

Certificate of Analysis



Lot status: **APPROVED**

| | | | |
|------------------------------|-----------------------------------|---------------------------|---|
| MODEL | 1000ml Screw Cap Bottle | PRODUCT CODE | 002.1/33PSC28.1L |
| MEDIA | Phosphate Buffer 1 (0.25M) pH 7.2 | MEDIA COMPOSITION | Monobasic Potassium Phosphate 34.00g/L |
| BATCH | 23K1402 | STORAGE CONDITIONS | at 2-25°C until expiry date |
| DATE OF MANUFACTURING | 14 Nov 2023 | EXPIRY DATE | 14 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 | 7.2±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 | No growth | <i>Conforms</i> |
| 22.5±2.5°C aerobic for 336 hours | | |

| Start analysis | 15 Nov 2023 | End analysis | 29 Nov 2023 |
|-------------------|-----------------|--------------|-------------|
| Quality Control | Elisabetta Peri | | |
| Quality Assurance | Alessia Diego | | |