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		
BATCH:	**21A1102**	**STORAGE CONDITIONS:**	at 2-25°C until expiry date
DATE OF MANUFACTURING:	**11 Jan 2021**	**EXPIRY DATE:**	**11 Jan 2022**

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Colourless clear solution. White cristals may appear. Swirl to dissolve.	***Conforms***
pH specification	6.0±0.1	***Conforms***
Filling media volume	1000ml	***Conforms***
Media composition	Monobasic potassium phosphate 6.80g/L Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	***Conforms***

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	***Conforms***

Start analisys	**14 Jan 2021**	**End analisys**	**28 Jan 2021**
Quality Control	**Stefania Nichele**	Nichele Stefania	
Quality Assurance	**Celeste Annovazzi**	Celeste Annovazzi	

GHIARONI CODE: 953821543