

# Certificate of Analysis



Lot status: **APPROVED**

|                               |                                      |                            |                                    |
|-------------------------------|--------------------------------------|----------------------------|------------------------------------|
| <b>MODEL:</b>                 | <b>100ml Screw Cap Bottle</b>        | <b>PRODUCT CODE:</b>       | <b>083A/30PSC28.100</b>            |
| <b>MEDIA:</b>                 | <b>MacConkey Broth Purple W/ BCP</b> | <b>STORAGE CONDITIONS:</b> | <b>at 2-25°C until expiry date</b> |
| <b>BATCH:</b>                 | <b>23D1802</b>                       | <b>EXPIRY DATE:</b>        | <b>18 Apr 2024</b>                 |
| <b>DATE OF MANUFACTURING:</b> | <b>18 Apr 2023</b>                   |                            |                                    |

| 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<br>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><br>ATCC 8739       | 10-100 viable microorganisms | 24 h<br>at 43 ± 1°C   | Positive growth.<br>Acid: + | Positive growth.<br>Acid: + | <b>Conforms</b>   |
| <i>E. aerogenes</i><br>ATCC 13048 | 10-100 viable microorganisms | 24 h<br>at 43 ± 1°C   | Positive growth.<br>Acid: + | Positive growth.<br>Acid: + | <b>Conforms</b>   |
| <i>S. aureus</i><br>ATCC 6538     | ≥100 viable microorganisms   | 48 h<br>at 43 ± 1°C   | Inhibited                   | Inhibited                   | <b>Conforms</b>   |

|                          |                    |                          |                    |
|--------------------------|--------------------|--------------------------|--------------------|
| <b>Start analysis</b>    | <b>19 Apr 2023</b> | <b>End analysis</b>      | <b>26 Apr 2023</b> |
| <b>Quality Control</b>   | Claudia Previtali  | <i>Claudia Previtali</i> |                    |
| <b>Quality Assurance</b> | Rosaria Cassese    | <i>Rosaria Cassese</i>   |                    |

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