

CERTIFICATE OF ANALYSIS

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PRODUCT PP2037

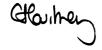
HBA/SAB

LOT NUMBER 1055018

EXPIRY DATE 2008.08.26

RELEASE DATE 2008.07.07

Physical Testing Side 1 Tested in accordance with Oxoid Method QC13	Results unless otherwise	Specification stated	
Appearance (Colour)	Pass	Red	
Clarity	Pass	Opaque	
Gel Strength	Pass	Satisfactory	
рН	7.4	7.2 - 7.6	
Microbiological Testing Side 1	Result	Specification	Method
Staphylococcus aureus ATCC® 25923	Pass	White colonies	QC27
Streptococcus pyogenes ATCC® 19615	Pass	Beta haemolytic colonies	QC27
Candida albicans ATCC® 10231	Pass	White colonies	QC27
Physical Testing Side 2	Results	Specification	
Tested in accordance with Oxoid Method QC13	unless otherwise	•	
Appearance (Colour)	Pass	Colourless/Beige	
Clarity	Pass	Translucent	
Gel Strength	Pass	Satisfactory	
рН	5.8	5.4 - 5.8	
Microbiological Testing Side 2	Result	Specification	Method
Staphylococcus aureus ATCC® 25923	Pass	No growth	QC27
Escherichia coli ATCC® 25922	Pass	No growth	QC27
Candida albicans ATCC® 10231	Pass	White colonies	QC27
Trichophyton mentagrophytes MVQC 0104	Pass	White fluffy	QC03
Sterility Testing	Results	Specification	



Approved Signatory

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Tested in accordance with Oxoid Method QC13 unless otherwise stated





MANUFACTURED AND TESTED BY: Thermo Fisher Scientific, Microbiology Division

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Sterility @ 30°C for 7days (sample plan) Pass Within Limits

This test is performed in accordance Oxoid method QC21, NATA FADs, ASM Guidelines: Normal inspection AQL 2.5,

General inspection level=1

The results reported were obtained at the time of release. Products microbiologically tested are inoculated with bacterial suspension containing either greater or equal to 10,000 cfu for non-target organisms or less than or equal to 100 cfu for target organisms.

Results are recorded semi-quantitatively in comparsion to an appropriate control medium. A pass for a target organism is 80-100% recovery (4-5+ growth). A pass for a non-target organism is less than 20% recovery (inhibited, less than 1+ growth).

This product is stable to the stated expiry date when stored in accordance with instructions as per product label.

Released by: Carissa Courtney

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