

# Certificate of Analysis



Lot status: **APPROVED**

|  |                           |                             |
|--|---------------------------|-----------------------------|
| <b>MODEL</b> Petri ø90mm Single Wrapped  | <b>PRODUCT CODE</b>       | <b>290/10</b>               |
| <b>MEDIA</b> TSA                         | <b>MEDIA COMPOSITION</b>  | <b>Tryptone Soy Agar</b>    |
| <b>BATCH</b> 98401                       | <b>STORAGE CONDITIONS</b> | at 2-25°C until expiry date |
| <b>DATE OF MANUFACTURING</b> 08 Feb 2024 | <b>EXPIRY DATE</b>        | <b>08 Oct 2024</b>          |

Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer

| CHEMICAL/PHYSICAL TESTS | SPECIFICATION  | RESULT   |
|-------------------------|--|----------|
| Appearance              | light amber coloured, clear to slightly opalescent gel forms in plates | Conforms |
| pH specification        | 7.3±0.2  | Conforms |
| Filling media volume    | 30±2 ml  | 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>E. coli</i><br>ATCC 8739          | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 87,6%            | Conforms          |
| <i>P. aeruginosa</i><br>ATCC 9027    | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 101,7%           | Conforms          |
| <i>S. aureus</i><br>ATCC 6538        | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 98,7%            | Conforms          |
| <i>B. subtilis</i><br>ATCC 6633      | 10-100 viable microorganisms | 24-72 h<br>at 32.5 ± 2.5°C  | 70%≤R%≤200%             | 98,5%            | Conforms          |
| <i>C. albicans</i><br>ATCC 10231     | 10-100 viable microorganisms | 72-120 h<br>at 32.5 ± 2.5°C | 70%≤R%≤200%             | 87,8%            | Conforms          |
| <i>A. brasiliensis</i><br>ATCC 16404 | 10-100 viable microorganisms | 72-120 h<br>at 32.5 ± 2.5°C | 70%≤R%≤200%             | 104,4%           | Conforms          |

|                          |                          |                            |                    |
|--------------------------|--------------------------|----------------------------|--------------------|
| <b>Start analysis</b>    | <b>08 Feb 2024</b>       | <b>End analysis</b>        | <b>13 Feb 2024</b> |
| <b>Quality Control</b>   | <b>Elisabetta Peri</b>   | <i>Elisabetta Peri</i>     |                    |
| <b>Quality Assurance</b> | <b>Celeste Annovazzi</b> | <i>(Celeste) Annovazzi</i> |                    |