

Certificate of Analysis



Lot status: **APPROVED**

| | | | |
|-------------------------------|--------------------------------------|----------------------------|------------------------------------|
| MODEL: | 100ml Screw Cap Bottle | PRODUCT CODE: | 083A/30PSC28.100 |
| MEDIA: | MacConkey Broth Purple W/ BCP | STORAGE CONDITIONS: | at 2-25°C until expiry date |
| BATCH: | 22J0402 | EXPIRY DATE: | 04 Apr 2023 |
| DATE OF MANUFACTURING: | 04 Oct 2022 | | |

| CHEMICAL/PHYSICAL TESTS | SPECIFICATION | RESULT |
|-------------------------|--|-----------------|
| Appearance | Purple coloured, clear solution | <i>Conforms</i> |
| pH specification | 7.3±0.2 | <i>Conforms</i> |
| Filling media volume | 100ml | <i>Conforms</i> |
| Media composition | MacConkey Broth Purple W/ BCP | <i>Conforms</i> |
| | 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 120 hours 22.5±2.5°C aerobic for 120 hours | No growth | <i>Conforms</i> |

- 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 h at 43 ± 1°C | Positive growth. Acid: + | Positive growth. Acid: + | Conforms |
| <i>E. aerogenes</i> ATCC 13048 | 10-100 viable microorganisms | 24 h at 43 ± 1°C | Positive growth. Acid: + | Positive growth. Acid: + | Conforms |
| <i>S. aureus</i> ATCC 6538 | ≥100 viable microorganisms | 48 h at 43 ± 1°C | Inhibited | Inhibited | Conforms |

| Start analysis | 04 Oct 2022 | End analysis | 10 Oct 2022 |
|-------------------|-------------------|--------------------------|-------------|
| Quality Control | Claudia Previtali | <i>Claudia Previtali</i> | |
| Quality Assurance | Rosaria Cassese | <i>Rosaria Cassese</i> | |

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