

Certificate of Analysis



Lot status: **APPROVED**

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|-------------------------------|--|----------------------------|------------------------------------|
| MODEL: | Petri ø90mm Triple Wrapped Sterile Irradiated | PRODUCT CODE: | 091LT/22 |
| MEDIA: | PCA+Lec+T80 | STORAGE CONDITIONS: | at 2-25°C until expiry date |
| BATCH: | 85303 | EXPIRY DATE: | 18 Nov 2023 |
| DATE OF MANUFACTURING: | 18 May 2023 | | |

| CHEMICAL/PHYSICAL TESTS | SPECIFICATION | RESULT |
|-------------------------|--|---|
| Appearance | Light yellow coloured, clear to slightly opalescent gel forms in plates | Conforms |
| pH specification | 7.0±0.2 | Conforms |
| Filling media volume | 30ml±2ml | Conforms |
| Media composition | Plate Count Agar + 0.07% Lecithin + 0.5% Tween80 Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer | Conforms |
| Packaging | Triple Wrapped Sterile Irradiated (T.W.S.I.) | Conforms |
| Dose of irradiation | 10-25 KGy | Conforms Irradiation certificate Nr: 3346714 |

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% | 92,9% | Conforms |
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 95,9% | Conforms |
| <i>S. aureus</i> ATCC 6538 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 73,0% | Conforms |
| <i>B. subtilis</i> ATCC 6633 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | 70%≤R%≤200% | 91,7% | Conforms |

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| Start analysis | Date 18 May 2023 | End analysis | Date 31 May 2023 |
| Quality Control | Giulia Brusati | | |
| Quality Assurance | Celeste Annovazzi | | |