

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:	23J0201	STORAGE CONDITIONS:	at 2-25°C until expiry date
DATE OF MANUFACTURING:	02 Oct 2023	EXPIRY DATE:	02 Oct 2024

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	<i>Conforms</i>
pH specification	7.3±0.2	<i>Conforms</i>
Filling media volume	800ml	<i>Conforms</i>

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	<i>Conforms</i>

- 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%	89.1%	<i>Conforms</i>
<i>P. aeruginosa</i> ATCC 9027	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	120.5%	<i>Conforms</i>
<i>S. aureus</i> ATCC 6538	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	98.5%	<i>Conforms</i>
<i>B. subtilis</i> ATCC 6633	10-100 viable microorganisms	24-72 h at 32.5 ± 2.5°C	70%≤R%≤200%	85.7%	<i>Conforms</i>
<i>C. albicans</i> ATCC 10231	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	101.1%	<i>Conforms</i>
<i>A. brasiliensis</i> ATCC 16404	10-100 viable microorganisms	72-120 h at 32.5 ± 2.5°C	70%≤R%≤200%	94.9%	<i>Conforms</i>

Start analysis	02 Oct 2023	End analysis	09 Oct 2023
Quality Control	Elisabetta Peri	<i>Peri Elisabetta</i>	
Quality Assurance	Celeste Annovazzi	<i>Celeste Annovazzi</i>	

GHIARONI CODE: 953808002