

測試報告

報告編號：UF/2017/40276

日期：2017年06月21日

頁數：1 of 8



麥克森生物科技股份有限公司

台中市西屯區西屯路二段上石南二巷2號

以下測試之樣品係由申請廠商所提供及確認：

產品名稱：麥克森3D 去角質足膜
申請廠商：麥克森生物科技股份有限公司
產品型號/批號：---
生產或供應廠商：麥克森生物科技股份有限公司
樣品狀態：請參考報告末頁樣品照片
製造日期：---
有效期限：---
送樣日期：2017年04月10日
測試日期：2017年04月10日 ~ 2017年06月21日

委託測試項目：防腐效能試驗測試。

試驗目的：依USP <51>所建議的五種試驗微生物，包括大腸桿菌 (*Escherichia coli*- BCRC 11634 ; ATCC 8739)，金黃色葡萄球菌 (*Staphylococcus aureus* BCRC 10451 ; ATCC 6538P)，綠膿桿菌 (*Pseudomonas aeruginosa* BCRC 11633 ; ATCC 9027)，白色念珠菌 (*Candida albicans* BCRC 21538 ; ATCC10231)，及黑麴菌 (*Aspergillus brasiliensis* BCRC 30506 ; ATCC 16404)，將測試樣品進行挑戰性試驗進而評估其防腐效能。

測試方法：本測試參考U.S. Pharmacopeia <51> Antimicrobial Effectiveness Testing方法檢測。

測試結果：- 請見下頁 -

Signed for and on behalf of
SGS Taiwan Ltd.

Yuan-Min Wen
Manager



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麥克森生物科技股份有限公司

台中市西屯區西屯路二段上石南二巷2號

測試結果：

測試流程：

樣本的處理步驟以無菌操作的環境下完成。取測試樣品在無菌燒杯中分別植入每一種試驗微生物，植入體積約佔樣品量之0.5~1.0%(v/v)，並使試驗微生物之最終濃度製備至 $1 \times 10^5 \sim 1 \times 10^6$ CFU/mL。將接種試驗微生物後的測試樣品，置於培養箱中震盪作用，分別於第14天及28天取出測試樣品，進行10倍序列稀釋後，於培養箱中進行培養，其培養條件如表一所示，之後進行計數。計算每一種試驗微生物在不同時間點之菌量減少之對數值(R)。

表1：接種原(Inoculation)製備的培養條件

微生物	培養基	培養溫度 (°C)	製備接種原之培養時間	培養時間
大腸桿菌 <i>Escherichia coli</i>	TSA	32.5±2.5	18~24 hrs	3~5 days
綠膿桿菌 <i>Pseudomonas aeruginosa</i>	TSA	32.5±2.5	18~24 hrs	3~5 days
金黃色葡萄球菌 <i>Staphylococcus</i>	TSA	32.5±2.5	18~24 hrs	3~5 days
白色念珠菌 <i>Candida albicans</i>	SDA	22.5±2.5	44~52 hrs	3~5 days
黑麴菌 <i>Aspergillus brasiliensis</i>	SDA	22.5±2.5	6~10 days	3~7 days

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麥克森生物科技股份有限公司

台中市西屯區西屯路二段上石南二巷2號

測試結果：

菌株名稱	原接菌量 (CFU/mL)	作用時間	樣品作用後之 菌量(CFU/mL)	菌量減少之 對數值R
黑麴菌 (<i>Aspergillus brasiliensis</i>)	6.20 × 10 ⁵	14 days	<1	>3
		28 days	<1	>3
白色念珠菌 (<i>Candida albicans</i>)	1.08 × 10 ⁵	14 days	<1	>3
		28 days	<1	>3
大腸桿菌 (<i>Escherichia coli</i>)	4.40 × 10 ⁵	14 days	<1	>3
		28 days	<1	>3
綠膿桿菌 (<i>Pseudomonas aeruginosa</i>)	3.10 × 10 ⁵	14 days	<1	>3
		28 days	<1	>3
金黃色葡萄球菌 (<i>Staphylococcus aureus</i>)	2.90 × 10 ⁵	14 days	<1	>3
		28 days	<1	>3

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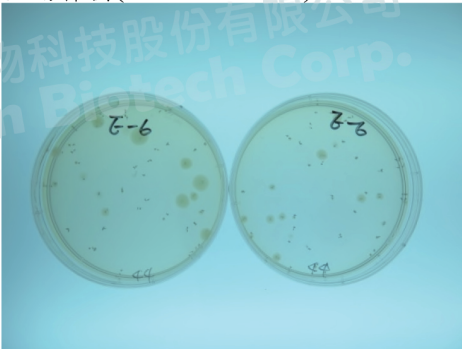
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麥克森生物科技股份有限公司

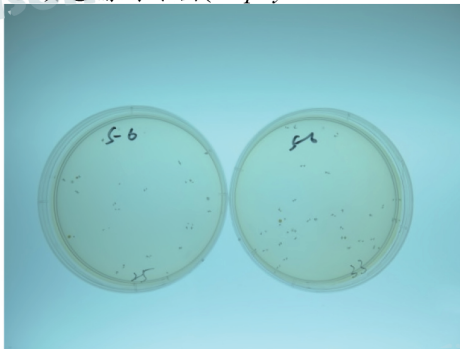
台中市西屯區西屯路二段上石南二巷2號

對照組(原接菌量)

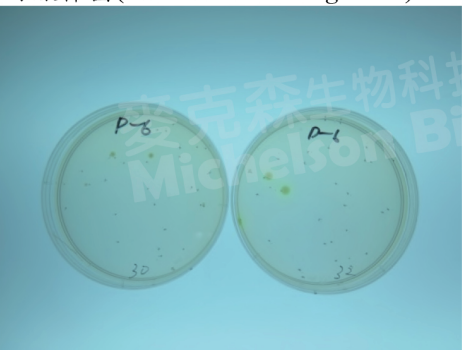
大腸桿菌(*Escherichia coli*)



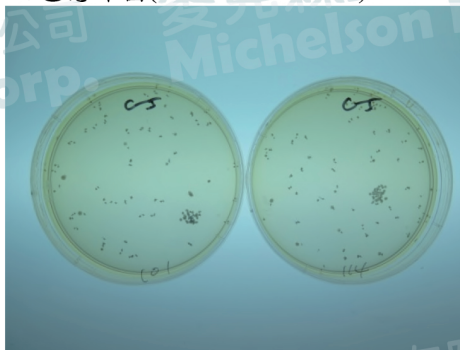
金黃色葡萄球菌(*Staphylococcus aureus*)



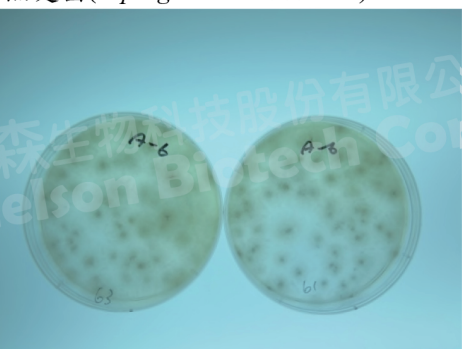
綠膿桿菌(*Pseudomonas aeruginosa*)



白色念珠菌(*Candida albicans*)



黑麴菌(*Aspergillus brasiliensis*)



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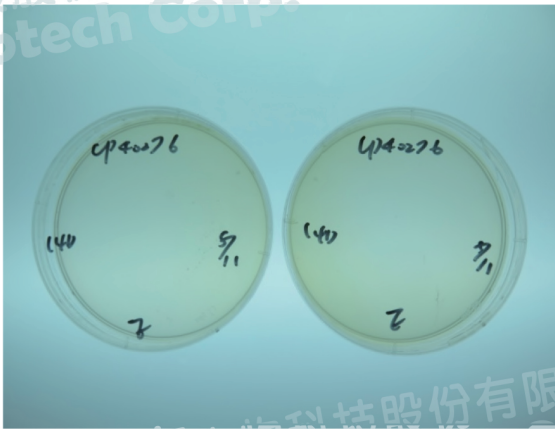
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台中市西屯區西屯路二段上石南二巷2號

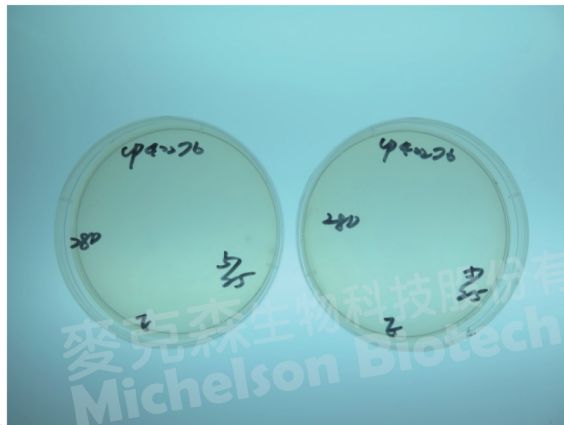
測試照片：

大腸桿菌(*Escherichia coli*)

(1) 作用時間(14天)

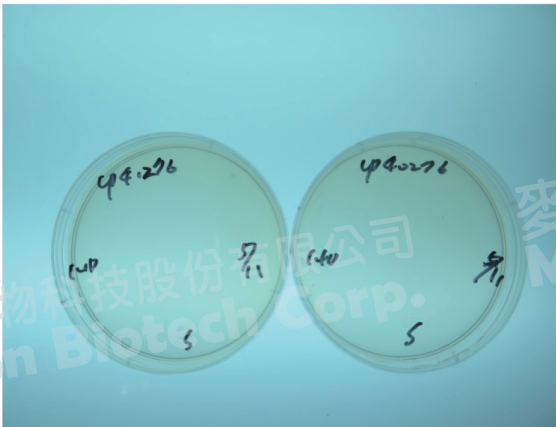


(2) 作用時間(28天)

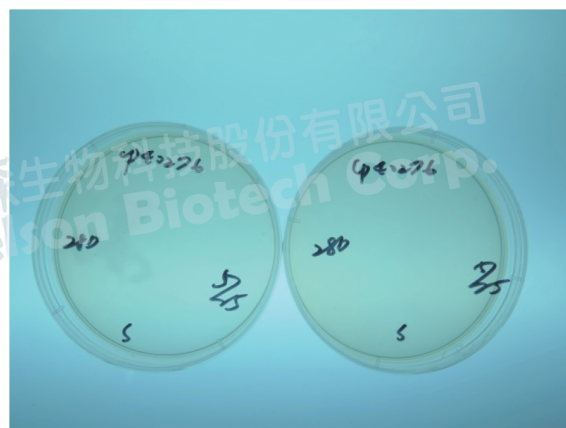


金黄色葡萄球菌(*Staphylococcus aureus*)

(1) 作用時間(14天)



(2) 作用時間(28天)



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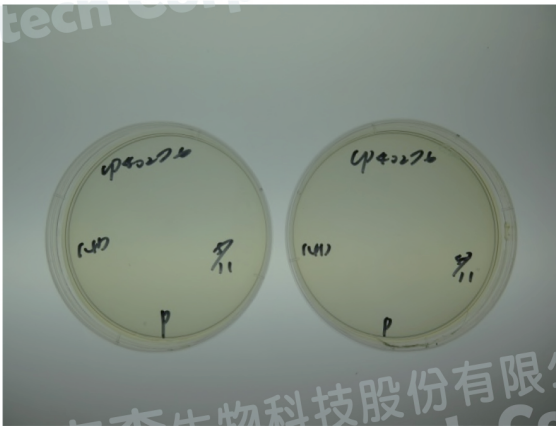


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台中市西屯區西屯路二段上石南二巷2號

綠膿桿菌(*Pseudomonas aeruginosa*)

(1) 作用時間(14天)

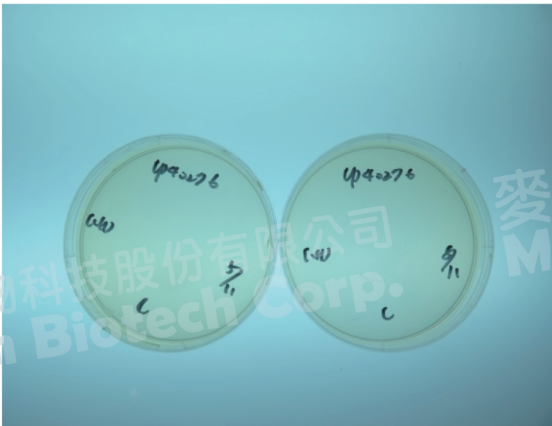


(2) 作用時間(28天)

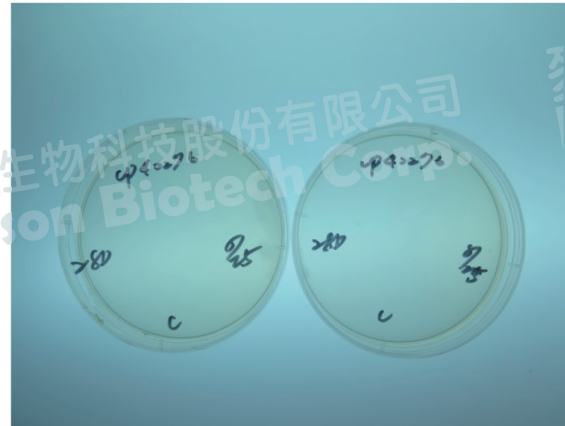


白色念珠菌(*Candida albicans*)

(1) 作用時間(14天)



(2) 作用時間(28天)



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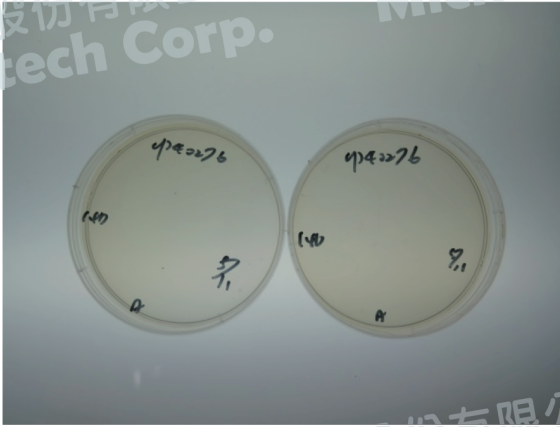
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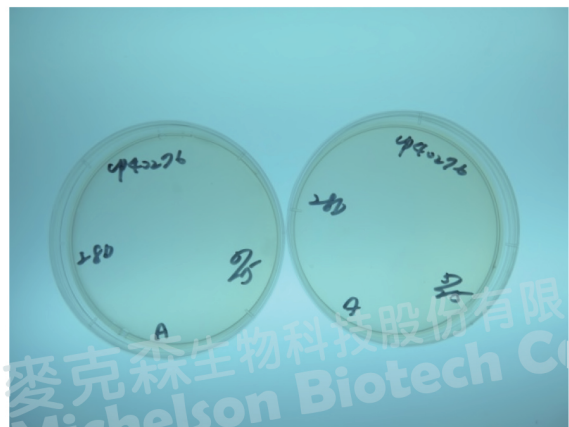
台中市西屯區西屯路二段上石南二巷2號

黑麴菌(*Aspergillus brasiliensis*)

(1) 作用時間(14天)



(2) 作用時間(28天)



備註: 1. 測試報告僅就委託測試者之委託事項提供測試結果, 至若本產品之合法性, 仍應由主管機關依法判斷。

2. 本報告不得分離, 分離使用無效。

3. R之計算: $R = \text{Log}(\text{原接菌量}) - \text{Log}(\text{樣品作用至第N天後之菌量})$; $N = 14, 28$

- END -

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麥克森生物科技股份有限公司

台中市西屯區西屯路二段上石南二巷2號

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