:2012+A2:2015, in order to satisfy the requirement of bactericidal efficacy in the medical area of chemical disinfectants and antiseptics, the product shall demonstrate at least a 5 decimal log (lg) reduction (for hygienic hand wash at least a 3 lg reduction) of the specified test organisms under the obligatory sample contact time, test temperature, and the simulated clean conditions according to its practical applications when the product is tested at its intended use dilution.



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Sample received condition: Sample in unopened original package.

Date sample received: Aug 28, 2020

Testing period: Aug 28, 2020 to Sep 10, 2020

End of report

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