

# Certificate of Analysis



Lot status: **APPROVED**

**MODEL:** 100ml Screw Cap Bottle

**MEDIA:** EE Broth, Mossel

**BATCH:** 23G3101

**DATE OF MANUFACTURING:** 31 Jul 2023

**PRODUCT CODE:** 287E/30PSC28.100

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

**EXPIRY DATE:** 31 Jan 2024

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Green coloured, clear solution	Conforms
pH specification	7.2±0.2	Conforms
Filling media volume	100ml	Conforms
Media composition	EE Broth, Mossel	Conforms
	Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer	

## MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 120 hours	No growth	Conforms
22.5±2.5°C aerobic for 120 hours		

- Fertility – Growth Promotion Test** according to USP/EP

Control strain	Medium inoculation level	Incubation Conditions	Recovery Specifications	Recovery Results	Cultural Response
<i>E. coli</i> ATCC 8739	10-100 viable microorganisms	18 h at 32.5 ± 2.5°C	Positive growth.	Positive growth.	Conforms
<i>E. aerogenes</i> ATCC 13048	10-100 viable microorganisms	18 h at 32.5 ± 2.5°C	Positive growth.	Positive growth.	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	18 h at 32.5 ± 2.5°C	Positive growth.	Positive growth.	Conforms
<i>S. aureus</i> ATCC 6538	≥100 viable microorganisms	48 h at 32.5 ± 2.5°C	Inhibited	Inhibited	Conforms

Start analisis	01 Aug 2023	End analisis	07 Aug 2023
Quality Control	Claudia Previtali	<i>Claudia Previtali</i>	
Quality Assurance	Rosaria Cassese	<i>Rosaria Cassese</i>	

**GHIARONI CODE: 953808009**