

QUALITY CONTROL CERTIFICATE**FINAL PRODUCT DATA**

| | |
|-----------------|------------------------|
| Description | DERMATOPHYTE TEST AGAR |
| Code | 050039 |
| Lot number | 2794d102 |
| Production date | 02/04/24 |
| Expiration date | 02/08/24 |

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 |
|-----------------------------------|------------------------|-----------------------------|----------------------------------|
| 1/050039 | 36 ± 1 °C for 48 hours | 1/050039 | 0 |

FINAL PRODUCT PERFORMANCE TEST

| Microorganism | Expected results | Observed results |
|--|--|---|
| <i>Candida albicans</i> (≥500 cfu/10μl) ATCC: 10231. Lot: 04205401 (productivity) Incubate: 36 ± 1 °C for 24 - 48 h | PR ≥ 0,5 Typical colonies consistent with the species | Typical colonies consistent with the species 282 cfu |
| <i>Aspergillus brasiliensis</i> (≥500 cfu/10μl) ATCC 16404 Lot: 09402201 (selectivity) Incubate: 25 ± 1 °C for 5 days | Inhibited (0) | 0 cfu |
| <i>Escherichia coli</i> (≥500 cfu/10μl) ATCC 25922. Lot: 00207501. (selectivity) Incubate: (36 ± 1) °C for (24 - 48) h | Inhibited (0) | 0 cfu |

- Production and quality control tests were carried out at the premises of Bioprep 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.

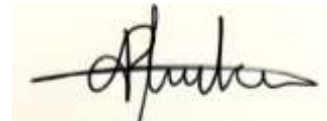
Release of the batch

YES NO

DATE

05/04/24

Iniotaki Fofi



Quality Control Manager