

# Certificate of Analysis



Lot status: **APPROVED**

<b>MODEL:</b>	<b>800ml Screw Cap Bottle</b>	<b>PRODUCT CODE:</b>	<b>290/33PSC28.800</b>
<b>MEDIA:</b>	<b>Tryptone Soy Agar</b>	<b>MEDIA COMPOSITION</b>	<b>Tryptone Soy Agar</b>
<b>BATCH:</b>	<b>24C1801</b>	<b>STORAGE CONDITIONS:</b>	<b>at 2-25°C until expiry date</b>
<b>DATE OF MANUFACTURING:</b>	<b>18 Mar 2024</b>	<b>EXPIRY DATE:</b>	<b>18 Mar 2025</b>

Medium is prepared utilizing raw materials declared to be TSE-BSE FREE by the manufacturer

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

## MICROBIOLOGICAL TEST CONTROLS

- Sterility control**

TESTS	SPECIFICATION	RESULT
32.5±2.5°C aerobic for 120 hours 22.5±2.5°C aerobic for 120 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>E. coli</i> ATCC 8739	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	87,8 %	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	124,2 %	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	107,0 %	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	121,7 %	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	70,8 %	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	111,0 %	Conforms

<b>Start analysis</b>	<b>19 Mar 2024</b>	<b>End analysis</b>	<b>25 Mar 2024</b>
<b>Quality Control</b>	Elisabetta Peri		
<b>Quality Assurance</b>	Alessia Diego		

**GHIARONI CODE: 953808002**