

# Certificate of Analysis



Lot status: **APPROVED**

**MODEL:** 800ml Screw Cap Bottle

**MEDIA:** Tryptone Soy Agar

**BATCH:** 23G0501

**DATE OF MANUFACTURING:** 05 Jul 2023

**PRODUCT CODE:** 290/33PSC28.800

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

**EXPIRY DATE:** 05 Jul 2024

CHEMICAL/PHYSICAL TESTS	SPECIFICATION	RESULT
Appearance	Light amber coloured, clear to slightly opalescent gel forms in plates	Conforms
pH specification	7.3±0.2	Conforms
Filling media volume	800ml	Conforms
Media composition	Tryptone Soy Agar	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	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	103.8%	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	120.5%	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	102.3%	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	87.5%	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	98.7%	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	88.5%	Conforms

Start analysis	06 Jul 2023	End analysis	12 Jul 2023
Quality Control	Claudia Previtali	 	
Quality Assurance	Rosaria Cassese		

**GHARONI CODE: 953808002**