

Certificate of Analysis



Lot status: **APPROVED**

| | | | |
|------------------------------|-------------------------------|---------------------------|-----------------------------|
| MODEL | 100ml Screw Cap Bottle | PRODUCT CODE | 287E/30PSC28.100 |
| MEDIA | EE Broth, Mossel | MEDIA COMPOSITION | EE Broth, Mossel |
| BATCH | 23L1401 | STORAGE CONDITIONS | at 2-25°C until expiry date |
| DATE OF MANUFACTURING | 14 Dec 2023 | EXPIRY DATE | 14 Jun 2024 |

Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer

| CHEMICAL/PHYSICAL TESTS | SPECIFICATION | RESULT |
|-----------------------------|--------------------------------|-----------------|
| Appearance | Green coloured, clear solution | <i>Conforms</i> |
| pH specification | 7.2±0.2 | <i>Conforms</i> |
| Filling media volume | 100ml | <i>Conforms</i> |

MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

| TESTS | SPECIFICATION | RESULT |
|----------------------------------|---------------|-----------------|
| 32.5±2.5°C aerobic for 120 hours | No growth | <i>Conforms</i> |
| 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 | 18 h at 32.5 ± 2.5°C | Positive growth. | Positive growth. | Conforms |
| <i>E. aerogenes</i> ATCC 13048 | 10-100 viable microorganisms | 18 h at 32.5 ± 2.5°C | Positive growth. | Positive growth. | Conforms |
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 18 h at 32.5 ± 2.5°C | Positive growth. | Positive growth. | Conforms |
| <i>S. aureus</i> ATCC 6538 | ≥100 viable microorganisms | 48 h at 32.5 ± 2.5°C | Inhibited | Inhibited | Conforms |

| Start analysis | 15 Dec 2023 | End analysis | 21 Dec 2023 |
|--------------------------|-----------------|--------------|-------------|
| Quality Control | Elisabetta Peri | | |
| Quality Assurance | Alessia Diego | | |

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