

Certificate of Analysis



Lot status: **APPROVED**

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|-------------------------------|------------------------|----------------------------|-----------------------------|
| MODEL: | 800ml Screw Cap Bottle | PRODUCT CODE: | 290/33PSC28.800 |
| MEDIA: | Tryptone Soy Agar | MEDIA COMPOSITION | Tryptone Soy Agar |
| BATCH: | 23J0401 | STORAGE CONDITIONS: | at 2-25°C until expiry date |
| DATE OF MANUFACTURING: | 04 Oct 2023 | EXPIRY DATE: | 04 Oct 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 | 800ml | Conforms |

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

| TESTS | SPECIFICATION | RESULT |
|--|---------------|----------|
| 32.5±2.5°C aerobic for 120 hours 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> ATCC 8739 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 90.1% | Conforms |
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 123.1% | Conforms |
| <i>S. aureus</i> ATCC 6538 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 90.9% | Conforms |
| <i>B. subtilis</i> ATCC 6633 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 101.6% | Conforms |
| <i>C. albicans</i> ATCC 10231 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 109.7% | Conforms |
| <i>A. brasiliensis</i> ATCC 16404 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 97.5% | Conforms |

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|--------------------------|-------------------|--------------------------|-------------|
| Start analysis | 04 Oct 2023 | End analysis | 09 Oct 2023 |
| Quality Control | Elisabetta Peri | <i>Peri Elisabetta</i> | |
| Quality Assurance | Celeste Annovazzi | <i>Celeste Annovazzi</i> | |

GHIARONI CODE: 953808002