

Certificate of Analysis



Lot status: **APPROVED**

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|-------------------------------|---|----------------------------|-----------------------------|
| MODEL: | 100ml w/Pierceable Flip-Off Cap Bottle | PRODUCT CODE: | ME009/30FLP32.100 |
| MEDIA: | Fluid Thioglycollate Medium | STORAGE CONDITIONS: | at 2-25°C until expiry date |
| BATCH: | 22A1702 | EXPIRY DATE: | 17 Gen 2023 |
| DATE OF MANUFACTURING: | 17 Gen 2022 | | |

| CHEMICAL/PHYSICAL TESTS | SPECIFICATION | RESULT |
|-------------------------|---|-----------------|
| Appearance | yellow straw coloured, clear to very slightly opalescent solution with upper 10% or less medium pink on standing. | <i>Conforms</i> |
| pH specification | 7.1±0.2 | <i>Conforms</i> |
| Filling media volume | 100ml | <i>Conforms</i> |
| Media composition | Fluid Thioglycollate Medium | <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 336 hours | No growth | <i>Conforms</i> |
| 22.5±2.5°C aerobic for 336 hours | | |

- Fertility – Growth Promotion Test** according to USP/EP

| Control strain | Medium inoculation level | Incubation Conditions | Recovery Specifications | Recovery Results | Cultural Response |
|------------------------------------|------------------------------|----------------------------|-------------------------|------------------|-------------------|
| <i>P. aeruginosa</i> ATCC 9027 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | Positive growth | Positive growth | Conforms |
| <i>C. sporogenes</i> ATCC 11437 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | Positive growth | Positive growth | Conforms |
| <i>S. aureus</i> ATCC 6538 | 10-100 viable microorganisms | 24-72 h at 32.5 ± 2.5°C | Positive growth | Positive growth | Conforms |

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|--------------------------|--------------------------|--------------------------|--------------------|
| Start analysis | 18 Gen 2022 | End analysis | 01 Feb 2022 |
| Quality Control | Giulia Brusati | <i>Giulia Brusati</i> | |
| Quality Assurance | Celeste Annovazzi | <i>Celeste Annovazzi</i> | |