

G. PAPANIKOLAOU & SIA E.E.

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QUALITY CONTROL CERTIFICATE

FINAL PRODUCT DATA

Description	DERMATOPHYTE TEST AGAR
Code	050039
Lot number	2748n225
Production date	25/01/24
Expiration date	25/05/24

PHYSICAL AND CHEMICAL CONTROL OF FINAL PRODUCT

Control	Expected results	Observed results
Final pH at 25°C	5,6 +/- 0,2	5,7 (Confirmed)
Quantity of material	10ml (050039)	Confirmed
Color & cleanliness of the material	Agar orange clear	Confirmed

STERILITY TEST OF FINAL PRODUCTS

Number of controlled products	Incubation	Number of suitable products	Number of inappropriate products
(3‰)			
1/050039	36 ± 1 °C for 48 hours	1/050039	0

FINAL PRODUCT PERFORMANCE TEST

Microorganism	Expected results	Observed results
Candida albicans (≥500 cfu/10μl)	PR ≥ 0,5	Typical colonies consistent with the species
ATCC: 10231. Lot: 04205401 (productivity)	Typical colonies consistent with the	263 cfu
Incubate: 36 ± 1 °C for 24 - 48 h	species	
Aspergillus brasiliensis (≥500 cfu/10μl)	Inhibited (0)	0 cfu
ATCC 16404 Lot: 09402201 (selectivity)		
Incubate: 25 ± 1 °C for 5 days		
Escherichia coli (≥500 cfu/10μl)	Inhibited (0)	0 cfu
ATCC 25922. Lot: 00207501. (selectivity)		
Incubate: (36 ± 1) °C for (24 - 48) h		

- Production and quality control tests were carried out at the premises of Bioprepare G. Papanikolaou & Co. According to EN ISO 9001:2015 / EAOT 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	30/01/24	Afrika
			Quality Control Manager