

Certificate of Analysis



Lot status: **APPROVED**

| | | | |
|-------------------------------|-----------------------------------|---------------------------|---------------------------------------|
| MODEL | 1000ml Screw Cap Bottle | PRODUCT CODE | 002.2/33PSC28.1L |
| MEDIA | Phosphate Buffer 2 (0.05M) pH 6.0 | MEDIA COMPOSITION | Monobasic potassium phosphate 6.80g/L |
| BATCH | 23K2902 | STORAGE CONDITIONS | at 2-25°C until expiry date |
| DATE OF MANUFACTURING: | 29 Nov 2023 | EXPIRY DATE | 29 Nov 2024 |

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

| CHEMICAL/PHYSICAL TESTS | SPECIFICATION | RESULT |
|-------------------------|--|-----------------|
| Appearance | Colourless clear solution. White crystals may appear. Swirl to dissolve. | <i>Conforms</i> |
| pH specification | 6.0±0.1 | <i>Conforms</i> |
| Filling media volume | 1000ml | <i>Conforms</i> |

MICROBIOLOGICAL TEST CONTROLS

- **Sterility control** according to USP/EP

| TESTS | SPECIFICATION | RESULT |
|--|---------------|-----------------|
| 32.5±2.5°C aerobic for 336 hours 22.5±2.5°C aerobic for 336 hours | No growth | <i>Conforms</i> |

| Start analysis | 01 Dec 2023 | End analysis | 15 Dec 2023 |
|-------------------|-----------------|--------------|------------------------|
| Quality Control | Elisabetta Peri | | <i>Elisabetta Peri</i> |
| Quality Assurance | Alessia Diego | | <i>Alessia Diego</i> |

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