

# Certificate of Analysis



Lot status: **APPROVED**

|                               |                               |                            |                                    |
|-------------------------------|-------------------------------|----------------------------|------------------------------------|
| <b>MODEL:</b>                 | <b>800ml Screw Cap Bottle</b> | <b>PRODUCT CODE:</b>       | <b>290/33PSC28.800</b>             |
| <b>MEDIA:</b>                 | <b>Tryptone Soy Agar</b>      | <b>MEDIA COMPOSITION</b>   | <b>Tryptone Soy Agar</b>           |
| <b>BATCH:</b>                 | <b>24C0501</b>                | <b>STORAGE CONDITIONS:</b> | <b>at 2-25°C until expiry date</b> |
| <b>DATE OF MANUFACTURING:</b> | <b>05 Mar 2024</b>            | <b>EXPIRY DATE:</b>        | <b>05 Mar 2025</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    | 800ml  | 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%             | 98,5 %           | 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%             | 94,1 %           | 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%             | 91,3 %           | 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%             | 112,0 %          | 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%             | 90,9 %           | 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%             | 85,8 %           | Conforms          |

|                          |                    |                        |                    |
|--------------------------|--------------------|------------------------|--------------------|
| <b>Start analysis</b>    | <b>05 Mar 2024</b> | <b>End analysis</b>    | <b>11 Mar 2024</b> |
| <b>Quality Control</b>   | Elisabetta Peri    | <i>Elisabetta Peri</i> |                    |
| <b>Quality Assurance</b> | Alessia Diego      | <i>Alessia Diego</i>   |                    |

**GHIARONI CODE: 953808002**