

G. PAPANIKOLAOU & SIA E.E.

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QUALITY CONTROL CERTIFICATE

FINAL PRODUCT DATA

Description	CHROMagar™ Malassezia	
Code	010518	
Lot number	2748e25	
Production date	25/01/24	
Expiration date	25/04/24	

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	6,3 +/- 0,3	6.3 (Confirmed)
Quantity of material	20ml (010518)	Confirmed
Color & cleanliness of the material	Beige agar light clear.	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products Incubation		Number of suitable products	Number of inappropriate products	
	(3‰)			
	1/010518	36 ± 1 °C for 48 hours	1/010518	0

FINAL PRODUCT PERFORMANCE TEST

Microorganism	Expected results	Observed results
Malassezia furfur (≥500 cfu/10μl)	PR ≥ 0.7	Colonies pale pink and wrinkled (2mm)
ATCC 14521. Lot: 06405831(productivity)	Colonies pale pink and wrinkled	358 cfu
Incubate: (30 ± 37) °C για (72 ± 2) h	(2-3mm)	
Candida albicans ((≥500 cfu/10µl)	PR ≥ 0.7	Colonies Green
ATCC: 2091 Lot: 04205401 (productivity)	Colonies Green	345 cfu
Incubate: (36 ± 1) °C για (24 ± 2) h		
Escherichia coli (≥500 cfu/10μl)	Inhibited (0)	0 cfu
ATCC 25922 Lot: 00207501 (selectivity)		
Incubate: (36 ± 1) °C γ I α (24 ± 2) h		

- Production and quality control tests were carried out at the premises of Bioprepare G. Papanikolaou & Co. According to EN ISO 9001:2015 / ΕΛΟΤ EN ISO 13485:2016. In addition, the company's audit department implements to ISO 11133: 2014.
- The products of this batch will have the results reported once the user receives them cool (8-25 °C) then keep them at the temperature indicated on the packaging until the expiration date and follow the using instructions of the brochure.
- 0: Growth zero. 1: Weak growth. 2: Good growth. PR: Productivity Rate.

Release of	the batch	DATE	Iniotaki Fofi
YES V	NO	30/01/2024	Afrila
			Quality Control Manager