

Certificate of Analysis



Lot status: **APPROVED**

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| MODEL Petri ø90mm Triple Wrapped Sterile Irradiated | PRODUCT CODE 449INH/22 |
| MEDIA TSA+Lec+T80+Hys+ThioS | MEDIA COMPOSITION Tryptone Soy Agar + 0.07% Lecithin + 0.5% Tween80 + 0.1% L-Hystidine + 0.05% S-Thiosulphate |
| BATCH 87310 | STORAGE CONDITIONS at 2-25°C until expiry date |
| DATE OF MANUFACTURING 24 Oct 2023 | EXPIRY DATE 24 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 | 30ml±1ml | Conforms |
| Packaging | Triple Wrapped Sterile Irradiated (T.W.S.I.) | Conforms |
| Dose of irradiation | 10-25 KGy | Conforms Irradiation certificate Nr: 3441045 3449348 |

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% | 92,3% | Conforms |
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 84,7% | Conforms |
| <i>S. aureus</i> ATCC 6538 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 93,5% | Conforms |
| <i>B. subtilis</i> ATCC 6633 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 73,5% | Conforms |
| <i>C. albicans</i> ATCC 10231 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 80,0% | Conforms |
| <i>A. brasiliensis</i> ATCC 16404 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 83,5% | Conforms |

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|--------------------------|-------------------|--------------------------|-------------|
| Start analysis | 24 Oct 2023 | End analysis | 27 Nov 2023 |
| Quality Control | Elisabetta Peri | <i>Elisabetta Peri</i> | |
| Quality Assurance | Celeste Annovazzi | <i>Celeste Annovazzi</i> | |