

# Certificate of Analysis



Lot status: **APPROVED**

|   |                                   |                            |                                    |
|---|-----------------------------------|----------------------------|------------------------------------|
| <b>MODEL:</b>                             | <b>Petri ø90mm Single Wrapped</b> | <b>PRODUCT CODE:</b>       | <b>1067/10</b>                     |
| <b>MEDIA:</b>                             | <b>SDA+CAF</b>                    | <b>STORAGE CONDITIONS:</b> | <b>at 2-25°C until expiry date</b> |
| <b>BATCH:</b>                             | <b>90302</b>                      | <b>EXPIRY DATE:</b>        | <b>27 Oct 2023</b>                 |
| <b>DATE OF MANUFACTURING: 27 Apr 2023</b> |                                   |                            |                                    |

| CHEMICAL/PHYSICAL TESTS | SPECIFICATION  | RESULT   |
|-------------------------|--|----------|
| Appearance              | Amber coloured, clear to slightly opalescent gel forms in plates   | Conforms |
| pH specification        | 5.6±0.2  | Conforms |
| Filling media volume    | 30ml±2ml   | Conforms |
| Media composition       | Sabouraud Dextrose Agar + 0.005% Chloramphenicol<br>Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer | Conforms |
| Packaging               | Single Wrapped ( S.W.)   | Conforms |

## MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

| TESTS                            | SPECIFICATION | RESULT   |
|----------------------------------|---------------|----------|
| 32.5±2.5°C aerobic for 120 hours | No growth     | Conforms |
| 22.5±2.5°C aerobic for 120 hours |               |          |

- Fertility – Growth Promotion Test** according to USP/EP

| Control strain                       | Medium inoculation level     | Incubation Conditions       | Recovery Specifications | Recovery Results | Cultural Response |
|--------------------------------------|------------------------------|-----------------------------|-------------------------|------------------|-------------------|
| <i>C. albicans</i><br>ATCC 10231     | 10-100 viable microorganisms | 48-120 h<br>at 22.5 ± 2.5°C | 70%≤R%≤200%             | 109,7%           | Conforms          |
| <i>A. brasiliensis</i><br>ATCC 16404 | 10-100 viable microorganisms | 48-120 h<br>at 22.5 ± 2.5°C | 70%≤R%≤200%             | 102,4%           | Conforms          |
| <i>E. coli</i><br>ATCC 8739          | ≥100 viable microorganisms   | 72-120 h<br>at 22.5 ± 2.5°C | Inhibited               | Inhibited        | Conforms          |

|                   |                   |                          |                  |
|-------------------|-------------------|--------------------------|------------------|
| Start analysis    | Date 27 Apr 2023  | End analysis             | Date 03 May 2023 |
| Quality Control   | Giulia Brusati    | <i>Giulia Brusati</i>    |                  |
| Quality Assurance | Celeste Annovazzi | <i>Celeste Annovazzi</i> |                  |