

Certificate of Analysis



Lot status: APPROVED

MODEL: RODAC ø55mm Triple Wrapped Sterile Irradiated PRODUCT CODE: 449/21
 MEDIA: TSA+Lec+T80
 BATCH: 35307 STORAGE CONDITIONS: at 2-25°C until expiry date
 DATE OF MANUFACTURING: 05 Jul 2023 EXPIRY DATE: 05 Mar 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 | 17ml±1ml | Conforms |
| Media composition | Tryptone Soy Agar + 0.07% Lecithin + 0.5% Tween80 | Conforms |
| | Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer | |
| Packaging | Triple Wrapped Sterile Irradiated (T.W.S.I.) | Conforms |
| Dose of irradiation | 10-25 KGy | Conforms Irradiation certificate Nr: 3375610 |

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

| TESTS | SPECIFICATION | RESULT |
|----------------------------------|---------------|----------|
| 32.5±2.5°C aerobic for 120 hours | No growth | Conforms |
| 22.5±2.5°C aerobic for 120 hours | | |

- 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% | 100,0% | Conforms |
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 102,6% | Conforms |
| <i>S. aureus</i> ATCC 6538 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 79,6% | Conforms |
| <i>B. subtilis</i> ATCC 6633 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 98,1% | Conforms |
| <i>C. albicans</i> ATCC 10231 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 105,2% | Conforms |
| <i>A. brasiliensis</i> ATCC 16404 | 10-100 viable microorganisms | 72-120 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 87,5% | Conforms |

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|-------------------|-------------------|--------------|-------------|
| Start analysis | 05 Jul 2023 | End analysis | 24 Jul 2023 |
| Quality Control | Giulia Brusati | | |
| Quality Assurance | Celeste Annovazzi | | |