

Certificate of Analysis



Lot status: **APPROVED**

MODEL: 1000ml Screw Cap Bottle
MEDIA: Phosphate Buffer 1 (0.25M) pH 7.2
BATCH: 23I1801
DATE OF MANUFACTURING: 18 Sep 2023

PRODUCT CODE: 002.1/33PSC28.1L
STORAGE CONDITIONS: at 2-25°C until expiry date
EXPIRY DATE: 18 Sep 2024

| 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> |
| Media composition | Monobasic Potassium Phosphate 34.00g/L Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer | <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> |

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|-------------------|-------------------|--------------------------|-------------|
| Start analysis | 19 Sep 2023 | End analysis | 03 Oct 2023 |
| Quality Control | Claudia Previtali | <i>Claudia Previtali</i> | |
| Quality Assurance | Rosaria Cassese | <i>Rosaria Cassese</i> | |