

Certificate of Analysis



Lot status: **APPROVED**

| | | | |
|-------------------------------|---|----------------------------|-----------------------------|
| MODEL: | 200ml Bottle with Pierceable Cap | PRODUCT CODE: | 011/31P.200 |
| MEDIA: | Tryptone Soy Broth | STORAGE CONDITIONS: | at 2-25°C until expiry date |
| BATCH: | 22F1601 | EXPIRY DATE: | 16 Jun 2024 |
| DATE OF MANUFACTURING: | 16 Jun 2022 | | |

| CHEMICAL/PHYSICAL TESTS | SPECIFICATION | RESULT |
|-------------------------|--|----------|
| Appearance | yellow coloured, clear solution | Conforms |
| pH specification | 7.3±0.2 | Conforms |
| Filling media volume | 200ml | Conforms |
| Media composition | Tryptone Soy Broth | 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 336 hours 22.5±2.5°C aerobic for 336 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 | 18-72 h at 32.5 ± 2.5°C | Positive growth | Positive growth | Conforms |
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 18-72 h at 32.5 ± 2.5°C | Positive growth | Positive growth | Conforms |
| <i>S. aureus</i> ATCC 6538 | 10-100 viable microorganisms | 18-72 h at 32.5 ± 2.5°C | Positive growth | Positive growth | Conforms |
| <i>B. subtilis</i> ATCC 6633 | 10-100 viable microorganisms | 18-72 h at 32.5 ± 2.5°C | Positive growth | Positive growth | Conforms |
| <i>B. subtilis</i> ATCC 6633 | 10-100 viable microorganisms | 18-72 h at 22.5 ± 2.5°C | Positive growth | Positive growth | Conforms |
| <i>C. albicans</i> ATCC 10231 | 10-100 viable microorganisms | 48-120 h at 22.5 ± 2.5°C | Positive growth | Positive growth | Conforms |
| <i>A. brasiliensis</i> ATCC 16404 | 10-100 viable microorganisms | 48-120 h at 22.5 ± 2.5°C | Positive growth | Positive growth | Conforms |

| Start analysis | 17 Jun 2022 | End analysis | 01 Jul 2022 |
|-------------------|-------------------|--------------------------|-------------|
| Quality Control | Claudia Previtali | <i>Claudia Previtali</i> | |
| Quality Assurance | Rosaria Cassese | <i>Rosaria Cassese</i> | |

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