

# Certificate of Analysis



Lot status: **APPROVED**

**MODEL:** 900ml Bottle with Pierceable Cap  
**MEDIA:** Fluid Thioglycollate Medium

**BATCH:** 23E1001

**DATE OF MANUFACTURING:** 10 May 2023

**PRODUCT CODE:** ME009/33P.900

**STORAGE CONDITIONS:** at 2-25°C until expiry date

**EXPIRY DATE:** 10 May 2024

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	yellow straw coloured, clear to very slightly opalescent solution with upper 10% or less medium pink on standing.	Conforms
pH specification	7.1±0.2	Conforms
Filling media volume	900ml	Conforms
Media composition	Fluid Thioglycollate Medium Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	Conforms

## MICROBIOLOGICAL TEST CONTROLS

### • Sterility control

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 336 hours 22.5±2.5°C aerobic for 336 hours	No growth	Conforms

### • Fertility – Growth Promotion Test according to USP/EP

Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	Conforms
<i>C. sporogenes</i> ATCC 11437	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	Positive growth	Positive growth	Conforms

Start analysis	12 May 2023	End analysis	26 May 2023
Quality Control	Claudia Previtali	Claudia Previtali	
Quality Assurance	Rosaria Cassese	Rosaria Cassese	

**GHIARONI CODE: 9538390010**