

Certificate of Analysis



Lot status: **APPROVED**

MODEL: 100ml Screw Cap Bottle
MEDIA: Phosphate Buffer 1 (0.25M) pH 7.2
BATCH: 22E2001
DATE OF MANUFACTURING: 20 May 2022

PRODUCT CODE: 002.1/30PSC28.100
STORAGE CONDITIONS: at 2-25°C until expiry date
EXPIRY DATE: 20 May 2023

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	100ml	<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>

Start analysis	20 May 2022	End analysis	03 Jun 2022
Quality Control	Claudia Previtali	<i>Claudia Previtali</i>	
Quality Assurance	Rosaria Cassese	<i>Rosaria Cassese</i>	