

Certificate of Analysis



Lot status: **APPROVED**

MODEL:	800ml Screw Cap Bottle	PRODUCT CODE:	290/33PSC28.800
MEDIA:	Tryptone Soy Agar	MEDIA COMPOSITION	Tryptone Soy Agar
BATCH:	24C2701	STORAGE CONDITIONS:	at 2-25°C until expiry date
DATE OF MANUFACTURING:	27 Mar 2024	EXPIRY DATE:	27 Mar 2025

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%	98,9 %	Conforms
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	110,0 %	Conforms
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	91,8 %	Conforms
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	127,5 %	Conforms
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	107,4 %	Conforms
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	99,3 %	Conforms

Start analysis	28 Mar 2024	End analysis	08 Apr 2024
Quality Control	Elisabetta Peri	 	
Quality Assurance	Alessia Diego		

GHIARONI CODE: 953808002