

# Certificate of Analysis



Lot status: APPROVED

|                       |                            |                    |                             |
|-----------------------|----------------------------|--------------------|-----------------------------|
| MODEL                 | Petri ø90mm Single Wrapped | PRODUCT CODE       | 290/10                      |
| MEDIA                 | TSA                        | MEDIA COMPOSITION  | Tryptone Soy Agar           |
| BATCH                 | 98309                      | STORAGE CONDITIONS | at 2-25°C until expiry date |
| DATE OF MANUFACTURING | 26 Oct 2023                | EXPIRY DATE        | 26 Jun 2024                 |

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<br>22.5±2.5°C aerobic for 120 hours | No growth     | Conforms |

- 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%         | 105,2%           | 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%         | 76,9%            | 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%         | 90,6%            | 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%         | 96,8%            | 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%         | 89,7%            | 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%         | 105,4%           | Conforms          |

| Start analysis    | 27 Oct 2023       | End analysis             | 31 Oct 2023 |
|-------------------|-------------------|--------------------------|-------------|
| Quality Control   | Elisabetta Peri   | <i>Elisabetta Peri</i>   |             |
| Quality Assurance | Celeste Annovazzi | <i>Celeste Annovazzi</i> |             |