

Certificate of Analysis



Lot status: **APPROVED**

MODEL: 800ml Screw Cap Bottle
MEDIA: Tryptone Soy Agar

PRODUCT CODE: 290/33PSC28.800

BATCH: 23F1501

STORAGE CONDITIONS: at 2-25°C until expiry date

DATE OF MANUFACTURING: 15 Jun 2023

EXPIRY DATE: 15 Jun 2024

| 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 |
| Media composition | Tryptone Soy Agar | Conforms |
| | Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer | |

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% | 103.2% | Conforms |
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 95.1% | Conforms |
| <i>S. aureus</i> ATCC 6538 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 95.9% | Conforms |
| <i>B. subtilis</i> ATCC 6633 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 123.6% | Conforms |
| <i>C. albicans</i> ATCC 10231 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 92.3% | Conforms |
| <i>A. brasiliensis</i> ATCC 16404 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 99.1% | Conforms |

| Start analysis | 16 Jun 2023 | End analysis | 22 Jun 2023 |
|-------------------|-------------------|--------------|-------------|
| Quality Control | Claudia Previtali | | |
| Quality Assurance | Rosaria Cassese | | |

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